

FROM GRASS ROOTS TO PHARMA PARTNERSHIPS: BREAST CANCER  
ADVOCACY IN CANADA

by

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Submitted in partial fulfilment of the requirements  
for the degree of Doctor of Philosophy

at

Dalhousie University  
Halifax, Nova Scotia  
February 2012

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DALHOUSIE UNIVERSITY

INTERDISCIPLINARY PhD PROGRAM

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DALHOUSIE UNIVERSITY

DATE: February 7, 2012

AUTHOR: Sharon Batt

TITLE: From Grass Roots to Pharma Partnerships: Breast Cancer Advocacy in  
Canada

DEPARTMENT OR SCHOOL: Interdisciplinary Ph.D. Program

DEGREE: Ph.D. CONVOCATION: May YEAR: 2012

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## **DEDICATION**

In memory of my parents, Jessie A. Harding Batt and Robert J. Batt,  
passionate believers in education and social justice.

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## ABSTRACT

*From Grass Roots to Pharma Partnerships* examines the development, over a twenty-year span, of alliances between grass roots breast cancer groups in Canada and the pharmaceutical industry. I conclude that these alliances alter the advocacy content and style of the groups in ways that silence grass roots critique and support the policy goals of the pharmaceutical industry. I present my results in three parts. First, narrative accounts depict differing responses among breast cancer organizations to overtures from the pharmaceutical industry, from outright rejection, to a middle stance that I label “pragmatic ambivalence,” to acceptance of complete funding by pharma. Second, I describe three features of Canada’s policy landscape that have been altered by the successive adoption of neoliberal policies and which affect the character of patients’ movements. These are: 1) the failure of Canada’s healthcare system to adapt to a generation of new, expensive drugs; 2) a weakening of the system of cost controls, drug approvals, and the regulation of truth claims about drugs; and 3) policies that restrict funding to, and critical advocacy by, the civil society sector. The third section of my results describes the gradual transition of the breast cancer movement over two decades, from small, local, independent groups to a national network of organizations, many of which now rely heavily on the pharmaceutical industry for support. A series of case studies of projects carried out by groups and funded by “big pharma” illustrates subtle misrepresentations of the state of knowledge about new cancer drugs. These findings suggest that patient-centred breast cancer groups need sources of funding and information independent of the pharmaceutical industry if they are to contribute a user’s perspective to pharmaceutical policy about drugs whose effects are still largely uncharted.

## LIST OF ABBREVIATIONS USED

<b>ANT:</b>	Actor-Network Theory
<b>ASCO:</b>	The American Society of Clinical Oncology (see Glossary)
<b>CAF:</b>	cylophosphamide + Adriamycin® + 5-fluoracil (also called 5-FU)
<b>CMF:</b>	cylophosphamide + methotrexate + 5-fluoracil (also called 5-FU)
<b>HCPO:</b>	Health Consumer and Patients' Organizations
<b>GATT:</b>	General Agreement on Tariffs and Trade
<b>“Mets”:</b>	Metastasis (the term used to indicate that cancer has spread to vital organs, rendering it incurable)
<b>NDS:</b>	New Drug Submission
<b>NOC/c:</b>	Notice of Compliance with conditions
<b>OCAPI:</b>	Office of Consumer and Public Involvement
<b>PAGs:</b>	Patient Advocacy Groups
<b>SABCS:</b>	San Antonio Breast Cancer Symposium
<b>TRIP:</b>	The Trade-related Aspects of Intellectual Property Rights
<b>STS:</b>	Science and Technology Studies
<b>VSI:</b>	Voluntary Statement of Information

## GLOSSARY

**Note:** The meanings of some of the terms in the glossary are contested. In my definitions, I indicate where this is the case and which of several meanings I have adopted.

**Activism, Activist:** Activism refers to organized efforts to shape public policy; activist individuals and groups engage in policy-shaping activities. Although group activism is most often associated with left-leaning grass roots organizations, in my analysis I adopt the perspective of Miriam Smith (2005) that right-of-centre organizations and corporations can also be termed “activist.”

**American Society of Clinical Oncology (ASCO):** A professional organization for cancer clinicians. ASCO meetings are among the main venues at which cancer researchers present new findings on cancer drug research.

**Astroturf Group:** This metaphor references the brand name for synthetic grass to pejoratively designate organizations that purport to be grass roots civil society groups but are actually industry-funded organizations established to promote industry-friendly policies (see Beder, 1998). An Astroturf health group may be created by the pharmaceutical industry, the insurance industry or other corporate entity; in looser usage, an Astroturf group may simply receive funding from through an industry alliance. I avoid designating specific groups as Astroturf; rather, I try to bring out the variations on the pharma funding question within the community.

**Biologics, Biological Drugs:** A subset of drug products. Health Canada defines biological drugs as including drug products that are “biologically based or using biological systems in their manufacturing” such as, “conventional viral and bacterial vaccines and products derived from animal and human fluids, tissues and organs; recombinant proteins including, blood products, hormones, growth factors, and enzymes manufactured in bacterial, yeast or mammalian cell lines; and gene therapy and cell therapy products.” (Health Canada 2006).

**Compassionate Access Drug Program (in Canada)** A program designed to allow critically ill patients to have access outside of clinical trials to promising new drugs that have not yet been approved. (A comparable program in the United States is called “Expanded Access”)

**Corporatism:** The term “corporatism” derives from the Latin term *corpus* or body and describes a model of governance which is characterized by arm’s length bargaining relationships among diverse bodies ( Lofgren 2004).

**Drug:** I use the term “drug” to refer to pharmaceutical treatments, whether brand name or generic, chemical based or biologic (see definition of “biological drugs”, above).

**Embodied knowledge:** The term “embodied knowledge” shifts the concept of understanding of a physical condition away from expert knowledge to a type of experiential, lay knowledge based on the ways in which people experience their bodies and make sense of a bodily state in their everyday lives. Embodied knowledge may differ from or align with expert knowledge. Thus, in a study of pregnant women, Emily Abel and C.H. Browner found they could either incorporate or refuse to incorporate clinical recommendations regarding their prenatal care based on “knowledge derived from [their] experiences with and perceptions of their bodies as they change throughout the course of pregnancy or knowledge derived from their previous pregnancies. Embodied knowledge can also be drawn from other women’s reports of their own pregnancy experiences” (Abel and Browner 1998: 315).

**Enrolment:** In Actor-Network Theory (ANT), *enrollment* is the third of the four moments in a *translation* (cf); having engaged other actors and defined their roles (*interessement*), in this stage of the process the primary actors negotiate to have these roles accepted (Callon 1986).

**Expanded Access (in the U.S.) Drug Programs:** These programs allow critically ill patients to have access outside of clinical trials to promising new drugs that have not yet been approved.

**Interessement:** In Actor-Network Theory (ANT), *interessement* is the second of the four moments in a *translation* (cf); it is a process in which the primary actors engage other actors and define their roles (Callon 1986).

**Metastases or “Mets”:** Spread of cancer to another organ, usually through the blood system (Love and Lindsey 2005)

**Mobilisation:** In Actor-Network Theory (ANT), *mobilisation* is the last of the four moments in a *translation* (cf) in which the main actors mobilize previously unengaged allies to provide a base of active support (Callon 1986).

**New Drug/new drug:** In drug policy circles, a “New Drug” is one that has passed the testing requirements to be submitted for approval; the product remains a “New Drug” until it has been in use long enough to permit a reasonable assessment of its effectiveness and risks. Used colloquially, the term refers to a drug that is beginning to penetrate public awareness, through media accounts, clinical trials, early use, and other social means.

**New Drug Submission:** Pharmaceutical companies seeking regulatory approval for a new product submit a New Drug Submission (NDS) to the Food and Drugs Division of Health Canada once they have obtained satisfactory data from clinical trials. Government regulatory reviewers examine the extensive statistical data, analysis, and pharmacological information yielded by the clinical research. Reviewers can ask for additional information, or reject an application if the data is insufficient. Regulatory approval signifies that the drug can be marketed.

**Notice of compliance (NOC) and Notice of compliance with conditions (NOC/c):** Health Canada uses the term “notice of compliance with conditions” or NOC/c to designate drugs that have been awarded conditional approval for marketing pending further results from clinical trials.

The designation was introduced as part of an initiative to bring new drugs to market sooner. Some drug policy analysts view the designation as an example of the government regulator giving into pressure from the industry to market drugs before sufficient evidence to assess them is in. Patients and the general public may assume that the efficacy and safety of any drug approved for sale has been demonstrated; similarly, groups that advocate to have new drugs approved and placed on formularies may not understand the probationary nature of a NOC/c designation. Drugs with a NOC/c designation are thus ripe for social construction through patient advocacy.

**Office of Consumer and Public Involvement (OCAPI):** An office set up within the Health Products and Food Branch of Health Canada in 2001 to demonstrate its commitment to public involvement in its activities and decision-making processes.

**Patient-centred Group or Organization:** A group whose core membership and leadership is made up of patients and which purports to speak for patients on matters of policy.

**Pink marketing:** a promotional practice in which a company pledges to donate some of the profits from the purchase of its product(s) towards the breast cancer cause with the expectation that aligning its product with a cause popular with its target market will boost sales.

**Programmatic Text:** A text which tries to impose a vision or a way of seeing a problem; such texts are particularly useful in discourse analyses used to uncover struggles over meaning (Kendall and Wickham 2004).

**Problematization:** In Actor-Network Theory (ANT), problematization is the first of the four moments in a *translation* (cf); it is a double-movement in which a group of

actors make themselves indispensable by formulating a set of questions that, they argue, need to be answered; they then form a network of other actors and define their identities/interests in relation to the question. This process positions the primary actors as an *obligatory passage point* – a site that others must consult for the knowledge-making process to be valid. (Callon 1986).

**Quality-adjusted Life Years (QALY):** A measure used to assess the benefit of a medical intervention in terms of its effects on both length of life and the quality of life.

**San Antonio Breast Cancer Symposium (SABCS):** The San Antonio Breast Cancer Symposium in San Antonio, Texas is an annual event that attracts thousands of cancer researchers and clinicians from around the world. It is a prime venue for presenting new clinical trial results. Many breast cancer patients' organizations now send one or more delegates to the Symposium which has a special registration rate for advocates, and "mentor sessions" where lay attendees can ask questions about the presentations. An Advocate Program that supplies travel grants to members of breast cancer groups is heavily sponsored by pharmaceutical companies. (See the Patient Advocate page of the San Antonio Breast Cancer Symposium website, accessed July 17, 2011 at: <http://www.sabcs.org/PatientAdvocates/index.asp>. )

**Science and Technology Studies, or Science, Technology and Society Studies (STS):** An interdisciplinary field that is "creating an integrative understanding of the origins, dynamics and consequences of science and technology. STS scholars engage activists, scientists, doctors, decision makers, engineers, and other stakeholders on matters of equity, policy, politics, social change, national development, and economic transformation" (Hackett, Amsterdamska, Lynch, and Wajcman 2008:1).

**Single-payer National Health Care:** Canada's health care system is often referred to as a "single-payer" system because it is based on the principle that all core expenses are paid by a single insurer (the provincial government). In fact, because the system only covers hospital and physician-provided core services, a significant percentage of health-related costs are currently paid for by private insurers or out-of-pocket. I use the term "single-payer" to refer to Canada's welfare state health care system; however, as explained in the text, out-patient pharmaceuticals are largely covered by private insurers. The proportion of public-sector spending decreased following the 1990 to 1992 recession and has been relatively stable at 70 per cent since 1997 (CIHI 2011). In 2009, public sector expenditures were \$129.1 billion and private sector expenditures were \$53.0 billion (ibid: 8).



**Staging:** A classification system for cancer TNM (which uses tumour size, number of affected lymph nodes, and the presence or absence of metastasis to indicate how advanced a cancer is and to compare different treatments in the same types of patients). Although still widely used, the TNM system is considered outmoded in an age of DNA analysis (Love with Lindsey 2005)

**Surrogate end-point:** In clinical trials a drug is said to pass the crucial test of efficacy if it can be shown to significantly alleviate symptoms and/or extend survival time, and/or (ideally) to cure the disease. A “surrogate end-point” does not meet this standard but rather demonstrates a response to the drug such as tumour shrinkage or extended time to disease recurrence. Such a response shows the drug is biologically active with respect to the cancer and *suggests* that the drug may eventually prove efficacious in extending survival time. Because mere biological activity does not constitute proof of efficacy, such a finding is termed a “surrogate” rather than a true endpoint (Fleming and DeMets 1996).

A drug that demonstrates tumor shrinkage or extended time to survival in a clinical trial needs continued follow-up, usually for many years, to determine whether or not it will show efficacy. In clinical trials of cancer drugs, actual evidence of extended life has been rare and the surrogate endpoint became the standard for showing efficacy, even though it meant researchers were “getting the right answer to the wrong question” (Löwy 2000; see also, Johnson, Williams and Pazdur 2003; Fleming 2005).

**Tacit knowledge:** Unarticulated, uncodified knowledge held in people’s minds and bodies. While tacit knowledge is sometimes contrasted to formal, scientific knowledge Collins (1999) argues that all knowledge consists in part of tacit rules that may be impossible to articulate. Despite this important qualification, the term seems useful to designate much of the non-scientific knowledge accrued by patients, such as how it feels to experience cancer, or to undergo a cancer treatment. This knowledge is an important component of what is exchanged informally within patients’ groups and what patient representatives are expected to “bring to the table” in policy discussions. Once expressed in these venues, the once-tacit knowledge loses its tacit status, while remaining outside the realm of the scientific.

**Translation:** In Actor-Network Theory, Michel Callon uses the term *translation* to describe a process of constructing scientific knowledge. Callon (1986) describes the four moments in a translation as: *Problematization*, *Interessement*, *Enrollment*, and *Mobilisation*.

**Voluntary Statement of Information (VSI):** A form developed in the Health Products and Food Branch of Health Canada in 2004 and updated in 2008 which is

designed to “recognize the importance and value of openness and transparency in public involvement activities and decision-making processes” (Health Canada 2008). The VSI invites individuals selected to represent the public on panels, committees and other forms of consultation related to drug regulation, to state whether they and/or an organization to which they belong, have a direct or indirect financial interest in “an organization or company likely to be affected by the outcome of this public involvement activity” (OCAPI 2008: 5). The VSI is wholly voluntary, a feature which drug safety advocates believe limits its use; however, the government claims that requiring individuals to divulge financial information would violate Canada’s Privacy Act (OCAPI 2004:3, Note 1).

**Welfare State:** I use the term “welfare state” to denote the era in Canada’s political-economic development in which a series of universal social programs were put in place and actively maintained, that is, the period from the mid-1940s and to the mid-1970s (Russell 2000). The welfare state era marked a high point for social justice in Canada, giving rise as it did to Unemployment Insurance, the Family Allowance, old age security augmented by the Canada/Quebec Pension Plan and (most central to my research) universal, publicly funded hospital and medical insurance.

Sociologist Bob Russell (2000) ties the demise of the welfare state to the economic crisis of the 1970s. An initial, brief, response to the crisis was to increase social benefits, but from 1975 to 1984 the programs marked time and “The era of building the welfare state was clearly over” (ibid: 36). Russell concludes, “As the outlines of the new economy become clearer, the welfare state does not figure as a major component in it. Moreover, the crisis of the welfare state is also a crisis of social democracy” (ibid: 37).

## **ACKNOWLEDGEMENTS**

First and foremost I give my heartfelt thanks to the research participants for sharing their stories and views on a topic that remains emotionally fraught and divisive. Most of those I interviewed were breast cancer and women's health activists; others were professionals from the government, pharmaceutical and research sectors. All spoke forthrightly about their experiences and this dissertation carries the weight of their trust.

I was privileged to have as my research supervisor Dr. Janice Graham who immediately understood my research problem as fodder for a science and technology studies dissertation. Her breadth and depth of scholarship, her passion for ethnography, her quick mind and rigorous standards, combined to make my graduate school experience both demanding and rewarding. Dr. Graham's qualitative research commons and studio, QuRCS, has been a site for ongoing stimulating encounters with a series of extraordinary PhD students and post-doctoral fellows. Christina Holmes, Mavis Jones and Amrita Mishra have been particularly valued fellow-travelers.

I have also been extremely fortunate to have a dissertation committee of outstanding scholars in their respective fields. Susan Sherwin (philosophy and bioethics), Ingrid Sketris (pharmacy policy), Paul Pross (public administration and political science) and Wendy McKeen (sociology and women's studies) challenged and supported me in the task of bridging interdisciplinary divides, providing me with readings, advice and opportunities along the way. Charles Weijer, an early member of my committee, taught me much about research ethics before departing for the University of Western Ontario.

For five years, I was a doctoral fellow in an extraordinary training program in Ethics of Health Research and Policy, funded by the Canadian Institutes for Health Research (CIHR) and housed jointly in the Department of Bioethics in the Faculty of Medicine at Dalhousie and the Maurice Young Centre for Applied Ethics at the University of British Columbia. This program provided me with funding, workshops, mentorship, and opportunities to attend conferences in health policy and bioethics; it also created a lasting community of critical thinkers working on issues of ethics in health policy issues.

I have been blessed to have funding from numerous other sources, including research grants from Dr. Janice Graham's CIHR grant MOP 74473, Risk and Regulation of Novel and Therapeutic Products, a Norah Stephen Oncology Summer Studentship (Dalhousie University), and conference travel grants from the Canadian Bioethics Society, the Faculty of Graduate Studies at Dalhousie University, and the Beatrice Hunter Cancer Research Training Program in the Faculty of Medicine, Dalhousie University. I have had the opportunity to present my research at three international workshops: the CESAGen Workshop, "Constructing/Contesting Mobilizations: Biopolitics, Activism and Identity," University of Lancaster, Lancaster U.K (June 2008), The 13<sup>th</sup> Berlin Roundtables on Transnationality, "Health Politics in an Interconnected World," sponsored by the Irmgard Coninx Foundation, Berlin, Germany (December 2010), and the Social Science and Humanities Perspectives Workshop, "Critically Interrogating Cancer Survivorship" at the University of British Columbia in Vancouver (July 2011).

This list of acknowledgements would be woefully remiss without mention of my colleagues in the national health policy working group, Women and Health Protection and its lively offshoot, "biojest", both enduring sources of debate about pharmaceutical issues and women's health. Some of the ideas in this dissertation appeared in early form in a paper commissioned by Women and Health Protection, titled Marching to Different Drummers: Health Advocacy Groups in Canada and Funding from the Pharmaceutical Industry, subsequently revised as a chapter titled Who Pays the Piper: Industry funding of Patients' Groups in the book, *The Push to Prescribe: Women and Canadian Drug Policy* edited by Anne Rochon Ford and Diane Saibil (2010).

Finally, I want to thank the many cherished friends and family members who supported my decision to return to university and urged me to carry on when a second bout of cancer interrupted my studies, especially Yukiko Asada, Louise Dulude, Chava Finkler, Monique Lanoix, Abby Lippman, Moira McConnell, my late sister Sylvia Batt, my brother Bob, and my niece Natasha. Within my close circle, Ted Schrecker, my partner for the past two years, has earned a special place, keeping me sane with daily support and a wondrous sense of the absurd.

## CHAPTER 1 INTRODUCTION

### 1.1 PREFACE: A JOURNEY FROM ACTIVISM, CONTINUED

The rapid emergence and growth of the breast cancer movement is arguably the most remarkable example of health activism in the 1990s; yet, despite many fine scholarly investigations of this phenomenon (e.g., Kaufert 1998, Klawiter 1999, Lerner 2002, Grieve 2003, Moffett 2003, Fosket 2004, Radin 2006, Ley 2009, Gibbon 2009, King 2006, Sulik 2010), one central theme of that movement's evolution remains largely overlooked: the bitterly divisive internal struggles over funding from the pharmaceutical industry. I am particularly aware of this neglect<sup>1</sup> because, as an activist in and chronicler of Canada's early breast cancer movement (Batt, 1994), I both observed and participated in these debates. In this dissertation I follow the fraught discourses over "pharma funding" as they played out over a period of two decades within the network of organizations that make up Canada's breast cancer movement. I wanted to understand the divided perspectives within the movement over this issue and to identify forces within and external to the movement that contributed to both the alliances and the debate. At the centre of my study is the question of how groups whose role includes speaking for patients' interests decide whether to accept funding from the pharmaceutical industry.

This story is both collective and personal. For ten hectic years, I was privileged to be part of events that transformed breast cancer from a taboo topic to a *cause du jour*. Diagnosed with breast cancer in 1988, I was still undergoing chemotherapy when I began to question many of the accepted truths about breast cancer and the absence of patients from policy discussions (Batt 1989). Many other women with breast cancer were

following a similar path at the same time. Sociologist Patricia Kaufert (1998) has documented the origins of patient-centred breast cancer groups in this country and in the United States as small groups of patients meeting in one another's homes and local community spaces in the early-to-mid 1990s. Now, the pharmaceutical industry is a taken-for-granted source of funding for many breast cancer groups that claim to speak for patients. As an activist within this movement, I was acutely aware of -- and disturbed by -- the increasingly close embrace of "big pharma." I participated in the fraught debates, within and among the network of interrelated groups that made up the movement but from my position on the ground I could not hope to see the larger picture. Certainly the hurly-burly of activist life left little time for analyzing how or why the shift was taking place. In undertaking this dissertation, I wanted to fill in as many of the blanks as I could in this aspect of the movement's transformation and to move the debate beyond its current, acrimonious stalemate.

I have chosen to study breast cancer organizations in Canada, but I believe the voices of my research participants will resonate beyond national borders and this particular disease. Partnerships between profit-driven companies and non-profit civil society groups are a hybrid construction of the modern neo-liberal state. For a child of the welfare state era, these mergers at the community level unsettle an understanding of democracy in which separations between government, industry and the citizenry were once a given. In examining one social movement in Canada I wanted to provide a case story reflecting a society's political underpinnings in flux -- one which, I hope will inform the understanding of democracy as a fragile ideal, a shared work-in-progress.

## 1.2 THE PROBLEM

*Jillian*<sup>2</sup>: There's always been a huge war between people within the community, between those who accept pharma funding -- as if it were black and white, you know, the "pharma-takers" -- and the sanctimonious ones on the other side who feel they've never been tarnished by that conflict. ...

Sharon: I don't think I've ever heard anyone put it that strongly, that there's been "a huge war." I mean, did you sense [the conflict] as really that strong?

*Jillian*: Absolutely.

*Interview with Jillian, cancer activist and former cancer patient, 2007*

Research conducted in a range of Western countries shows that many patient-run groups are now funded to some degree by the pharmaceutical industry, raising concerns outside these organizations about whether they can truly represent the interests of patients on issues of pharmaceutical and health policy (Baggott and Forster 2008; Ball et al 2006; Chalmers 2007; Day 2005; Hemminki, Toivianinen, and Vuorenkoski 2010; Herxheimer 2003; Jones 2008; Jones, Baggott and Allsop 2004; Mintzes 2007; Vitry and Lofgren 2011). In this dissertation I look at this question from inside the groups and diachronically, with a focus on three sets of actors: the groups, the drug treatments, and the policies affecting both.

I examine the rise of patient-run breast cancer groups in Canada and their transformation over two decades from small, local, autonomous organizations to an intricate network of groups, many of which receive "pharma funding" – and a few that don't. Breast cancer groups are a particularly instructive subset of patients' organizations because they constitute a large, well-organized international network that has developed over a period of approximately two decades; an additional feature of interest to me as a

feminist is the fact that the groups are predominantly run by and for women and women's health organizations have a tradition of health policy activism (Morrow 2007).<sup>3</sup> Breast cancer groups are also an apt site for the study of the social construction of knowledge about drugs because the ontology of the disease has been reconfigured in the past several decades in ways that have moved pharmaceutical treatments from the periphery to the centre of the treatment regimen.<sup>4</sup> In the years since the mid-eighties, much of the debate in breast cancer treatment has centred on breast cancer chemotherapy treatments: which ones, in which combinations, and at which doses might a drug therapy provide the elusive cure?

I wanted to know how the women active in breast cancer organizations saw the alliances with the pharmaceutical industry, as these groups evolved, particularly because the groups developed in tandem with the debates over various treatment regimes these same companies were bringing to market. I was also interested in the relationship of these new organizations with the women's health and consumer rights movements that developed in the immediately preceding decades (as a journalist, I had been active in both). I therefore looked at the different groups and the transformations they underwent over time from the perspectives of their members. A particular focus was the way that members parsed the decisions within their own group(s) over the "pharma funding" question. Taken together, these life histories of multiple organizations create a collective biographical account of Canada's breast cancer movement in its relationship to the pharmaceutical industry, as told by key participants.

To understand the interrelationships between the drug treatment debates, the funding of groups, and the groups' advocacy activities regarding the groups, I also



tracked the social lives of breast cancer drug treatments over the same time period. The concept of drugs having social lives (van der Geest , Whyte and Hardon 1996; Whyte, van der Geest and Hardon 2002) is based on the fact that a drug is both a chemical substance with measurable physical attributes and an entity that acquires social meanings as it passes through its life cycle (i.e., the trajectory from development to actual use and eventual obsolescence). Consider, for example, the range of expertise and personal investment of the following categories of actors: the scientists who develop a drug, the company that invests in the drug's development, the members of the public who buy stocks and watch their values rise and fall, the medical journals that publish peer reviewed articles, the regulators who decide whether or not a new drug will go to market, the insurers who decide whether or not to cover the costs of prescriptions, the news, health and business media that cover stories on pharmaceuticals, and finally, the end-users. In the case of cancer drugs, the latter include cancer patients, but oncologists, general practitioners, pharmacists, nurse practitioners and oncology nurses also "use" the drug in their professional practice. The profoundly subjective meanings which are conferred by a wide range of actors with varied values and vested interests combine with the objective data to shape our understandings or knowledge about the drug. Patients' groups comprise a relatively new addition to the array of social actors and they are positioned to engage in this process of negotiated meaning-making in a more politically effective way than individual patients.

The policies relevant to drugs and to advocacy groups were a third focus of my research. My research spans two decades in which Canada was still in the process of making a radical transition from a welfare state to a nation in which policies were

reconfigured to reflect the trade-based assumptions of neo-liberalism and neo-conservatism (Smith 2005). Patient-centred health advocacy began its ascent on the cusp of this political restructuring: the high-profile AIDS groups that began organizing in the mid-to-late 1980s (Epstein 1996; Silversides 2003) were soon followed by breast cancer groups in the early 1990s (Kaufert 1998); many other disease-specific organizations have modeled on these examples (Landzelius 2006; Orsini 2008). One would expect certain policy shifts to reverberate through these groups as they did for groups within already-established civil society movements, such as services for children and families (Laforest 2004).

How exactly Canada's transformed policy landscape has shaped the patients' advocacy movement is an important question which I look at from the perspective of two policy fields: drug policy and policies governing civil society groups. With respect to drug policies, following the thalidomide tragedy in the 1960s Canada and other wealthy countries introduced a regulatory regime to improve drug safety (Avorn 2011; Regush 1993); in the 1970s the federal government passed controversial regulation to control drug prices (Lang 1974). Both moves were designed to benefit patients: the first, by reducing the risk of dangerous drugs reaching the market, and the second, by ensuring that necessary drugs would be affordable to all. Both initiatives underwent radical change in the 1990s when Canada joined an international movement to harmonize drug regulation (Abraham 2004; Graham 2008). The goal of the harmonization process was to move new drugs to market sooner and to delay the availability of lower-priced generics by tightening patent protection; whether these changes on balance benefit or harm patients' interests is a hotly contested question (Lexchin 2005; Lexchin 2008). By tracing

the evolution of patients' groups that organized around one particular disease, and whose hopes were focused on a particular set of drugs, my research is designed to illuminate how the decision-makers within the groups viewed these controversial policy changes and whether and how they intervened to affect them.

The two decades under study also saw dramatic changes in Canadian policies governing of advocacy groups (Brock 2003, Smith 2005). Throughout the 1970s and 1980s, civil society organizations in Canada were recognized as having a useful role in shaping public policy (Pross 1992). Beginning in the 1960s, the federal government put programs in place to provide public funding to advocacy groups as a mechanism to increase the power of underrepresented segments of the population. This regime culminated with the 1982 Charter of Rights and Freedoms, which recognizes citizens both as individuals and as members of particular categories (Jensen and Phillips 1996). In the 1980s, government and business actors destabilized this construction of citizenship. The term "special interests" entered the discourse, undermining the legitimacy of groups whose purpose included advocating for the equity rights of a particular sector; meanwhile, government funding cuts reduced their capacity (Jensen and Phillips 1996). These changes had the potential to affect patients' organizations in a number of significant ways, in particular their financial viability (through reduced sources of public funding) and their identities (by calling their advocacy role into question). How this recent addition to the advocacy sector navigated these barriers is a question with theoretical as well as policy implications.

### 1.3 RESEARCH QUESTIONS

My central question is: *How did patient advocacy groups that engage in knowledge claims about pharmaceutical drugs come to form alliances with the pharmaceutical industry?*

Related questions explore the politics and policy implications of these alliances:

- What are discursive struggles within the groups studied, and what underlies them?
- What is the nature of the alliances, particularly with respect to advocacy concerning drugs and drug policies?
- What distinct periods can be identified in the evolution of the alliances between pharmaceutical companies and breast cancer groups and what are the factors underlying them?
- Do the periods suggest industry cooptation or incorporation of the groups by industry interests?
- What codes of conduct govern the alliances, and how did they evolve?
- Do these codes serve the public interest? If not, whose interests do they serve and what are the alternatives?
- What typologies best characterize the perspectives and conflicts within the groups studied?
- How have transformations in Canada's policy landscape brought by successive neoliberal and neoconservative governments since circa 1980 reverberated within the breast cancer movement?

## **1.4 OUTLINE OF CHAPTERS**

The dissertation has six chapters: Chapter 1 comprises the introduction and review of the literature, in Chapter 2 I explain my methods, in Chapters 3, 4 and 5 I present my findings, and Chapter 6 is my conclusion. I summarize each of the chapters below before moving to my literature review.

In the first two sections of Chapter 1 (above) I introduced the problem, citing relevant literature, and stated the questions my research addresses. The next section of this introductory chapter is a Literature Review in which I compare disciplinary approaches to the questions stated above and indicate gaps that my research is designed to address. Because I am interested in critically examining the social processes of constructing knowledge about medications, I centre my theoretical approach in the interdisciplinary field of science and technology studies (STS) then broaden my review to include additional research in other disciplines and fields. Foremost among the latter are bioethics, health policy (including pharmaceutical policy) and three specialties within the social sciences: anthropology, psychology, and political science. I also examine contributions in several areas of scholarship that cut across disciplines: women's studies, development studies, and the social movement literature. The final section of my literature review looks at the numerous typologies of health-related and disease groups that analysts of these movements have developed (Brown and Zavestoski 2004; Epstein 2008; Hess 2005; Jones 2008; Klawiter 1999; O'Donovan 2007; Rabelharisoa and Callon 2002; Ruzek and Becker 1999). I conclude Chapter One with summary observations from this review that informed my choice of methods.

In Chapter 2, I discuss my research methods. My basic methodological approach is ethnographic, drawn from anthropology and applied to science studies (Franklin 1995). Specifically, I use ethnography to compare the way different cultures within the breast cancer movement, the pharmaceutical industry, government, and other spheres of influence, construct knowledge claims about treatments. I use ethnographic methods of data collection including participant observation, interviews, text analysis and autoethnography, with ongoing thematic analysis of the collected data. I also use two methodologies from science studies, actor-network analysis (Callon 1999[1986]; Latour 1999; Law 1999) and archeological and genealogical analyses (Foucault 1972, 1980, 1994). Actor-network analysis is a methodology for studying processes of social negotiation and conflict among actors engaged in knowledge construction, and has been effectively applied in science studies to the study of medical technologies (e.g., Epstein 1996, Heath 1997; Singleton and Michael 1993; Williams-Jones and Graham 2003). A Foucaultian archaeology seeks to uncover underlying structural shifts in society – such as the emergence of a new class of experts -- that change the rules about what is sayable and thinkable and what can be called “true” or “false” (Foucault 1994; Hacking 2002). Genealogical analysis is based the assumption that scientific knowledge does not develop through a smooth progression of formal scientific discoveries, but rather includes the marginalized knowledges of the “unqualified,” such as patients (Foucault 1980: 82). A genealogy seeks to uncover contestations among actors that create shifts, breaks and discontinuities. As a methodology for exposing hidden struggles and discredited knowledges a genealogy is thus a suitable tool for examining patients’ movements and their contribution to scientific knowledge (Epstein 1996).

To present my findings I use several approaches to descriptive narrative. To highlight changes over time, I use a narrative history throughout to report my results, but each chapter has a different depth of field (Singleton and Michael 1993). My Chapter 3 narratives are close-ups, presented as the biographies of three groups which were selected, on the basis of their views of pharma funding, as *critical cases* (Snow and Trom 2002) among the numerous groups that emerged as Canada's breast cancer movement developed. None of these groups is necessarily typical of breast cancer groups in Canada; rather, they are distinct points on a "No-Maybe-Yes" continuum. In Chapter 4 I use three overlapping historical narratives to depict landscapes. Stepping back, I describe the evolution of competing discourses in Canada over three contentious questions: government-funded healthcare, pharmaceuticals and the regulation of pharmaceutical companies, and the place of civil society groups. In Chapter 5 my perspective is mid-range. I use three consecutive meso-level narratives to create a moving panorama that depicts the sequential periods in Canada's breast cancer movement that my analysis exposes.

This final chapter of results concludes with a Supplement, titled, "A Socially Constructed Pharmacopoeia of Breast Cancer Treatments." A pharmacopoeia is intended to be an authoritative reference for pharmacists (or in earlier times, apothecaries) that specifies the herbal, chemical, or other ingredients that make up a drug remedy – essentially, an authorized recipe book. In this Supplement, I use three examples from my research to show that, in addition to these tangible ingredients, a variety of social influences also "makes up" the various breast cancer treatments discussed in the text. Accounts of these influences appear throughout the narratives of Chapters 3, 4 and 5. I

structure my socially constructed pharmacopeia as entries in which I list the “social ingredients” that, based on my research, contributed to the construction of knowledge about a specific treatment or pharmaceutical policy.

In Chapter Six, the Conclusions, I discuss the findings and their implications for theory, pharmaceutical and health policy, and for the groups themselves. As part of my discussion, I include self-reflection on my prior engagement in the movement and the pharma funding issue and its relation to my research. I use three concepts from the science studies literature to interpret my findings: 1) *periodicity* (based on Foucault’s theories and discussed in reference to patients’ groups by Epstein (2008); 2) *boundary objects* (Star and Greisemer 1989), which I discuss in relation to the multiple understandings which different actors assign to an “Unrestricted Educational Grant” from the pharmaceutical industry; 3) and *translation*, a process in which a realignment of actors’ interests disrupts, stabilizes or shifts the complexity of a network, reconfiguring in turn the power of factions struggling to shape the meanings of a technology (Callon 1999 [1986]; Williams-Jones and Graham 2003). Next, I draw from the typologies of groups discussed at the end of this chapter to construct a typology that captures the essence of my groups.

Based on my conclusions, I assess the contribution of my research project to the literature and suggest research directions that would answer some of the questions I was not able to answer, or to answer questions that my research raises. Finally, I discuss the policy implications of my research, first from the perspective of internal policies of the groups, and second from the perspective of state or provincial/local policies.



## **1.5 LITERATURE REVIEW: AN INTERDISCIPLINARY VIEW**

As mentioned above, I centre my theoretical approach in the interdisciplinary field of science and technology studies (STS) then broaden my review to include additional research in other disciplines and fields.

### **1.5.1 Science and Technology Studies**

Science and technology studies provides the theoretical and methodological tools I need to examine how social actors -- in my research, primarily patients' organizations -- affect the process of creating and interpreting scientific knowledge about cancer treatments. A *critical* science studies inquiry assumes that scientific discovery should contribute to the public good. To capture this ethical dimension, the methodology may incorporate an analysis of power relationships, and macro-level political economy influences on the local (Hess 1998), and/or shift the locus from the work of scientists to that of the user of scientific discoveries (Oudshoorn and Pinch 2004). Fine-grained ethnographic-historical analysis of change to local social, institutional, and/or regulatory structures, combined with a critique that shows the social construction of the phenomena and the actors involved, are used to provide a multi-level perspective (Mirowski and Sent 2008).

Two features have drawn STS researchers to study patients' groups and health movements: first, the groups bring lay expertise to bear to shape the scientific agenda politically; and second, these organizations have an inherent interest in the science and technologies that are applied to predicting, diagnosing and treating disease (Epstein

2008). Interest in social movements and activist groups is relatively recent in STS literature, however; early incarnations of STS, which date historically to Kuhn's (1962) challenge to positivism in science, focused on scientists and their laboratories (Hess 1997). Sociologists and political scientists, by contrast, have studied social movements and the role of interest groups in these movements since the 1960s (Pross 1992, Klandermans and Staggenborg 2002, Smith 2008). The bellwether STS analysis of a patients' movement is Steven Epstein's (1996) ethnographic study of the AIDS movement in the United States. In a 2008 review article of STS research on health movements and patients' organizations, Epstein argues that, having begun by borrowing from medical anthropology, medical sociology and social movement scholarship, STS "now has something to offer back to scholars in other domains" (2008: 524). The two contributions derive from the same aspects that drew STS researchers to study patients' groups: insights into the politics of expertise and into the effects on identity of the intermingling of humans and non-human technologies.

While STS provides a unique lens for examining health movement and patients' groups, the questions related to pharma funding of these groups have not been of paramount interest in the STS literature. STS researchers have acknowledged the issue of corporate ties (Goldner 2004, Novas 2005, Hess 2005, Rose 2007, Epstein 2008, Hess et al 2008, Zavestoski et al 2004); however, researchers in other fields have arguably taken a more active interest in problematizing pharma-related conflicts of interest in patients' groups. O'Donovan (2007) suggests that sociologists and STS theorists, because of their interest in challenges to dominant cultural authorities, have selectively studied the more radical health organizations, conceptualizing them as social movement organizations

when in fact many health-related and patients' organizations -- such as those with corporate ties -- may be "contributing to the intensification of biomedicine's authority and further widening its jurisdiction" (O'Donovan 2007:713). Mirowski and Sent (2008) offer a further insight into the relative neglect of corporate ties in STS research on patients groups with their observation that "STS has only very recently begun to come to grips with the phenomenon of commercialization, lagging behind the Cassandras and the science policy bureaucrats by perhaps a decade or more" (Mirowski and Sent 2008: 636).

In his ethnographic study of the AIDS movement in the United States, Stephen Epstein (1996) demonstrated how AIDS activist groups changed the practice of science by demanding changes in the clinical trials process used to test the safety and efficacy of HIV/AIDS medications. With a cry of "drugs into bodies" they contested the ethics of placebo-controlled trials which required desperately ill patients participating in trials of new medications to risk being randomly assigned to the "no drug" arm of a trial. They also altered American drug policy by challenging the American drug regulator, the Food and Drug Administration (FDA), to approve new drugs for HIV/AIDS more quickly, shifting the agency's priority from safety to access (Epstein 1996, Hilts 2003). Patients can and, Epstein implies, should have a say in the shape and societal application of medical research. In highlighting the impact of HIV/AIDS activist groups on research and regulatory policy, Epstein's study illustrates how actors with non-credentialed expertise can leverage their power to affect the practice of medical science and the regulation of medical technologies. This knowledge, furthermore, is not simply a less sophisticated grasp of the knowledge experts possess, but rather constitutes an epistemology that merits study in its own right. It is an "embodied" knowledge which

derives from the activists' first-hand experience of their illness as it affects their everyday lives. This includes their knowledge of drugs (as users), of clinical trials (as participants), and of drug regulation (as the actors arguably most profoundly affected by these regulations). STS theorizing addresses this embodied quality in its attention to the "intermingling of humans and non-humans" (Epstein 2008: 534); in the case of a drug, the entity literally becomes one with the patient's body.

For all its richness, Epstein's analysis of the HIV/AIDS movement does not incorporate an analysis of the movement's corporate ties, nor does he explore the influence of the macro-level political economy environment on American AIDS activist groups. Both themes make provocative cameo appearances, however. His narrative includes a revealing example of a polarization that occurred within the movement when Burroughs Wellcome, the manufacturer of the anti-retroviral treatment drug azidothymidine (better known as AZT), donated money to several HIV/AIDS groups in New York and San Francisco (Epstein 1996: 199-200). And while Epstein's treatment does not emphasize the macro-level political economy environment in which American AIDS activist groups functioned, the rise of AIDS activism in the 1980s coincided with the rise of neo-liberal politics. The following passage, in particular, suggests that activists were aware that some of their demands for regulatory change meshed comfortably with the goals of the conservative administration of Ronald Reagan.

The FDA was killing the drug companies and preventing useful products from getting to market, the [conservative] argument ran; the best solution would be to repeal the Kefauver-Harris amendment, which had granted to FDA the authority to assess the safety and efficacy of drugs. "Especially considering who was the president, we had concern" about adding fuel to the deregulatory movement, recalled David Barr of ACT UP/New York: "But it wasn't enough concern that it would stop us from doing what we were

doing.” Soon, an unlikely alliance had developed – usually tacit, but sometimes explicit – between AIDS treatment activists and conservatives, leaving consumer protection groups and treatment liberals on the other side.” (Epstein 1996: 223).

Other analyses of the FDA’s transformation in the Reagan era reinforce the suggestion that parts of the AIDS activists’ agenda coincided with the push by neoliberal governments and corporations towards relaxing safety regulations and speeding new pharmaceuticals to market (Hilts 2003, Abraham and Courtney 2007, Mirowski and Sent 2008).

More recently, in a review of the contribution of science and technology studies to theorizing about patient groups and health movements, Epstein says that a “hallmark of recent work has been the attempt to make sense of the multivalent politics of incorporation and cooptation” (2008: 522). He defines *incorporation* as occurring when “the insights and legacies of patient advocacy are channeled back into institutionalized biomedical practice” while *cooptation* occurs when “the radical potential of an activist critique is blunted or contained” (ibid: 522). Both processes may be hard to interpret, Epstein cautions: what appears as a taming of radicalism may instead (or at the same time) reflect activists’ success in transforming biomedicine; similarly, a moderated critique may reflect a deepened understanding of the issues rather than (or mixed with) cooptation. “Astroturf” or front groups masquerading as patient advocacy groups (Beder 1998; O’Donovan 2007), created by pharmaceutical companies to promote their products or gain support for regulatory approval, are best viewed as “one end of a continuum” in which patient groups receive funding from the pharmaceutical industry, says Epstein (ibid: 522). As a more ambiguous example of what might appear to be cooptation, he

cites the moderation of AIDS activists' political goals and methods over time, a change which he attributes in part to changes in the research trajectory and in part to activists' advances in their understanding of AIDS. In this case, he says, "blunt and accusatory terms such as 'cooptation' appear unhelpful" (ibid: 523).

The literature on "biological citizens" (Petryna 2002) and "biocitizenship" (Rabinow 1992, Rose 2004, Rose 2007, Novas 2007, Rose and Novas 2006, Gibbon and Novas 2007, Rabinow 2007) represent another STS contribution to theorizing about patients' organizations, i.e., the assertion of rights based on patient status. Adriana Petryna (2002) analyses the post-Chernobyl mobilization of citizens of the Ukraine who suffered adverse health effects. Collectively, they claimed recognition and resources based on their suffering, asserting a new type of citizenship rights which she terms "biological citizenship." In a similar vein, a central concern of Paul Rabinow, Nicholas Rose and colleagues is to understand how the Human Genome Project has affected social and ethical practices. Rabinow argues that the new genetics re-articulate Foucault's two poles of biopower, creating sites of new knowledges and powers (a new episteme) based on genomics. Using as his prototype the French muscular dystrophy organization, the *Association française contre les myopathies (AFCM)*, Rabinow identifies new types of groups that have arisen in response to genetic diagnoses, monitoring techniques and therapies. These groups of individuals, their relatives and other supporters mobilize under the umbrella of people at genetic risk of developing a disease. In doing so, Rabinow argues, they create a new type of identity in response to genetic technologies which he calls "biosociality." Building on Rabinow's analysis, Rose and Novas have conducted additional case studies which depict partnerships among patients' groups, biotech

companies, and biomedical researchers as valuable developments (Rose and Novas 2006). They propose the concept of “biocitizenship” to theorize innovative citizenship projects where patients and their allies sometimes lead in setting ethical standards and pushing scientific boundaries.

While the work of Rabinow, Rose and Novas draws attention to a striking subset of patients’ and disease-specific organizations, numerous scholars have advanced critiques of the biocitizenship concept (Gibbon and Novas 2007). Margaret Lock (2007) highlights limit to genomics as the basis for the concept of biosociality in an ethnographic study of the biosocial networks that developed after Alzheimer’s disease was named as a heritable condition in the late 1970s. Alzheimer’s disease support groups, which are attended mainly by family members involved in care giving, can be conceptualized as a form of biosociality, she observes; yet the discussions among participants at these meetings is overwhelmingly about practical coping strategies for caregivers, with little attention paid to whether or not genes are implicated in the condition. Plows and Boddington (2006), in a critical examination of biocitizenship, argue further that the “bio” prefix in biocitizenship masks the social and ecological issues central to movement discourses about health. The use of biocitizenship as an analytic concept therefore risks obscuring debates which require urgent attention, these authors argue, including the need to distinguish among groups that mobilize to contest corporate power in the health field, and those that support a gene-focused research and policy agenda while using funding from the pharmaceutical industry to mobilize. Plows and Boddington suggest that the forced focus on biotechnological research implicit in biocitizenship could readily be co-opted to serve biotechnology.

These diverse examples suggest the need to distinguish and unpack the different types of illness and/or disease-risk rights claims. Critical analyses of patients' groups need to capture the tension inherent in our relationship to technologies (Haraway 1985). Medical technologies have an inherent appeal (Lock and Kaufert 1998) that co-exists alongside counterdiscourses in illness-related discourses on citizenship (Brenner 2000, Plows 2005, Hess 2005, Lock 2007).

### 1.5.2 Health and Pharmaceutical Policy

Analyses that focus on health policy highlight concerns that collaborations with the pharmaceutical industry may skew the priorities of the organizations, leading them to push for policy decisions that support industry goals but adversely affect health outcomes, burden health systems with unnecessary costs and/or direct resources to a few disease communities that happen to be well organized (Baggott and Forster 2008; Ball et al 2006; Chalmers 2007; Day 2005; Hemminki, Toivianinen, and Vuorenkoski 2010; Herxheimer 2003, Jones, Baggott and Allsop 2004; Jones 2008; Mintzes 2007). Underlying this concern is the expectation that collaboration with a drug company may expose a group to pressure from the company and/or to biased truth claims about its products.

Pharmaceutical drug policy analysts note the potential for groups comprised of patients and/or their family members to portray their members as “caring humanitarians” pitted against “cold guardians of the public purse” as they demand that a new, untested therapy be added to a drug formulary (Graham 2001:131). Graham continues:



So we are prescribing and funding drugs, despite the lack of strong, publicly sponsored best-evidence of efficacy, to satisfy family (and, one presumes, clinician and industry) demands. (Graham 2001:133)

In contrast to Steven Epstein's (1996) study of how the advocacy of HIV/AIDS organizations changed scientific knowledge by intervening in clinical trial design, Graham's focus is on a later stage of the drug's life cycle (Van der Geest, Whyte and Hardon 1996; Whyte, van der Geest and Hardon 2002; Cohen et al 2002), that is, the point at which an insuring body makes the decision whether or not to fund the use of a drug. An exchange in the *British Medical Journal* highlights the fact that members of a disease-group are not always in unanimous support of the organization's policy initiatives in this regard. Iain Chalmers (2007) in the U.K. and Linda Furlini (2007) in Quebec each turned to the Alzheimer's Society for support and each was disillusioned to see the Society push to have state coverage for Aricept, a drug for dementia. In the view of both Chalmers and Furlini, the Alzheimer's Society had responded to pressure from Pfizer, the drug's manufacturer, which had provided funding to the Society in each country. The Canadian Alzheimer's Society's CEO denied Furlini's allegations of corporate influence and asserted, "The Alzheimer Society is not in the business of evaluating the effectiveness of different therapies, but instead advocates that all treatment options deemed safe and effective by Health Canada be available and accessible to all those who might benefit from them" (Dudgeon 2007). The conflicting discourses over industry funding of an organization revealed in this series of letters illustrates the complex play of knowledge/power among members that can underlie an organization's advocacy regarding drug policies.

Health policy researchers have flagged this area as one in need of further study. At a pan-European workshop held in 2006, twenty-two health researchers from ten countries discussed health consumer and patients' organizations (HCPOs) in Europe (Baggott and Forster 2008). In all countries, the number of organizations representing patients, users and caregivers had increased. Researchers from most countries reported that groups had moved from self-help to greater political awareness and lobbying, but their financial and human resources were often limited. Their impact on policy was only apparent if the organizations were supported by powerful interests: the medical profession, state agencies or the pharmaceutical industry. In this regard, "researchers from almost every county ... identified funding by drug companies as a major issue" (ibid 2008: 90). Delegates to the workshop worried (but had not demonstrated) that dependence on pharmaceutical companies increased the likelihood that the organizations would support the industry's line although they recognized that dependence on professionals and government could also compromise independence. Only in Ireland, Finland, and the U.K. had researchers studied actual organizations. Workshop participants considered the internal workings of health consumer and patients' organizations to be mysterious but expressed concerns that some were not democratic or representative. They concluded that health consumer and patients' organizations were an underresearched area in need of a systematic research program to address issues of structure, aims, activities and resources, to capture specific health care cultures and systems, and to examine questions of representativeness, legitimacy, and independence from other stakeholder interests.

The observations of these researchers complicate the focus on a democratic broadening of expertise which is a theme in the STS literature and which characterizes the participation of lay participants in decision-making as positive. Terms like “representativeness”, “legitimacy”, and “high jacked” indicate process concerns related to pharma funding and other aspects of group structure; a group’s ability to participate as an actor does not rest solely (or even primarily) on claims to knowledge. Potential problems arise from the sheer number of groups jockeying for place, from internal disagreement within patients’ groups over the question of pharma funding, and from the possibility that the groups with the most resources (including those with pharma industry resources) – are most likely to achieve their advocacy goals, even though the funding itself (as Chalmers and Furlini imply) may undermine the organization’s mission. In Canada, two physicians writing in Canada’s medical journal of record make a similar point: that organized political activism by patients’ organizations contributes to the misallocation of health resources because of inequalities in representation among disease groups:

Although federal leaders elsewhere have galvanized their citizens to develop national evidence-based health care institutions ... Canada’s parliamentarians issue occasional impassioned pleas on behalf of specific patient groups fortunate enough to make their concerns appear politically expedient.  
(Hébert and Stanbrook 2010)

### 1.5.3 Bioethics

The central theme in the bioethics literature regarding funding from the pharmaceutical industry is the ethical one of conflicts of interest and the potential of these conflicts to

undermine social trust by distorting truth claims about drugs (Angell 2004) and by eroding medicine's professional obligation to the patient (Relman 1980). To date, the pharmaceutical industry funding of patient groups has attracted less attention than industry financing to more established actors in the system, such as medical researchers, departments of continuing medical education, or prescribing physicians. Some contend that funding from the pharmaceutical industry (and the prospect of losing such funding once it has been granted) may unduly influence physicians' prescribing patterns (Orlowski and Wateska 1992, Oldani, 2004, Adair and Holmgren 2005), clinical trial study designs and/or interpretation of results (e.g., Angell 2004; Bekelman, Mphil, & Gross, 2003; Johnston 2008; Krinsky, 2003; Downie 2006; Graham, 2008), the decisions of medical journal editors' about which articles to publish (Goozner, 2004), bioethicists' judgements about whether a practice in medicine is right or wrong (Elliott, 2001, 2004), universities' decisions about whom to hire and fire (Somerville 2002, Schafer, 2004), the content of continuing medical education (Angell 2004; Wazana et al 2000, Brennan et al 2006, Hebert et al 2008, Steinbrook 2008) and drug regulatory agencies' rulings about whether a drug is effective and safe enough to allow on the market (Abraham, 2004).

In forming alliances with the pharmaceutical industry, patients' groups thus join a long line of actors who have done the same. Proposed remedies to address the potential problems arising from these conflicts include varying degrees of disclosure, professional guidelines or regulations that set limits on the type and size of gifts which are acceptable, and "zero-tolerance" measures that encourage the refusal of gifts and promote such practices as recusing oneself from decision-making where a conflict might affect one's view or taint the process. Over the past two decades the bioethics literature has wrestled

to find a satisfactory definition of “conflicts of interest” (Lemmens and Singer 1998; Schafer 2004; Thompson 1993), with recent entries acknowledging both the seriousness of the problem and of the lack of consensus within the medical community about how to address it (Bean 2011; Brody 2011; de Melo-Martin 2011; Harter 2011; Huddle 2011; Hurst and Mauron 2011; Kitsis 2011; Komesaroff and Kerridge 2011; Lexchin and O’Donovan 2010; Morreim 2011; Stell and Stossel 2011; Stretch and Knüppel 2011; Tsai 2011; Williams Jones 2011).

In 2007 the British Medical Journal invited contrasting commentaries on the question, “Should patient groups accept money from drug companies?” (Kent 2007, Mintzes 2007). The articles illustrate the competing ethical discourses as well as the identities of the actors on each side of the debate. Alastair Kent, director of the Genetic Interest Group in London, England, argues that money from the pharmaceutical and biotech industries allows groups, including his own, to provide better services and support for the individuals and families they represent. There is nothing inherently wrong with drug industry funding, he says, provided that “the source is acknowledged and there are no hidden strings” (ibid: 934). Besides, he argues, public money and grants from charitable foundations cannot be assumed to be strings-free either, as “no person or group will be overly keen to support a campaigning organization if they think that their money will be used to ‘buy a stick to beat them with’” (ibid: 934). Barbara Mintzes, an epidemiologist at the University of British Columbia, argues that funding to patients’ groups from industries that sell products to treat their illnesses involves an inherent conflict that compromises the groups’ ability to provide impartial information and to speak on behalf of people who are ill (Mintzes 2007). Mintzes cites three dangers to

patients: disguised product promotion funnelled through a seemingly impartial party, confusion between the interests of the group and the corporate sponsor, and “inadequate representation [for patients] when those interests diverge” (ibid: 935). While she welcomes steps to make funding arrangements more transparent, Mintzes contends that the problems remain: groups are reluctant to discuss safety concerns about a drug if they have received money from the company that makes it; similarly, the groups are likely to side with a sponsoring company in policy disputes over issues such as which drugs to insure. The evidence points to even small donations compromising a group’s impartiality, says Mintzes, and groups eventually may lose public trust.

The debates, themes and methodological approaches in the bioethics literature help to situate patients’ and health consumer organizations within a broad network of institutions in which the pharmaceutical industry is an influential and much-discussed actor. Alliances with patients’ groups take on a different meaning if they are part of a coherent system of relationships formed by the pharmaceutical industry with scientists and health care professionals rather than a phenomenon specific to the citizens within social movements who are interested in, or would-be users of, medical technologies. Arthur Schafer, a philosopher-bioethicist and director of the Centre for Professional and Applied Ethics at the University of Manitoba argues that, “...all of modern medicine is floating on a sea of drug company money and the result has been utterly corrosive” (Taylor 2008).

#### 1.5.4 The Social Science Literature

Within the social sciences, anthropology, psychology, and political science are three specialties that provide theoretical and methodological frameworks for studying funding from the pharmaceutical industry.

*Anthropology and the Gift Culture* Anthropologists have approached pharmaceutical funding as a feature of medical culture. Two anthropologists who have used ethnographic methods to study conflicts of interest in medical settings (Oldani 2004, Mather 2005) both build theoretically on Marcel Mauss's (1967 [1923-24]) analysis of the cultural role of gifts and on sociologist Pierre Bourdieu's idea that particular cultures have "rules of practice" (Bourdieu 1984). Michael Oldani (2004), a former drug representative turned anthropologist, draws from Mauss' concept of the gift as a practice which, in studies across varied cultures, Mauss found set up expectations of reciprocity. In Oldani's analysis of the "pharmaceutical gift cycle," the gift exchange is at the core of the relationship between the physician and the drug representative. Most scholars, Oldani says, make the mistake of studying pharmaceutical gifts "divergently", by classifying the gifts according to type (e.g., personal use items, meals, educational opportunities). Pharmaceutical gifting has a cycle, Oldani argues, in which the meaning of the parts resides in their contribution to the whole and these interrelationships are only visible when the gift culture is viewed convergently. The cycle of pharmaceutical gifting to physicians relies heavily on food and begins with the training of medical students. A process of introducing a physician to the "rules of the game," continues when the doctor enters practice and can take years. Physicians who become influential, for example as faculty members in key teaching hospitals, are cultivated as "expert speakers" and

“product champions.” In Oldani’s analysis, patients are a “third party,” another concept borrowed from Bourdieu. They have value in the gift cycle because their bodies contain endless sites for potential pharmaceutical cures which in turn generate prescriptions. The goal of the gift exchange culture is to maintain a “feel-good economy” in which physicians and company representatives co-exist, and where decisions, paradoxically, are both “all about the patient, while simultaneously not about the patient at all.” (Oldani, 2004: 343). The “rationales” of the marketplace and the gift economy often usurp the rational world of medicine, concealing or ignoring the risk for drug-induced side effects, including patient death.

Charles Mather (2005), an anthropologist at the University of Calgary, similarly draws on the theories of Mauss and Bourdieu in an ethnographic study of the physician/industry relationship in which his focus is on the pharmaceutical industry’s effect on the culture of medical research at a Canadian hospital. Mather’s perspective also draws on theories of political economy theory: he frames the incursions of industry into medicine in Canada as part of a worldwide trend over the past 25 years to shift the burden of research and development (R & D) from public to private institutions. This trend was supported by the international trade agreement, the Trade-related Aspects of Intellectual Property Rights (TRIPS). In Canada TRIPS took the form of an agreement that the industry would spend more on research and development (which the Canadian government believed would help stimulate the economy), but only on the condition that the government change its patent protection laws to be similar to those in the U.S.

Like Oldani, Mather found that pharmaceutical company gift-giving was extensive, took varied forms, and created social spaces for other types of relationships to



develop. Many university researchers, if not all, felt they could not do their jobs without attending industry-funded functions; they also felt powerless to effect change. They differed, however, in their assessment of the ethical implications of the relationships. Some believed the industry manipulated them to make a profit and worried that doctors did not have enough control over educational events; others felt that industry and practitioners mutually benefit from interaction and were sceptical that doctors were affected by industry public relations strategies (“We don't check our scientific judgment at the door”). Opinion was also divided as to whether professional/ institutional guidelines were helpful, or whether they simply created an illusion that ethical decisions were a personal choice, when in fact large institutions are already ethically compromised by industry.

My research extends these analyses to the patient advocacy community where I ask whether the relationships between pharmaceutical companies and organizations have created a gift culture and, if so, what “rules of the game” have been established. Oldani argues that the term “consumer demand” is used to imply consumers are involved in a one-way process of demanding drugs, even though doctors and the industry often fuel these demands by circulating pro-drug discourses on critical issues where the evidence is under debate. Has the participation of patients’ organizations in alliances with drug companies functioned to integrate these groups into the larger system of the circulating discourses and/or drug promotion by reciprocal favours that Oldani and Mather have documented?

*Psychology and Human Decision-making* Evidence to support conflict-of-interest as potentially harmful to the practice of good medicine appears in research that applies

psychological studies in the processes of decision-making to physician practice. Dana & Loewenstein (2003) reviewed this body of work and concluded that attempts to control bias in physician decision-making by mandatory disclosure, limiting gift size, or educational initiatives (classic strategies advocated by bioethicists to resolve ethical problems) are likely to fail because they rest on a flawed model of human behaviour. For example, controlled decision-making experiments (Katz, Merz, & Caplan, 2003) found that participants incorrectly assumed that their decisions would reflect little or no bias, although their estimation of their colleagues was less sanguine; furthermore, people were unable to avoid bias even when it was in their best interest to do so. Studies of actual physician behaviour yield similar results. Attending educational events given by a pharmaceutical company-sponsored speaker does increase prescribing of that company's drugs, yet physicians persist in the belief that they (but not their colleagues) will be unaffected (Orlowski & Wateska, 1992, Steinman, Shlipak, & McPhee, 2001, Katz et al., 2003; Krinsky, 2003).

*Political Science* Political scientists bring to their analyses a sophisticated understanding of the role of pressure groups and how they have evolved within democratic systems over time (Pross 1992; Smith 2005). They are interested in patients' organizations as actors in the political process: how influential are they? Does their political activism enhance the democratic process? What do these collaborations mean for citizenship, for democratic debate, and for the exercise of political power? Like STS theorists, political scientists recognize and take an interest in the policy expertise of members of the public. Paul Pross (1992), for example, describes spheres of influence on public policy in terms of concentric policy circles. In this schema, the most

knowledgeable political activists participate in a circle called the “sub-government” whereas those with less expertise form part of the next circle, the “attentive public.”

Political science theories of group activism have long recognized the importance of resources, including money, for effective group mobilization, including the acquisition and maintenance of expertise; they flag the potential of funding from outside sources to subvert the democratic integrity of an organization (McCarthy and Zald 1977, Pross 1992). In this tradition, Bruce Wood, a political scientist in Birmingham, England compiled a data-base of groups engaged in patients’ advocacy in the U.S. and the U.K. in the late 1990s. He discovered well over 200 national groups in each of the two countries plus many more at the regional or local levels; most had been founded in the past ten to 15 years (Wood 2000). Wood describes his analysis as the first comparative study of patients’ associations to focus on their political power and influence. He identifies the pharmaceutical industry and other suppliers of medical technologies, as one of “three groups of interests with an incentive to ‘colonize’ associations” (Wood 2000:79). The other two groups of potential colonizers are medical professionals, notably physicians and researchers, and health care providers and insurers. Within a particular industry sector such as pharmaceuticals or biologics, companies have shared as well as individual interests in patients’ organizations, Wood observes. Individually, each company wants to promote its own brand; collectively, they all benefit by encouraging demand for their type of product.

At the time of his research, however, Woods concluded that the groups were relatively unaware of their political potential and with a few exceptions, such as AIDS campaigns, these groups had not begun to flex their political muscle – a situation that has

changed over the past decade. Although Woods documented “large donations from drug companies to certain skin conditions’ associations” (ibid:16), in a book of almost 200 pages he devotes only two pages to discussing alliances between pharmaceutical companies and patient groups that emerged from his research. He concludes that organizations may not be sufficiently aware that they risk losing credibility if they appear to be endorsing the product of a company from which they received financial support.

Hans Lofgren’s more recent analysis (2004), based on patient advocacy web sites in Australia and on the literature of consumer and patient advocacy groups in Australia and globally, suggests that Woods’ research may have predated the “pharma partnership” era by a few short years. A political economist based in Australia, Lofgren identifies a process of diachronic change within consumer and patient advocacy organizations and in his analysis highlights the conflicting perspectives among groups over pharma funding. Depending on their mandates, he concludes, groups today play contradictory roles in the pharmaceutical policy domain. Some resemble the critical social movements of the 1960s and 1970s which questioned established experts and powerful institutions, but many others exhibit characteristics of corporations -- “with chief executive officers, large budgets and business plans” (ibid: 224) -- and may be fully incorporated into dominant power structures.

Lofgren is among the political theorists who use a political economy lens to look at ways in which the macro-level political economy influences local institutions, events and relationships. He interprets the changing influence of patient advocacy groups in pharmaceutical policy using two conceptual analyses he views as complementary. First, the “risk society” (Beck 1992, Giddons 1999) considers various societal sectors as having

a claim to political participation, based on their different stakes; thus, patient groups have been awarded participant status in the drug policy arena because of their obvious stake in the availability of pharmaceuticals and in the particulars of drug regulation. Second, Lofgren notes the usefulness of analyses comparing corporatist and neoliberal governance models and the way in which post-industrial societies have evolved from one to the other. The term “corporatism” derives from the Latin term *corpus* or body and corporatist governance refers to arm’s length bargaining relationships between diverse bodies. In the corporatist model of governance, bargaining relationships (especially capital *versus* labour, but also the state and sectorial interests) are arm's length; neoliberal governance, by contrast, is premised on the notion of partnerships between actors who span a wider range. Australia, like other industrially developed countries, still accepts government regulation of pharmaceuticals as necessary to the market economy, says Lofgren, but in a neoliberal era the government's role is no longer to ensure public health above all, but rather to retain social acceptability while coordinating and facilitating international market exchange. To achieve this, governments manage pharmaceutical policy by orchestrating negotiations among large numbers of public and private stakeholders organized in complex networks of partnerships -- networks in which patient and other health-sector advocacy groups play a prominent role. Neo-liberal era relationships – whether between government and industry, government and health sector groups, or industry and health sector groups -- are no longer arm’s length and the emergence of pharma-funded patient groups reflects this political evolution. Historically, Australian patient advocacy groups were allied with the Health Department on such regulatory matters as equity, accessibility, rational drug policy and appropriate

prescribing; over the past decade, Lofgren concludes, the pharmaceutical industry has purposefully weakened the alliances with the Health Department through dialogue, collaborative marketing, and sponsorships.

### 1.5.5 Three Cross-Cutting Fields

*Women's Studies* Two areas of feminist scholarship that intersect with the question of pharmaceutical funding of breast cancer groups are studies of women's health activism, including the critical body of research on the marketing of pharmaceutical drugs to women, and the effect on the women's movement of the neo-liberal discourse on rights.

Feminist scholars have a longstanding interest in women's health activism, including groups that advocate for health/medical choices that are more holistic and inclusive than a heterosexual, male-centred biomedical model (Shildrick 1997, Wilkerson 1998). Morrow (2007) traces women's activism on health issues in Canada back to Confederation and identifies three periods that coincide with the three waves of the women's movement. Feminist political reformers of the 19<sup>th</sup> and early 20<sup>th</sup> century did not fashion a women's health movement as such, but did take up public health causes, such as housing for poor and especially single women, violence against women and birth control information. By contrast, the second wave of feminism, which began in the 1960s, did spawn organizations dedicated specifically to women's health, including rape crisis centres and a network of women's health collectives and centres. Activism on issues related to women's reproductive health and mental health were two areas that intersected with concerns about the marketing of pharmaceuticals, the potential of these

drugs to harm women's health and the power of the pharmaceutical industry as a structural force. The term "medicalization," came into usage during this period, referring to the rise of medical authority in the past century and to the use of medical explanations for problems which are primarily social (Zola 1972, Morgan 1998). The feminist critique of medicalization highlights medicine's historical bias to a male-centred view of the human body (for example, treating pregnancy and menopause as abnormal states requiring routine medical intervention) and the marketing of interventions to "correct" conditions in women, such as depression or shyness, which have a strong social component (Cooperstock 1979). As one Canadian study points out, however, breast cancer was not a priority in the second wave women's health movement in Canada, despite the existence of sexist and heterosexist assumptions in the approaches to detecting and treating the disease (Waserman 1997). This author attributes the limited politicization of breast cancer during Canada's second wave of women's health activism primarily to the relatively young age of the movement's leaders and their preoccupation with reproductive health issues.

Morrow describes the third wave of feminism as continuing a preoccupation with many of the same women's health concerns but with significant additions, including concerns about cuts to health services and women's organizations, and the effects of neo-liberal politics and trade agreements on women's health, including the risks of co-optation of women's organizations. Third wave feminist analyses also seek to recognize the complexity and diversity of women's lives (Morrow 2007). Consistent with this observation, feminist scholars of this period have cautioned against an over-simplified critique of pharmaceuticals in women's health, arguing that women respond to

medicalization in ambivalent ways, negotiating rather than rejecting medical procedures and pragmatically accepting medical relief from pain, infertility, or premature death (Harding 1997, Lock and Kaufert 1998). These analyses invoke Foucault's conception of power as a diffuse force with positive as well as negative attributes; as such these authors problematize the understanding of power as an oppressive force imposed from the top down, recognizing that women's bodies are a source, as well as a target, of power. Applying Foucault's analysis to medicalization, Lock and Kaufert argue that people have the agency to choose among available discourses and practices and can reflect on and use them creatively (Lock and Kaufert 1998).

Apart from the literature on the women's health movement *per se*, the impact of neoliberal politics on women's activism, as well as on social policies that affect women, has been a central theme of Canadian feminist scholars (e.g., Bashevkin 1998; Fudge, 2002; Smith, 2005; Dobrowolski 2004; McKeen 2004). These analyses document the ways in which neoliberal discourses and funding policies altered the political environment to weaken conflictual group activism and privilege a depoliticized, consumerist, non-contentious individual engagement in the political system. Having stripped away their advocacy role, governments rebranded civil society groups as the "voluntary sector" (Smith 2005). Lawyer Judy Fudge (2002) proposes that neo-liberal policies encouraging alliances between health charities and drug companies were a setback for women's equity struggles in the area of health. Governments in the new order are loath to discourage these alliances, she says, because they now rely on health charities to provide their members with services that once were the domain of the health care system. Fudge notes that health charities now have extensive websites with disease-



specific information including drug information, which will probably increase pressure on the health budget by promoting new, expensive, and not necessarily better drugs. The sites also carry useful information on topics like self-care and family support that alleviates pressures on the health-care system. While charities are becoming larger, richer, more powerful, and more “corporate” Fudge argues that they are losing their autonomy, via strings to corporations.

*Development studies* Development studies, with its focus on the contribution of colonial and post-colonial politics to the inequalities between rich and poor countries, offers yet another view of the pharma funding of patient groups. A letter to the editor of the *Lancet* (Wibulpolprasert et al 2007) provides a vivid example in which the pharmaceutical industry is suspected of using patient groups from wealthy countries to undermine public consultations carried out under the auspices of the World Health Organization and intended to benefit poor countries. The hearings concerned a draft global strategy and action plan to promote research into neglected diseases and access to medicines in developing countries. Predictably, almost all the submissions from organizations directly affiliated with the pharmaceutical industry argued for strong intellectual property (IP) protections. The authors of the letter, representatives of public health ministries in Thailand, the Maldives, India, and Sri Lanka, observed that fourteen patient advocacy groups adopted the same stance in submissions that used the same phrases or concepts as the industry; further investigation showed that eleven of the groups received financial support from the pharmaceutical industry and sometimes these ties were extensive. “For example,” they wrote, “a Canadian patient advocacy group whose submission was in favour of IP received financial support from Actelion

Pharmaceuticals, Amgen Canada, Bayer, Gilead Sciences Canada, INO Therapeutics, Merck Frosst Canada, Novartis Pharmaceuticals Canada, Ortho Biotech, Amicus Therapeutics, Apopharma, BioMarin Pharmaceutical, Hoffmann-La Roche and Sigma-Tau Pharmaceuticals” (Wibulpolprasert et al 2007).<sup>5</sup>

Scholars and activists in development studies have also critically analyzed the concept of public-private partnerships or “PPPs” (Buse and Harmer 2004, Murphy et al 2004, Richter 2004) depicting them as a social construction introduced by international agencies such as the World Bank to achieve neoliberal objectives which are often at odds with the interests of local communities. This analysis emerges from experiences of agencies who work in low-income countries; it may, nonetheless, provide insights into the phenomenon of public-private partnerships in high-income countries. Certainly the funding of patients’ groups by pharmaceutical companies has gained the attention of organizations with a development mandate, such as Health Action International and Inter Pares (Mintzes 1998, Murphey et al 2004, Perehudoff and Alves 2010, Perehudoff and Alves 2011); in addition, as the example of intellectual property regulation cited above illustrates, a Canadian group with pharmaceutical company funding can advocate for industry-friendly policies that will affect patients in low-income countries on the other side of the globe.

In a more theoretical framing from a development studies perspective, Orla O’Donovan (2005) examines patients’ groups as community development organizations and critiques pharma funding of these organizations in relation to Habermas’ ideal of the public sphere. Habermas’ term “deliberative democracy” refers to an arena of debate which is open to all citizens and fundamental to liberal democracy in its original sense.

O'Donovan proposes deliberative democracy, as articulated by Habermas and subsequent theorists (e.g., Fraser 1992, Collins 2002, Crossley 2004), as a useful construct for theorizing corporate sponsorship of civil society groups. She incorporates Fraser's (1992) refinement of a multiplicity of overlapping spheres, including "parallel discursive arenas" where "counterpublics" meet, discuss issues among themselves, and prepare oppositional discourses and modes of expression that they can use to influence the wider debate. Seen through a Habermasian lens, government bureaucratization and market commodification are both colonizing forces that undermine the public sphere by impoverishing public debate; social movements that resist these forces, by contrast, enliven public dialogue.

To enrich her theorizing of how commercial compromise within patients' groups takes place, O'Donovan draws on Pierre Bourdieu's argument that open public dialogue requires a relative autonomy of fields; the economic dependence of agents in one field on agents in another inevitably results in compromise. This process is incremental; rigorous past standards are gradually and imperceptibly abandoned, then forgotten, as a new set of practices and discourses take root and come to feel natural. Thus, a group in the health advocacy field may accept pharma funding because of economic circumstances and gradually, through successive compromises, experience "shifts in tacit understandings that may take place over time" (O'Donovan 2005: 12). O'Donovan cautions that reliance on a grass roots/Astroturf binary obscures the complexity within organizations. The "authentic" grass roots group is an ideal which can be compromised by a number of influences, not only commercialization but also "professionalism, colonization by the state, and the inevitably limited system of internal democracy" (O'Donovan 2005:14).

She proposes ethnographic research as a methodology capable of capturing this complexity.

## **1.6 TYPOLOGIES OF HEALTH AND PATIENTS' ADVOCACY GROUPS**

The final section of my literature review examines typologies of groups. One goal of my research is to develop a typology of groups that captures the diversity of views and actions of patients' groups in relation to pharmaceutical company funding, including the factors that underlie shifts in the groups' positions over time, if they occur. Of interest, however, is Epstein's suggestion that typologies of patients' organizations and health movements have become something of an obsession in the field to the point where a typology of typologies is warranted (2008):

... it may be wise to be skeptical of the idea that any single unidimensional typology adequately can capture the variation of patient groups and health movements: each well-posed research question about patient groups will generate a unique classificatory scheme that chops up the universe of cases in a distinctive way. (Epstein 2008: 509).

Epstein argues that "the point then is to consider what some of those important questions might be" (ibid: 509). He presents a list of six, of which the one that corresponds most closely to my focus is independence from corporations, state agencies, or professional associations. A second question which also underlies my research is the group's relationship to medicalization (some groups seek medical recognition for a condition while others contest or resist medical interventions). Epstein's four other dimensions are the constitution of the group (the pathways by which groups emerge); social organization (size, geography, degree of formal structure, etc.); militancy and

oppositionality (tactics used and the extent to which they challenge the status quo); and goals, which may include supporting the search for medical cures, improving quality of life for people with a medical condition, opposing stigmatization, and changing medical priorities (many groups have more than one goal). Figure 1 schematically depicts Epstein's proposed axes for constructing typologies of patients' organizations and uses this ordering to compare the typologies proposed by other scholars in the field, which I discuss below.

Because my research has a diachronic structure, I separate these approaches to classification into two categories: classifications used to differentiate groups from one another based on their relationship to the corporate funding issue, and classifications used to characterize changes that groups undergo over time. In the social movement literature, the distinction between "grass roots" and "professionalized" social movement organizations incorporates both of these foci (McCarthy and Zald 1977, Ruzek and Becker 1999; Kleidman 2004). Social movement literature, including studies of groups within the women's movement, distinguishes "grass roots" from "professionalized" social movement organizations (McCarthy and Zald 1977, Ruzek and Becker 1999). Groups are theorized as moving from a grass roots model to a more professionalized model as they grow from volunteer-run organizations to organizations with paid staff. Often this shift includes an acceptance of corporate funding which, in concert with other changes such as recognition by establishment actors (such as physicians and government players), moves the group's perception of issues -- its epistemology -- closer to that of professionals and renders the group less able to represent the interests and knowledge of people at the grass roots (Ruzek and Becker 1999).

Kleidman (1994) critiques the simple grass-roots/professional binary as too simplistic since a rise in professionalism is not necessarily inimical to grass roots activism. Paid staff, for example, can be used to train local activists in radical tactics, making the organization more radical, not less so. Consistent with this critique, Kleidman urges social theorists to develop models that consider not only resources and political opportunities but also the values and strategies of movement professionals. Orla O'Donovan adopts a perspective similar to Kleidman's when she observes that pharmaceutical companies have successfully defined themselves as a philanthropic force and rightful players in Irish health activism, but cautions against concluding that this is evidence of corporate colonization. Such an interpretation assumes that organizations start out as wholly counter-hegemonic then have their mandate to contest the status quo eroded by industry funding, a transformation that research has yet to demonstrate. She also rejects a straightforward Astroturf/authentic dualism, arguing the possibility that health advocacy organizations can both disturb orthodox understandings of health, illness and patienthood while contributing to the hegemonization of pharma-centric health discourses and the commodification of health activism (O'Donovan 2007).

Typologies of health movements and patient groups in STS differ from social movement typologies in their focus on knowledge construction, which manifests in a formalized attention to technologies and to the concept of expertise in relation to these technologies. Partnerships or alliances between patients' groups and pharmaceutical companies provoke questions about the sharing or mixing of lay and credentialed expertise, power differentials, and the potential for conflicting goals and interests with respect to a technology. Two science studies analyses that grapple with the issues of this

dissertation are those of Hess (2005) and Rabelharisoa and Callon (2002). O'Donovan (2007) and Jones (2008) develop typologies that draw less from STS theorizing and more from the concerns of development studies and bioethics, respectively.

David Hess (2005) identifies three processes that he hypothesizes take place over time in what he calls “technology and product-oriented movements (TPMs)” -- the subset of social movements that promote a particular alternative technology or product. He draws from his research on movements in which cancer patients promote alternative therapies and extends his analysis to movements promoting wind-power as a renewable energy, and open-source software. Integrating scholarship from the study of social movements and from STS, he identifies three processes which he proposes as useful for comparative analysis across movements, technologies and fields. “Private sector symbiosis” occurs early on as civil society groups articulate their goals with the inventors, entrepreneurs, and industrial reformers in private sector firms and thus develop a cooperative relationship with them. A second process, the incorporation/cooptation of the social movement takes place as established industries incorporate the novel products and technologies but adapt them to existing markets and technologies. Third, “object conflicts” occur as the field of objects becomes more and more diversified and different social worlds dispute the range of products and their design.

Although Hess focuses on technologies which are alternative to the mainstream (which are not the focus of my research), his study of technology and product-oriented social movements draws attention to the complex and varied relations between social movements and the private sector. His model of change processes may apply to some aspects of movements that are oriented to mainstream technologies and products,

particularly private sector symbiosis and object conflicts. Hess raises a philosophical question related to these alliances: what type of change constitutes success for a social movement, given that success to some may be cooptation to others?

Rabeharisoa and Callon's (Rabeharisoa and Callon 2002, Rabeharisoa 2003) typology of patient associations rests on the organisations' orientations to partnerships with biomedical specialists -- of interest to my research because these partnerships cross the lay/expert divide and may include pharmaceutical companies as well as researchers and physicians. Their typology maps on the concept of joint decision-making: the *auxiliary* association engages in fundraising and other supportive activities but leaves decision-making to the professionals, the *partner* association also supports the experts but plays a more active role in decision-making, and the *opposing* association distances itself from medical experts.

O'Donovan (2007) and Jones (2008) have also developed typologies to characterize health consumer and/or patients' groups and their relationships to the pharmaceutical industry, although neither adopts an STS framework. Based on her study of health advocacy organizations in Ireland and their modes of engagement with the pharmaceutical industry (2007), O'Donovan arrived at a continuum based on the group's orientation to pharma funding -- *corporatist*, *cautious cooperation*, or *confrontational*. To make sense of the framings that underlie these three modalities, she adapts another tool for typology-building, a concept Maren Klawiter's (1999) calls "cultures of action."<sup>6</sup> O'Donovan proposes four axes in these cultures of action that reveal the legitimating logics that underlie the groups' diverging positions around pharmaceutical industry sponsorship. These are: the group's social *construction of the health cause* -- "the



complex of meanings which provide grounds for collective action” (ibid: [4]); the *identity banners* the group adopts, for example, ways of reframing stigmatized patient identities; the *modes of political action* taken to redress the problems in (a); and the group’s *positioning in relation to other actors*, especially the boundaries between friends/protagonists/heroes versus foes/antagonists/ anti-heroes, and money that is “dirty” or “clean”.

Kathryn Jones’s (2008) typology, based on group and industry websites in the U.K. and a small number of interviews, maps on the practices of disclosure or transparency in health consumer group/industry relationships – an issue central to theorizing in bioethics. Jones categorizes groups as *Refusers* (those with explicit policies to refuse pharma funding), *Accepters* (those that accept pharma funding and disclose that they do), and *Non-disclosers* (groups that do not reveal whether they accept or refuse pharma funding). In her interviews, Jones also explores the groups’ decision-rules for links with industry, and the type of partnerships agreements that define the partnerships.

Figure 1 depicts these typologies and shows their points of difference and overlap. The typologies of O’Donovan and Jones, which are both based on studies of groups in relationship to the pharmaceutical industry, clearly relate to Epstein’s first axis, as does the more general model of Rabelharisoa and Callon, which emphasizes medical expertise rather than funding as the bond to corporate entities (including but not only pharmaceutical companies). Ruzek and Becker’s model contrasting grass roots and professionalized women’s health groups has a binary structure which combines all six of Epstein’s axes and posits a tendency to move over time from a grass roots model to a professional one. Hess’s model of movements that promote innovative products is also

designed to capture change over time, but the model is circular with respect to the expected relationship of groups to corporations: the groups begin as independent, then move into cooperative relationships with industry, only to distance themselves from industry as their innovative products are “mainstreamed” for the market. Klawiter’s model is ostensibly most related to Epstein’s sixth axis, which concerns the group’s goals, and Brown and Zavestovki’s model has its primary relationship to the second axis (relationship to medicalization); both, however, incorporate the tension between organizations that are closely allied to industry goals (expressed through the goals like “cure” or “health access”) and groups that are more likely to oppose industry via their concerns with “environmental justice” or “embodied health”.

## **1.7 INTEGRATION OF RESEARCH QUESTIONS AND THE LITERATURE REVIEW**

My research aims to address several areas in which studies to date are lacking or limited. In particular, researchers interested in the relationship between patients’ organizations and the pharmaceutical industry have called for more studies of actual organizations (Baggott and Forster 2008; Vitry and Lofgren 2011). With few exceptions (Anglen 2009; O’Donovan 2006; Hemminki, Toivianinen, and Vourenkoski 2010; Jones 2008), the studies to date have relied on surveys and internet records to document the existence of alliances between patients’ groups and the pharmaceutical industry relationships. While such research has established pharma funding of patients’ groups as a widespread practice, survey methodology does not provide an understanding of how the alliances actually work. Key questions are left open to debate, such as how decisions are

made, whether pharmaceutical companies actually wield influence on the groups' decision-making processes (and if so how this is manifested), and whether and how the relationships change over time.

As well as studying actual organizations, my research examines changes in the relationships over time and is, to my knowledge, the first study of patients' organizations and pharmaceutical company funding to do so. Several researchers of patients' groups have pointed out that diachronic analysis are essential to answer questions about cooptation of groups by the pharmaceutical industry as a result of funding from companies in this sector (O'Donovan 2007, Epstein 2008). As these analysts note, a group or movement can only be said to have been co-opted if detailed studies show that the donor corporations increased their influence within the groups over time. A particularly critical question is whether this influence shifts the group to endorse positions (particularly with respect to pharmaceuticals and related policies) that are counter to its members' interests. Epstein argues, for example, that a group's position may appear to move closer to that of industry for reasons unrelated to cooptation as occurred when AIDs organizations nuanced some of their more radical demands once they had gained a more sophisticated understanding of clinical trials and drug regulations.

The third goal of my research is to examine how the macro-level political economy environment in Canada contributed to the alliances between patients' organizations and the pharmaceutical industry and what these alliances mean for the functioning of Canadian society as a democracy. A political economy perspective is used as a tool for critical analysis of social phenomena and allows the researcher to address questions of social justice. To date, only a few studies of the pharma funding of patients'

organizations (Lofgren 2004; O'Donovan 2007) have included a macro-level analysis that ties these alliances to the broad ideals of citizenship, justice and democracy.

These three broad research goals dictated my methods. To respond to the need for studies of actual patients' groups, I conducted an ethnographic study of groups in Canada's breast cancer movement. To ensure that my study captured the diversity of views within the movement, I selected three groups that differed in their stance towards funding from the pharmaceutical industry for detailed ethnographic analysis. My research focused on the discourses within the groups about whether or not to accept funding from the industry, and the activities of each group as they related to co-constructing knowledge about breast cancer treatment drugs.

To respond to the need for studies that examine changes in groups over time with respect to pharma funding and pharma-related advocacy, I conducted my ethnographic research diachronically, beginning with the period circa 1990 when Canada's breast cancer movement began and continuing to the present. As O'Donovan states, ethnographic research over time is a methodology capable of capturing a complex of concepts like "authenticity" in grass roots groups, given that numerous influences can compromise the "authentic" grass roots group. In addition to commercialization, groups can lose their accountability through "professionalism, colonization by the state, and the inevitably limited system of internal democracy" (ibid 2005:14). I chose to trace the evolution of patients' groups that organized around one particular disease and whose interests were therefore focused on a particular set of drugs in order to illuminate how the decision-makers within the groups viewed these treatment technologies and whether and how they intervened in the policies that affected the life cycles of these drug treatments. I

use discourse analysis and actor-network theory, two methods used in science and technology studies to capture the way actors engage in the process of constructing the meanings of technologies over time. To interpret the changes I observed over time, I used “periodization,” a methodology based on Foucault’s concepts of archeology and genealogy which involves “systematically track[ing] patient groups and health movements through distinct phases of their evolution” (Epstein 2008: 525).

For my third goal -- the assessment of social justice with respect to advocacy groups, funding from pharmaceutical companies and medications -- I link these periods to macro-system influences. Canada’s radical transformation from a liberal welfare state to one in which neo-liberal and neo-conservative beliefs dominate has reshaped the contours of public policy in this country dramatically in the past thirty years. This transformation makes Canada a useful site in which to study the interrelationship between neo-liberal policies and pharmaceutical company funding of patients’ groups. Grass roots patients’ advocacy groups and movements are largely a phenomenon of the past thirty years and have inevitably felt the force of these concurrent policy changes. I relied on library research to understand how the political shift that began circa 1980 transformed Canada’s political, economic and policy landscape in two policy fields – health and pharmaceutical policy and policies concerning civil society groups. I combined this analysis of secondary sources with my original ethnographic research to assess how these changes contributed to the events within the breast cancer movement that are the focus of my inquiry. This aspect of my research highlights moral contestations and speaks to another area of study in patients’ groups that Epstein has identified as in need of research

attention: “struggles over rights and inclusion in the domain of health” (Epstein 2008: 526).

The next chapter lays out these methods in detail.

## **CHAPTER 2      RESEARCH GOALS AND METHODS USED**

### **2.1    INTRODUCTION: LINKING RESEARCH GOALS TO METHODS**

I set out to study the practices of corporate funding of patient-centred breast cancer groups in Canada and the discursive processes through which these practices become normalized. As stated in the conclusion of the last chapter, the project encompasses three broad research goals which dictated my research methods. I have organized this chapter accordingly into three main sections: the holistic study of actual patients' activist groups, studying changes in the patients' activist movement over time, and studying macro-system influences on the movement. In each section I begin by explaining what the methodology needed to accomplish, followed by a discussion of my choice of specific methods. A fourth section discusses broad methodological questions of authenticity, validity and ethics. I conclude by linking the methods to my results, which I report in the three subsequent chapters. I summarize the Goals and Methods Used in Table 1.

### **2.2    THE IMPORTANCE OF STUDYING GROUPS HOLISTICALLY**

As my review of literature has shown, researchers in countries throughout the developed world have taken an interest during the last decade in the phenomenon of alliances between patients groups and movements and pharmaceutical companies. The majority of studies to date, however, have been conducted from afar, using questionnaires and analyses of public documents such as web sites and annual reports. I chose instead to

undertake a case study of a social movement (Snow and Trom 2002). My research design uses ethnography, the methods developed by anthropologists to describe “people and culture, using firsthand observation and participation in a setting or situation” (Ellis, 2004: 26). The researcher adopts the stance of “an involved participant” who views the world both “holistically and naturalistically” (ibid: 26). Snow and Trom contrast a case study of a social movement to a study based on quantitative methods (e.g., a survey), noting that the former foregoes breadth and quantification for the in-depth, holistic understanding of a cultural system of action as revealed in a single detailed account. A case study, they explain, achieves generalization through empirical, theoretical and conceptual analysis rather than statistically.

Ethnography combines the data collection methods of participant observation, interviews, and document analysis to paint a detailed, holistic picture of a particular culture. Early ethnographers focused intensively on a single geographical site. I used “multi-sited ethnography” (Marcus 1995), which adapts traditional methods to the mobile and “wired” communities of the globalized capitalist system -- of which patient-centred groups are a good example. My research encompasses other postmodern influences, notably the inclusion of multiple perspectives, including my own. I discuss each of these methods and the way in which I use them below. First, however, I explain my choice of a particular patients’ movement.

### 2.2.1 Choosing a Movement for Case Study

As stated in the Preface, my interest in the phenomenon of pharmaceutical company funding of patients’ groups began with my own experience in the breast cancer activist arena and one of my first design questions was whether to make breast cancer



patients' groups as the focus of my research. This decision entailed considerable self-reflection. Patients' organizations representing other diseases in Canada are on record as accepting this source of funding (Mintzes, 1998; Picard, 2001); furthermore, the practice of accepting funds from pharmaceutical companies is not unique to Canadian patients groups (Brenner, 2000; Herxheimer, 2003; O'Donovan, 2005; O'Donovan, 2007).

Alternatives were to choose another disease arena in Canada which this issue had been debated, such as Alzheimer's organizations (Furlini, 2007), to compare groups from different disease arenas as O'Donovan did in Ireland (2007), or to include groups from outside Canada.

I decided to focus my research on "patient-centred" breast cancer advocacy groups in Canada (i.e., groups whose core membership and leadership is made up of patients and who purport to speak for patients), aware that my prior knowledge of this community carried both advantages and disadvantages. Following the Australian policy analyst Hans Lofgren (2004), I adopt the term Patient Advocacy Group or PAG to refer to organizations which devote some of their resources to addressing the policy concerns of patients. Note that the membership and leadership of a particular group may not be restricted to patients and the composition may evolve over time. Advantages of choosing this community include the fact that, at the time I began my research (2005), breast cancer PAGs in Canada had a history of about fifteen years, a sufficient stretch of time to allow discourses and practices to evolve. A network of diverse groups was well established and debates over the question of pharmaceutical company funding had produced a number of documents that fit the Foucaultian description of being "programmatic" (I discuss this concept below, page 70). I knew the breast cancer activist

community to be highly interactive, with considerable overlap of groups, collaborative projects, rivalries and movement of individual activists from group to group. A central goal of my project was to understand *how* groups with the same ostensible goals arrived at conflicting positions when faced with similar choices. I therefore wanted to treat the organized patient community or movement as a coherent unit, rather than as a collection of groups that could be studied as discrete entities. These characteristics made the breast cancer arena well suited for a project that is designed to examine exactly the types of shifts and rifts that are inherent to the process of knowledge construction in a contested terrain.

My own participation in several breast cancer organizations gave me an insider understanding of the early PAGs as a community, including knowledge of actors who had participated in nascent internal debates about pharmaceutical company funding. From my experience in patient advocacy organizations, I anticipated that many PAGs would have poor institutional memories. My reasons for this expectation include lack of administrative infrastructure (especially in an organization's start-up years), a high mortality rate within patients' groups when the disease in question is life-threatening, and the transient involvement of members who decide to "put the disease behind them" once their health has returned. My involvement in breast cancer groups in the 1990s would be an advantage in identifying actors who could help me historicize the early discourses.

A third factor that weighed in favour of studying breast cancer patients' organizations was the emergence of new treatments and the existence of ongoing policy debates over efficacy, safety, costs and access to novel pharmaceutical and biologic treatments for breast cancer medications since the early 1990s. Tracing the evolution of

patients' groups that organized around one particular disease allowed me to focus on the competition among drugs, both old and new, developed for one particular disease (I use the term "drugs" to include brand name pharmaceuticals, generics, and the newer biologics). I could examine how the decision-makers within the groups viewed these treatment technologies and whether and how different groups intervened in the policies that affect the life cycles of these treatments.

Based on these considerations, I chose to focus on the pharmaceutical funding of Canadian breast cancer PAGs, but remained open to including actors from other health and disease arenas if they were part of a particular "situation" that involved breast cancer groups. The next task was to develop criteria for including actual groups and activists.

### 2.2.2 Choosing Groups for Study

Consistent with my research objectives, I wanted the groups selected for study to provide both a longitudinal and a multi-perspectival understanding of Pharma funding of the breast cancer movement in Canada. I also wanted to select groups that would help me identify empirical and theoretical issues relevant to the decisions groups make about pharma funding. Following Snow and Trom, this meant *theoretical sampling* to include groups that could be termed *critical cases*, that is, groups that represent polar contrasts. The inclusion of critical cases helps to identify empirical and theoretical issues that underlie the competing discourses within groups about pharma funding. I thus sought groups whose practices with respect to funding from the pharmaceutical industry were at the two extremes (e.g., either 0% or 100% of the group's funding would come from the industry), as well as groups that were more *representative* or *typical*. As these authors

point out, however, in case study research claims of “typicality” are rarely demonstrated empirically (Snow and Trom 2002: 158-159). Based on the existing literature on the subject, on media reports, and on my own insider familiarity with breast cancer patients’ groups, it is clear that many (perhaps most) patients’ groups in Canada currently receive a portion of their funding from Pharma (Johnson 2000; Picard 2001). Since groups rarely publicize the amount or terms of their Pharma financing, the most accurate statement possible may be that a “typical” patients’ group sometimes receives some Pharma money, for some purposes. I therefore sought to include three to five currently active groups whose funding from the pharmaceutical industry fell along a continuum from 0% to 100% of their total revenues and whose members would agree to have their organization profiled in the research. My research plan also included an additional *composite* patient group designed to provide a historical perspective and help fill in gaps in the narrative of the breast cancer movement’s development. I discuss this group in the next section.

Participant-observation, or field work, is a method for understanding a culture by participating in the day-to-day discussions and performances of its members in their natural surroundings. While taking part in the ongoing talk and activity, the ethnographer maintains enough detachment to notice the exceptions in the ordinary, and the inevitable contradictions between what is said and what is done. These observations are the basis for the researcher’s conceptual analysis. My eight years as an activist in the breast cancer arena gave me a “deep knowledge of the field community” (Hess, 2001: 239), the basis for a rigorous standard of quality that ethnographers usually acquire through many years of field work. I supplemented this knowledge with ongoing engagement in community events, such as site visits to the offices or events of participating groups, attendance at

conferences, reading newsletters and website materials, and participation in webinars. Some of these activities were Pharma-funded, others not. As described below, my methodology was to “follow the groups” to the sites of their interactions. To maintain a focus on the patients’ groups in the study, and their decisions related to relationships with pharmaceutical companies, I include self-referential materials judiciously, for example if other participants mention them, or if they are important to my self-reflections. I use the term “Autoethnographic Interlude” to separate these descriptions from the more objective text.

While my method of studying each of the participating groups had common elements (e.g., participating in meetings and public events), in each group the exact methods were adapted to the realities of the organization. Does it have an office? Has the group agreed to allow access to financial records, or minutes of meetings? Taken together the methods contribute to a holistic understanding of the particular group and the way Pharma funding fits into its overall history, thinking, and way of doing things. I was interested in similarities in and differences between the each of the groups; for example, do groups with Pharma funding operate on a more professionalized model (Ruzek and Becker 1999)? Do their discourses about issues such as risks from drug treatments and environmental contaminants from the group that is not pharma-funded?

To use the three opportunities for generalization that a case study of a social movement offers (theoretical discovery, theoretical extension and theoretical refinement) I also planned to incorporate a small number of selected interviews with activists from other health and patients’ movements in Canada and/or the United States. This portion of my data collection, along with findings from other studies of patients groups in the

literature that were either wholly qualitative or had a qualitative component (Anglin, 2009; Delaney, 2005; Epstein, 1996; Hemminki et al., 2010; Jones, 2008; Lofgren, 2004; O'Donovan, 2007; Rabeharisoa, 2003; Rabeharisoa & Callon, 2002) were designed to help me assess the extent to which my conclusions might apply to other patients' movements, in Canada or elsewhere.

A final subset of interviews built into my design was with individuals from the pharmaceutical industry, the government, and the research community. These carefully selected interviewees were included to provide key informant perspectives on the issue of pharma funding to PAGs from other actor-communities within other breast cancer arenas.

### 2.2.3 Narrative Techniques

A contribution of contemporary feminists to ethnographic research is that, in all science, the observer inevitably changes the events by her very presence. All knowledge is situated because every researcher is positioned in a particular social location which allows only a partial perspective (Haraway 1999). An understanding of situated knowledge imposes an obligation on ethnographic observers to acknowledge the effects of their presence and to use self-reflexivity to become aware of their own positioning *vis à vis* the other, including their social identity (e.g., gender, cultural, class, age). To recognize her inherent fields of power, and her limited fields of vision, the researcher looks inward and self-examines the particular social and individual locations from which she views the other's reality (Narayan 1993).

My own position includes an identity as a former breast cancer patient who was a member of several PAGs. I used self reflection on, and openness about, these aspects of

my identity throughout the research to help me achieve “strong objectivity” (Harding 1998), a belief that my analysis will be more objective and scientific if I maintain an ongoing self-awareness of my values and beliefs and open them to challenge by exposing them to public scrutiny. My public stance opposing pharmaceutical company funding of patients’ organizations thus imposed a strong imperative for ongoing self-reflection and rigour in my interpretation, with particular attention to fairness. I discuss these concerns further in the section below on ethics.

Although situated knowledges (Haraway, 1991) and strong objectivity (Harding, 1991) are assumptions built into in the qualitative methodologies I adopted, they don’t eliminate the potential complexity of the researcher’s partisan involvement in her area of study (Foley & Valenzuela, 2005). Among researchers who have considered the difficulties of studying a polarized debate on which they themselves hold strong views, Brian Martin (Martin, 1996) and Faye Ginsburg (1993) are two whose self-reflections informed my methodology. Martin intervened in a debate over a controversial theory about the origins of HIV/AIDS. His partisan participation gave him access to large quantities of material from actors sympathetic to his views that would normally be unavailable to researchers; however, he did not have access to comparable documents from people who opposed his position and some of his correspondents asked that their materials be kept confidential. He nevertheless concluded that his intervention provided unique insights into his question, namely, how ideas spread within the scientific system.

In my case, I could not have conducted the study as planned without at least some participation by activists with differing views and access to some documents representing their positions. Despite my efforts to ensure fairness, however, I recognized that some

actors who held opinions contrary to mine might well decline to participate in the research, leaving those holding positions similar to mine numerically overrepresented. Reasons for being reluctant to participate could include a concern that the group's position on pharmaceutical funding would be presented less sympathetically than the views of groups opposed to pharmaceutical support. A second, concern could be a potential loss of funding from industry sponsors, or loss of public support – particularly if the group's acceptance of pharmaceutical funding was cast in a critical light. An unavoidable fact of the situation I chose to study is that groups that accepted pharmaceutical company funds had more to lose, financially, if they were identified; furthermore, regardless of any assurances I gave to the contrary, my own history of opposition to pharmaceutical company funding may have heightened the perception of that risk for these groups.

In order to present the debates fairly, I sought to overcome this imbalance in the presentation of my findings. I decided to anonymize the identities of all interviewees and groups, even if the person or group in question was willing to be identified (I discuss one exception to this general rule below, in my discussion of ethics). I made a conscious effort to balance the complexity of the contrasting arguments and to allot equal space to actors whose views differed from my own. To respect the integrity of speakers I did not always agree with, I incorporated several narrative techniques that Faye Ginsburg (1993 [1998]) adapted for this purpose in an ethnographic study of the right-to-life movement in North Dakota in the 1980s. Because the views of many of her participants challenged her own, she framed her interviews using a “life stories” approach designed to find out how each woman connected her involvement in the abortion rights and anti-abortion



movements to their own lived experience and identity. Their stories gave her insight into the worldviews of women whose perspectives differed from her own, allowing her to move beyond stereotypes and to see the women as active agents. She also sought common elements in the views of women in the pro-life and pro-choice movements and found they indeed shared certain values (e.g., opposition to a materialistic culture, appreciation of women as nurturers). She used narrative techniques that allowed polyphonic voices to be heard, employing extensive quotes as a counterpoint to her own words and highlighting the voice of one particular woman to capture the world of the pro-life movement activist. She assumed that no one voice had an exclusive claim on the truth and that personal narratives must be respected in their entirety, not “simply expropriated in the interests of some good cause” (Ginsburg 1993: 174).

These techniques of polyvocality are among those that Guba and Lincoln (2005), two scholars in qualitative methodology, encourage to ensure a fair balance in interpretation. Numerous researchers studying patients’ and health social movements provide additional rationales for the use of narrative methods (Epstein, 1996; Klawiter, 2004; Orsini, 2008; Orsini & Scala, 2006). In an argument that resembles Ginsburg’s reflections on the way life story narratives reveal the connections between women’s lives and their political activism in the abortion arena, Orsini notes that marrying narrative with social movement approaches to health can reveal “how people experience or make sense of illness in their everyday lives ... [and thereby] ... allow us to understand the dynamic processes of politicization which accompany some illnesses and not others” (Orsini 2007: 343).

My methods are thus designed to provide a situated and partial understanding of the evolution of the relationships of Canadian breast cancer groups with the pharmaceutical industry. Thus, while I cannot claim my findings tell “the whole story,” or that I include all relevant points of view, my methods are designed to provide an authentic account of the situation, inclusive of multiple, competing perspectives. Further, while my focus on Canadian groups may not map to the experiences of breast cancer groups in other countries or to patients’ organizations from other disease groups, my theory-driven, extended case approach (Lichterman, 2002) has the potential to generate new theoretical questions about partnerships between patient groups and the pharmaceutical industry, and about related concepts such as pharmaceutical policy, neoliberalism and civil society, patient advocacy movements and technology, the participation of advocacy groups in public policy, and conflicts of interest in medicine.

#### 2.2.4 Breast Cancer Treatment Drugs as Actors

Central to the discourse about patients’ organizations and funding from pharmaceutical companies is the potential of patients’ groups to construct knowledge in a way that influences policy about the drugs developed for a particular disease. Within my design, breast cancer drugs are nonhuman actors with life cycles (van der Geest, Whyte & Hardon, 1996) and social lives (Fraser et al., 2009; Whyte, van der Geest & Hardon, 2002). My research plan includes the stories about breast cancer treatments as they arise in the narratives of the various groups. I then use a variety of sources to create a narrative understanding of the lives of each of the drugs and their relationships to actors in key social worlds. Research scientists, drug companies, physicians, drug regulators, medical

journals and the media are prominent actors who contribute to the construction of knowledge about drugs at different points in the a particular entity's life cycle. I wanted to understand the ways in which patients' groups became part of this mix.

I was particularly interested in advocacy initiatives that groups undertook to change policies concerning a particular drug or breast cancer drugs in general. Figure 2 is a schematic representation of hypothetical ways in which a PAG might intervene to co-construct the way a drug is defined. To construct the stories of drug treatments from the perspectives of the groups in my study, I relied primarily on interviews and organizational documents (e.g., websites, newsletters, minutes of meetings, position statements) and on media reports citing PAG spokespersons, concerning the drug's perceived risks, benefits, effects on lifestyle, and cost. To determine what patients individually were saying about drugs they were taking or had heard about, I conducted searches, using names of the drugs in question, of two Canadian breast cancer sites designed to enable patients to provide peer support and to exchange experience-based knowledge. Both internet-based services maintain searchable archives.<sup>7</sup>

I compared these constructions with statements and documents about the same drugs from other actors, particularly the officially designated experts in industry, government, and medical research. Key sources for statements from drug companies were the companies' own websites and press releases, industry publications such as *Pharmaceutical Marketing*, and popular media accounts of cancer treatments reported as news, health news or business news. Two federal government databases administered by Health Canada provide the results of the government's drug approval process. Called the Notice of Compliance (NOC) database and the Drug Products Database, they provide

approval dates, conditions on the approval, and safety warnings issued. Following a methodology developed by Graham and Nuttall (Personal communication 2008), I used these two databases to establish approval dates for drugs and biologics, and Health Canada's Advisories and Warnings web-page to establish the date and content of any safety warnings for the drugs of interest. *The Notice of Compliance (NOC) database* has two parts: the Notice of Compliance List (Health Canada 2011a) provides an alphabetical listing of all pharmaceuticals and biologics for which NOCs were granted in a given year, from 1991 to the present (Health Canada 2011b). Companies' approvals must be issued each time a new indication is requested. A drug can also be approved "with conditions" (NOC-c), which means that some of the evidence provided was judged wanting and the approval is granted on the condition that additional research be carried out within a certain timeframe. The second part lists the date when the federal drug regulatory agency approved a drug company's application for approval of a specific indication of a specific drug. This database goes back to 1994 and some breast cancer drugs were approved prior to that date. The absence of these drugs from the database is not a serious limitation for my research, however, because Canadian breast cancer PAGs engaged in very little drug-related advocacy before 1994.

The American drug regulator (the Food and Drug Administration, or FDA), also has databases for drugs and drug approval times and these were another useful source of government claims-making discourses. Although American drug monographs are likely to be similar, if not identical to the Canadian counterparts, the decisions of the drug approval agencies in the two countries do not always correspond in substance or timing. A safety warning may be issued in the U.S. and not in Canada, for example (because of

its larger population, drug safety issues are likely to surface sooner in the United States); conversely, companies will often apply for and gain approval of a drug in the U.S. before they apply in Canada, in part because the American market is so much larger. A safety warning or the launch of a new cancer drug on the American market can generate a lot of press coverage in Canada and has the potential to make waves here, stimulating interest among patients who may wonder (in the case of withdrawals), why the drug is still being sold here, or (in the case of a launch), why it is not.

The significance of these databases for my research lies in the importance for companies of government drug approvals and regulatory limitations on truth claims. Because companies cannot legally market their drugs in Canada until the federal government has reviewed and approved the drug for safety and efficacy, the date of approval is an crucial milestone in the drug's life cycle. Advocacy to speed approvals or to prime sales around the time of a drug's approval date could substantially increase a company's profits. Furthermore, the company cannot legally make claims about the drug that are inconsistent with the evidence from clinical trials as detailed in the drug's Product Monograph, a scientific document that details what is known about the drug's properties, conditions of use and other research-based findings. The company must prepare the monograph in accordance with the government regulator's guidelines and submit the document for review as part of its application package. The information in the Product Monograph thus becomes the official statement of what is known about the drug. It includes the evidence for benefits and potential side-effects as well as the "indications" for which the drug is deemed suitable. Thus a drug may be approved (i.e., "indicated") for advanced breast cancer, but not for early stage breast cancer. Advocacy claims that

deviate from this profile would be noteworthy from the perspective of my research since they could contribute to constructing knowledge about the drug that is at odds with the official position.

Articles in medical journals and the popular press were my main source for mapping the views of medical researchers about drugs. Controversies about drugs are a regular feature of debate in the medical press and such controversies often spill over into the popular press, generating debate among patients and their circles of support. One trigger for such debates is ambiguity in the evidence of a drug's safety, efficacy or superiority to an established drug. I looked for such controversies about breast cancer drugs because they are a sign that experts are still contesting knowledge about the drug. Such controversies provide an ideal window for activists to enter the discourse, on one side or the other. I used Dow Jones Factiva to conduct systematic searches of the newspapers and other media stories about specific drugs and complemented this information with Google searches for media stories from other sources.

An additional, invaluable source of information on breast cancer drugs worth mentioning is *Dr. Susan Love's Breast Book*, by American surgeon and activist Dr. Susan Love and her co-author, writer Karen Lindsey. Love and Lindsey first published their comprehensive guide to breasts and breast cancer in 1990. The book is intended to be both authoritative and accessible to patients and their families and quickly became a standard reference for breast cancer patients in Canada as well as the United States and abroad. Subsequent editions appeared in 1995, 2000, 2005, and 2010. The book thus provides a systematic, detailed paper trail of breast cancer treatments and treatment controversies over the period that is the focus of my research. Finally, I supplemented

these systematic searches with a more improvised gathering of “stories and available collectibles – stuff of all sorts” about the drugs in question (Clarke 2005: 166).

I summarize the constructed knowledge about selected breast cancer drugs (i.e., the drugs that were the focus of PAG advocacy) in a document I call *The Breast Cancer Pharmacopoeia*. A pharmacopoeia is an official reference book on medicinal drugs, their preparation and use (Huguet-Termes 2008). While the intent is to provide the most trustworthy knowledge about drugs at the time, a pharmacopoeia is subject to social influences, including corrupting ones (ibid 2008). My *Breast Cancer Pharmacopoeia* highlights the socially constructed aspect of drugs, in particular, the ways in which PAGs can influence these practices.

#### 2.2.5 Visual Maps Using VUE Computer Software

I used the mapping software Visual Understanding Environment (VUE) as an aid to coding, mapping and managing the data. VUE was developed by the Academic Technology group at Tufts University. While there are many “mind-mapping” software programs available, most that I have seen are designed for business use and incorporate hierarchical assumptions. The Tufts software is designed for academic research and teaching and does not assume hierarchical structures. It is easy to use and allows the user to construct and “play with” simple or complex representations of actors, linking elements and adding labels and colours. I also used VUE to create figures included throughout the text, where appropriate (e.g., Figure 1 in this chapter).

## **2.3 STUDYING CHANGES OVER TIME**

### **2.3.1 The Rationale for Studying Changes Over Time**

Including an examination of changes in the groups over time was critical to evaluating whether the groups that accepted funding from pharmaceutical companies could be said to have been co-opted by this process or if they remained “authentic”. Numerous influences can compromise complex concepts like “authenticity” in grass roots groups; for example, in addition to commercialization, groups can lose their accountability through “professionalism, colonization by the state, and the inevitably limited system of internal democracy” (O’Donovan 2005:14). Ethnographic research over time is a methodology capable of capturing these multiple influences. To assess whether groups that accepted funds from the industry were able to remain independent from the industry, particularly with respect to their advocacy work in relation to drugs, I conducted my ethnographic research into pharma funding and pharma-related advocacy diachronically, beginning with the period circa 1990 when Canada’s breast cancer movement began and continuing to the present.

The positions that patients’ groups take with respect to entities like cancer treatments, funding from pharmaceutical companies, and government policies on drugs are not a given; they are negotiated and renegotiated over time. A central goal of my research is to understand this negotiation process as it evolves.



### 2.3.2 Actor-Network Theory (ANT) and Discourse Analysis

Actor network theory (ANT) is an approach to studying processes of social negotiation and conflict among actors, including negotiations involving non-human actors. The term “discourse analysis” refers to a variety of analytic methodologies based on language and other forms of symbolic communication. The approach I use, derived from the theories of Michel Foucault, is concerned with the way reality or truth is constructed at a given point in time. I draw from both ANT and discourse analysis to map the development of breast cancer organizations and their networks, including how their understanding of drugs and drug policy structures evolves over time.

#### *Using Actor-network analysis to track the reconstruction of meanings over time*

Actor-network theory (ANT) is an analytic framework that sociologists Bruno Latour and Michel Callon developed in Paris in the 1980s to study the strategies that scientists use to construct knowledge in science and technology projects (Callon, 1986; Latour, 1983). A basic assumption underlying ANT is that the meanings of technological entities are not fixed; rather they are constructed and may be maintained or changed. Thus, all entities, human and non-human, “take their form and acquire their attributes as a result of their relations with other entities” (Law 1999: 3). ANT provides conceptual tools for studying these changes: an “actor” is an entity whose meaning is of interest to the research (in my research, a breast cancer group, a breast cancer drug, and a pharmaceutical company are all actors); while the “network” refers to all those surrounding entities in an actor’s environment to which the actor is connected and which give it meaning (Figure 3). Another assumption built into ANT is that these meanings are inherently unstable. The concept of an actor-network embodies a tension that evokes the instability of the social

world: agency *versus* structure; the centred actor within a decentred network (Law 1999). ANT's focus on meaning-making as a process that changes over time makes it a useful methodological tool to address the chronological aspect of my research.

ANT's developers depart from the orthodox social science focus on humans alone because ANT was "specifically designed to describe and analyse those imbroglios in which ... it is difficult to separate humans and non-humans" (Callon 1999:182-183). For ANT's detractors, however, the conflation of human actors and inanimate entities into a single model is problematic because it suggests that inanimate entities have agency.

David Hess attributes this criticism of ANT to a misunderstanding:

A much misunderstood point, which Callon clarified in a conversation with me, is that his framework does not ascribe agency to things but instead focuses on the ways in which agency is attributed to or delegated to things. In this way he provides a counterargument to the criticism I raised with him that his theory involves a version of reification, commodity fetishism, or even animism..." (Hess 1997:150).

For research focused on the cultural aspects of pharmaceutical use, the construct of non-human actors provides a useful means of emphasizing the centrality of material objects such as drugs in contemporary social life (Busfield, 2006; Williams-Jones & Graham, 2003). The editors of a special journal issue on drugs as cultural entities further argue that recognizing them as agents sets a cultural inquiry into drugs apart from a scientific or clinical one:

In framing and indeed shaping lives, drugs are social and political agents. In a strange way, they too have lives – as much as we live through drugs, they live through us. The notion of "living drugs" means taking drugs seriously as agents and as analytical objects: as social scientists we cannot afford to leave this field to the scientists and clinicians, or to simply join the wait for 'better' drugs.... Collectively, the papers [in this special issue] argue that drugs – like

the clinical encounter, corporations and patient organizations – must be understood as culture.

(Fraser, Valentine and Roberts 2009:124)

I take ANT's conflation of the human and non-human to be an advantage for my research, not a drawback. A drug, once taken, literally interacts with the body and "produces" effects; this "activity" is its purpose. Furthermore, the centrality of drugs for patients facing a life-threatening illness can scarcely be underestimated (and may even approach commodity fetishism or animism, as suggested by common terms like "life-saving drug" or "miracle-drug"). The meanings patient groups assign to cancer treatment drugs are central to my research question and explicit recognition of the non-human actor is a way to capture exactly this type meaning-making as it evolves through discourses and over time.

A second controversial aspect of ANT is potentially more troublesome for my research. In early ANT research, the lead actor in a translation/knowledge construction project was typically a scientist or group of scientists (Callon 1986, Latour 1983). Anthropologist David Hess, for example, has critiqued ANT for assuming a level playing field populated by aggressively competitive actors. Ignoring the perspective of actors who are less powerful or non-aggressive, he argues, limits ANT's usefulness for examining moral questions (Hess 1997). In a similar early critique, Steven Epstein comments:

At least in practice, Latour tends to assume a hierarchical model in which it is the all-powerful scientist who does the claims-making, and who seeks to recruit others, including members of lay publics, behind his or her banner (Epstein, 1993: 47).

Based on his research on the American AIDS movement, Epstein concluded that ANT's emphasis on "power, conflict and disorder" provides a useful, but only a partial picture of how credible scientific knowledge is constructed. For the purposes of studying the intersection of AIDS activism and science, he argues that a vocabulary of "solidarity, integration and order" is necessary as well (Epstein, 1993: 44). Indeed, ANT's developers point out that ANT has evolved (Latour 1999, Law 1999, Latour 2005) in response to depictions of ANT as "the male like, hairy gorilla character" in a "field of forces where morality, humanity [and] psychology was absent" (Latour 1999:16).

Feminist scholars in science and technology studies are among those who have countered the STS bias towards (usually male) scientist-inventors with research and theorizing that foregrounds end-users, who are often female (Oudshoorn & Pinch, 2004: 6-7). Patients are a prime example of end-users of a technology. Because end-users are seldom a homogeneous group, diversity is a central concept in this theorizing (Cowan 1987; Oudshoorn, Brouns and Varnes 2005). Feminist STS scholars incorporate power relations into their theorizing by rejecting the stereotypical depiction of the female lay user of technologies as passive and as inherently less powerful than scientific and technological experts (Clarke and Montini 1993; Clarke 1998; Locke and Kaufert 1998); rather, they propose that the power relationships among multiple actors in socio-technological networks be left as an empirical question (Oudshoorn and Pinch 2003: 7). This re-theorizing of power issues aligns well with Hess's re-vision of ANT, in which he reworks central concepts to incorporate a critical analysis that is prescriptive, explores power and cultural values through a social justice lens, and positions the researcher inside the controversy (Hess 1997).

I use a version of ANT that incorporates these modifications. I also borrow at times from the “social worlds/arena” model, a similar conceptual framework that American social scientists developed during approximately the same time period that ANT was developed in Europe (Clarke 1990; Clarke and Star 2008; Strauss 1987). Social worlds are “groups with shared commitments to certain activities” (Clarke and Star 2008:115) through which people organize their social lives, sharing resources and ideologies. They are much like actor-networks and are used to study the ongoing processes by which participants in the same social world/arena co-construct meanings. The social worlds/arenas framework assumes that actors, both individual and collective, form “universes of discourse” which may overlap, divide into subworlds, and otherwise interact and mutate (Clarke and Star 2008: 116).

In using ANT to understand how patient groups and their networks affect the process of assigning meaning to treatments and to pharmaceutical companies, I theorize the groups as representing end-users within a socio-technological network. The groups are neither homogenous nor inherently powerless; they may act competitively, collaboratively or in some combination thereof, and they may, at times “speak” by means of their silence, whether by choice or in response to oppression. Figure 3 illustrates a hypothetical actor-network centring on breast cancer groups with links indicating processes that will shape the meaning that each entity has for the other.

*Translation*, a central concept in Actor-Network Theory, describes a four-step process of change that actors use to (re)construct scientific knowledge so that it aligns more closely with their own interests. Callon (1986) terms the four moments in a translation as *Problematization*, *Interessement*, *Enrollment*, and *Mobilisation*.

*Problematization* is a double-movement in which a group of actors make themselves indispensable by formulating a set of questions that, they argue, need to be answered; they then form a network of other actors and define their identities/interests in relation to the question. This process positions the primary actors as an *obligatory passage point* – a site that others must consult for the knowledge-making process to be valid. They then engage other actors and define their roles (*interessement*); they negotiate to have these roles accepted (*enrolment*); and they mobilize previously unengaged allies to provide a base of active support (*mobilization*). The translation, if successful, realigns the area of scientific knowledge in question to fit the perspective of the primary actors. In my analysis, I use the concept of *translation* to identify turning points in the narration, in which the actor-network is realigned in a significant way.

### 2.3.3 A Framework for Studying Discourses over Time

To map competing discourses and analyze the way they interact and change over time, I apply a form of discourse analysis based on Foucault's ideas about discourse and the "archeology of knowledge" (Foucault 1972 [1969], that is, how ideas are constructed at different moments in history). The term "discourse analysis" refers to a variety of language-based analytic methodologies, each with its own theoretical underpinnings. Rather than focusing on the structural aspects of language, a Foucault-based analysis, sometimes called "critical discourse analysis" (Hodges et al 2008: 570), attends to the ways that an issue is "spoken of" in speech, texts, writing and practice and to how these ways of acting, thinking and valuing come together to "define ... what is 'truth' at different moments" (Carabine 2001: 268). In my research, for example, I am interested in

the ways that breast cancer drugs are spoken and written about and valued; and how these representations define whether or not that treatment is considered life-extending, life-saving, or worth paying a high price for.

Struck by the ways that historical structures shape the organization of everyday life, Foucault reconceptualized the concept of history as changes in daily practices and struggles over truths. He theorized the latter as intimately connected: social groups base their practices on what they understand to be true. The task in understanding history, then, is to uncover the conditions from which particular knowledges, practices, objects or programs emerged rather than to construct a detailed total or “social” history (Kendall and Wickham 2004: 144). This process of inquiry contests accepted narratives about how knowledge in a particular field accrues.

Foucault developed two methodological approaches to conduct these critiques of established scientific discourses, archaeology and genealogy. An archaeology seeks to uncover underlying structural shifts in society – such as the emergence of a new class of experts -- that change the rules about what is sayable and thinkable and what can be called “true” or “false” (Foucault 1994; Hacking 2002). Genealogical analysis is based on the assumption that scientific knowledge does not develop through a smooth progression of formal scientific discoveries, but rather includes the marginalized knowledges of the “unqualified,” such as patients (Foucault 1980: 82). A genealogy seeks to uncover contestations among actors that create shifts, breaks and discontinuities. Central to both concepts is Foucault’s understanding of discourse, in particular his distinction between *connaissance*, the formal content of a field of knowledge (e.g., psychiatry or evolutionary theory) and *savoir*, a “depth knowledge” which are the field’s societal underpinnings:

institutions, commercial practices, mores and the like. The network of implicit knowledges allows a particular theory or discipline to emerge at a certain point in time.

Epstein (1996) proposes genealogical analysis as a useful methodological tool for examining patients' movements and their contribution to scientific knowledge. He draws particularly on the idea of "periodicity" as a feature in the history of knowledges which is revealed by identifying shifts and breaks and comparing two adjacent periods.

"Periodization," involves "systematically track[ing] patient groups and health movements through distinct phases of their evolution" (Epstein 2008: 525).

This analytic framework provides a useful perspective from which to examine the structural changes at the heart of my inquiry: at the forefront, the emergence of patient advocacy groups as an actor in the breast cancer arena with its internal struggles and rifts over knowledge claims in relation to breast cancer and its treatments; and in the background, the broader societal contestations and shifts associated with neoliberalism and globalism.

Although Foucault developed genealogical analysis as a methodological approach to study discourses (Foucault 1990 [1978]) he did not specify how such an analysis should be conducted and different researchers have developed their own methods. I used a four-step approach set out by Gavin Kendall and Gary Wickham (2004). The first step is to ask a "how" question, in my case: *How did patient advocacy groups that engage in knowledge claims about pharmaceutical drugs come to form alliances with the pharmaceutical industry?* The other three steps are: locating an archive of appropriate materials, seeking texts that are "programmatic" in the sense that they try to impose a



vision or a way of seeing a problem, and “digging” until the relative beginnings of a practice are uncovered (Kendall and Wickham 2004: 144-5).

*Locating an Archive* To locate individuals and documents that would help me trace current practices “back to their source” I sought people to interview who had participated in breast cancer groups that were begun in the first decade of the movement, other than those mentioned in the first section, and with a small number of health advocates from other health and disease groups that had struggled with the question of funding from the pharmaceutical industry. These are the participants discussed above whom I refer to as a composite group. They do not form an actual organization; rather, I use the term “group” as an umbrella term for advocates who have, over the years, been involved in health activism in Canada and whose individual narrative histories contribute to understanding how the patient group/pharmaceutical industry collaborations evolved. Many members of the composite group would have known one another through their activism in one or more patients’ organizations or health-related movements; however, they did not actually interact with one another as part of the study. The initial members of this group were selected because they had authored a document or were suggested by members of the groups chosen to be the critical and representative cases. I used theoretical sampling throughout the study to strategically add participants to the group when I identified gaps or discrepancies in the narrative. To understand the ways in which actors in the network contributed to structuring the practice, I interviewed a select number of individuals from government and industry. All of those interviewed had some discursive relationship to the issue of pharmaceutical company funding.

*Seeking Programmatic Texts* While conducting my interviews with members of the composite group and with other actors in the network, I developed an archive of materials, looking particularly for programmatic texts designed to construct the problem of pharmaceutical funding to patients' groups in a particular way. I sought programmatic documents from actors in different parts of the actor-network (Figure 3), for example, breast cancer patients' organizations, health/consumer movement organizations, pharmaceutical companies, government agencies and the media. I was particularly interested in Canadian documents; in some cases, however, where interviews or other materials indicated that a programmatic document produced in another country intersected with discourses in Canada, I included it as relevant to the Canadian genealogy. Similarly, although the majority of documents listed pertain to breast cancer organizations, I included some documents from other health and disease arenas (e.g., HIV/AIDS, women's health organizations).

Organizational websites are frequently updated and the current site of an organization may not accurately reflect its identity, mandate, programs or personnel ten or fifteen years ago. To locate historical material on the internet, I used the *Internet Archive* (<http://web.archive.org>), colloquially known as "The Wayback Machine."<sup>8</sup> The archive allowed me to find documents an organization had posted in an earlier period and taken down, such as earlier annual reports and to double-check statements made in interviews about organizations, for example, if an interviewee said, "I can't recall what year we did that, but it would have been around '98 or '99", I could search for documentation of that activity on her organization's website to verify the year. I was also able to use the Internet Archive to locate materials, such as conference or government

documents, that were online at an earlier stage of my research but which were no longer posted when I compiled my reference list.

An initial review of these interviews and documents suggested that they comprised a sufficiently large and varied archive to form the basis of a genealogical analysis. The documents, in conjunction with interviews I had conducted with patient group and health activists from the past two decades, also began to provide the basis for periodization, that is, evidence of shifts in the underlying structures (*savoir*), giving rise to distinct periods.

I analysed my interviews and documents using analytic techniques from grounded theory (Strauss 1987) and situational analysis (Clarke 2005), such as thematic coding, discourse analysis, and memoing. From my literature review and experiential knowledge, I expected certain themes to be the subject of discursive struggles, such as “advocacy,” “public interest,” “patients’ rights,” “partnerships,” “public participation,” and “drug access.” I also looked for emerging themes which I had not anticipated but which on analysis of the materials were central to the discourses. I examined changes in discourses over time, including silences and reversals in which a dominant discourse underwent a shift in tone or nuance. Central to my research question is an ethical dilemma so my analysis was directed to comparing understandings across and within sectors about right and wrong, as well as about truth.

*Digging to Find the Origins of a Practice:* In the last stage of theoretical sampling I sought to trace the struggles over the pharmaceutical funding of patients’ groups to their origins in the historical discourses of previous decades and centuries. Adele Clarke uses the term “historicizing” to distinguish this process from “doing ‘full on’ history” (Clarke

2005: 264-265). The purpose is to document those “historical dimensions that should be taken into explicit account to make better sense of a contemporary situation of interest” (ibid: 264). The process is essentially the same as that used to research and analyse contemporary events, but with a greater reliance on secondary sources than primary ones: thematic coding, discourse analysis and memoing of oral, written and visual materials allow the researcher to identify the themes, discourses, counter-discourses, shifts and breaks that signal changes in structures and the meanings of terms.

From my literature review, I had identified three key areas of structural change in the decades immediately prior to the advent of the breast cancer movement in Canada: government-funded healthcare, pharmaceuticals and the regulation of pharmaceutical companies, and the place of civil society groups in Canada’s political fabric. Most of the data for my analysis came from secondary sources but I also sought individuals to interview who could provide first-hand accounts of relevant discursive struggles in the 1980s.

## **2.4 STUDYING MACRO-SYSTEM INFLUENCES**

### **2.4.1 Incorporating Macro-system Influences**

My third main goal was to assess the meaning of PAG alliances for the functioning of Canadian society as a democracy. Tying these alliances to the broad ideals of citizenship, justice and democracy implies linking them to macro-system influences. Canada’s radical transformation from a liberal welfare state to one in which neo-liberal and neo-conservative beliefs dominate has dramatically reshaped the contours of public

policy in this country in the past thirty years. This transformation makes Canada a useful site in which to study the interrelationship between neo-liberal policies and pharmaceutical company funding of patients' groups. Grass roots patients' advocacy groups and movements are largely phenomena of the past thirty years and have inevitably felt the force of these concurrent policy changes.

Critical theory traditions highlight the importance of macro-level political economy influences on the local institutions, events and social/political relationships (Baer, Singer and Susser 1997; O'Donovan 2000; Smith 2005) and a political economy perspective provides tools for critical analysis of social phenomena, allowing the researcher to address questions of social justice. Such research is not without challenges; in particular, the researcher must go beyond simply invoking "the state," "Big Pharma" or "neoliberalism" as influences. Even proponents acknowledge that such research risks being "messier" than research that remains focused at the meso-level (Löwy 2000); furthermore, the result may be "deeply unsatisfying, tethered ... to totemic monolithic abstractions" (Mirowski and Sent 2008: 636).

Lynn Haney's research on the state's power on female prisoners suggests a way out of this dilemma. She conducted ethnographic research in two state institutions of the juvenile justice system to study the effects of state power on female clients and found that the dynamics of dominance and resistance in each were expressed in distinct -- even conflicting -- patterns. She argues that feminist researchers need to avoid invoking the state as a uniform, abstract force; rather, feminist state theory should recognize the state as a network of differentiated meso-level institutions in which even women who suffer multiple oppressions express agency (Haney, 1996).

Haney's analysis corresponds well with the position of ANT theorists, particularly when the feminist perspective of all actors (e.g., breast cancer patients' groups) having the potential of agency is taken into account. ANT recognizes the importance of social embeddedness on group behavior, yet its developers reject the traditional structuring of the social into micro, meso and macro levels. ANT takes as its research model the qualitative empirical case study, with data collection taking place exclusively at the local or meso-level of social interaction. As in my project, the research design often incorporates Marcus's concept of multi-sited ethnography (Marcus 1995).

ANT theorists reassemble actor and network as "two faces of the same phenomenon" (Latour 1999:19). The social becomes a "circulating entity", neither micro (an actor's interaction is always framed in some way), nor macro (the network is "a summing up of interactions" that are practical and local) (ibid: 17). The ANT researcher learns about the social order by following the movement of the actor-network. ANT, combined with multi-sited ethnography, provides a means of studying the culture(s) of patients' organizations in a variety of local settings that also include the state and/or multinational corporations as actors. These sites include government policy consultations, breast cancer conferences, webinars, websites, YouTube postings and community-level meetings.

My research situates PAG interactions with Pharma, the State and other macro-level actors at the local level, making visible the effect of policies on these local organizations. In my analysis, I looked for subtleties within the interactions between PAGs and ostensibly more powerful entities, including expressions of resistance to

oppressive policies. I interviewed representatives from Pharma, the State and the research community, to avoid stereotyping their positions.

## **2.5 AUTHENTICITY, VALIDITY, AND QUESTIONS OF ETHICS**

A postmodern qualitative research project radically challenges the conventional concept of validity, carried over from the days when qualitative research had the goal of uncovering a single hidden truth. In a review of the central controversies engendered by post-modern paradigms in qualitative research, qualitative methodology theorists Egan Guba and Yvonne Lincoln acknowledge that the question of validity in constructivist research is “irritating” (Guba and Lincoln 2005: 205). Modernist qualitative research triangulated the findings from several methods (typically, interviews, participant observation, and text documents) to establish validity; however, in rejecting the concept of knowledge-as-buried-treasure, postmodern research requires a radical reformulation of validity and “methodological rigour,” as the taken-for-granted route to it. Postmodern paradigms have thus largely replaced validity with *authenticity* as an indication of rigour, Guba and Lincoln observe. Authenticity means the findings should be trustworthy, they should be isomorphic to some reality, and related to the way others construct their social worlds. They should merit sufficient confidence to be the basis for action, by members of the community in which the research is conducted, and for developing social policy or legislation.

Reconfigurations of what constitutes rigorous qualitative research have been confusing, Guba and Lincoln contend, because they have tended to conflate two arguments, one for *methodological* rigour, the other for rigour in *interpretation*. A new-

paradigm inquiry requires both. With respect to the former, Guba and Lincoln conclude that no single method or collection thereof is the “royal road to ultimate knowledge” (2005: 205), although some methods are more suited than others to social constructivist research (the primary paradigm of my project). This leaves methodological rigour to be established by taking seriously such time-honoured issues as prolonged engagement and persistent observation.

Rigorous *interpretation*, by contrast, is evaluated in largely ethical terms, such as fairness, authenticity, and the capacity to catalyze political and social action. Various approximations of these goals have been articulated and debated in the qualitative literature in the past two decades. Guba and Lincoln note of one such list of standards (Lincoln 1995) they are “all rooted in the epistemology/ethics nexus” (2005: 209); this is true of other discussions they review as well. Dimensions that have emerged with some consistency include: i) a *fair balance* of perspectives, which can be expressed through some form of polyvocality in the research text, through the researcher’s self-reflexivity, and through a presentation of perspectives that is non-hierarchical; ii) *ontological authenticity*, which refers to a critical intelligence on the part of the researcher; iii) *educative authenticity*, or a capacity to engage in moral critique; and iv) *catalytic and tactical authenticity*, such as include training research participants in forms of political and social action. I have attempted to meet the standards of methodological rigour as well as the first three of the four criteria of interpretive authenticity. (I originally planned a phase of the research designed to address catalytic authenticity but dropped it because of time constraints; I will provide participants with summaries of the research and discuss



potential of the project as a basis for political action. If possible, I will pursue my original plan to undertake a catalytic project based on the research in the near future.)

### 2.5.1 Moral Positionings: Ethics and the Question of Relativity<sup>9</sup>

At the centre of my research is the ethics debate which bioethicists have framed as “conflicts of interest.” My project deviates from much of that analysis to date, however, because I approach the issue as a social scientist. Social scientists working in bioethics assume judgments about morality must be grounded in the complex and ambiguous lived reality of participants and ethnography is the preferred methodology for accomplishing this. In the discussion that follows I explore the implications of making ethnography central to my methodology.

Since its inception as an area of academic study in the 1960s, the field of bioethics has been characterized by a tension between moral philosophers and social scientists (Borry, Schotmans and Dierickx 2005). Analytic philosophers have dominated the field with the result that much of the theorizing came to share with philosophy “the aim of logical reasoning, conceptual clarity, coherence, and rational justification” (Borry et al, 2005: 60). Social scientists, by contrast, begin their analyses with empirical investigation and assume the centrality of social context and emotion to human decision-making.

While bioethics has carved out a specialty with a particular focus on ethics in health and medicine, morality is part of any cultural fabric and so most anthropological research includes the study of ethics. Anthropologist Signe Howell argues, however, that direct research on the *process* by which morals are socially constructed is rare within anthropology (Howell 1997). A researcher/theorist who is “neutral” about ethics is

unlikely to conduct a sociological or anthropological inquiry into ethics, reasons Howell, so the methodology has to take into account the researcher's engaged stance in some way.

An assumption of contemporary ethnographic research is that, in all research, the observer inevitably changes the events by her very presence. All knowledge is situated because every researcher is positioned in a particular social location which allows only a partial perspective (Haraway 1999). Ethnographic observers acknowledge the effects of their presence and use a process of self-reflexivity to become aware of their own positioning *vis à vis* the other, including their social identity (e.g., gender, cultural, class, age). The researcher looks inward and self-examines the particular social and individual locations from which she views the other's reality, recognizing her limited fields of vision and well as her inherent fields of power (Narayan, 2005). My own position includes an identity as a former breast cancer patient who was a member of several patients' organizations, including one that was included in the study and a second that was frequently referred to by participants in the study. I have written and spoken critically about pharmaceutical funding of patients' groups (Batt 2000; Batt 2002; Batt 2009). I use self reflection on, and openness about, these aspects of my identity throughout the research to help me achieve "strong objectivity" (Harding 1991; Harding 1998). That is, the assumption that a researcher achieves greater objectivity by maintaining awareness of her values and beliefs and by exposing them to public scrutiny and challenge.

Recognizing multiple perspectives in the study of morality raises the issue of moral relativism, a long-debated subject which is part of the aforementioned tension between philosophers and social scientists (Callahan 1999; Geertz 2000; Good 1995;

Kleinman 2004). Philosophers lean towards formulating universal abstract principles and social scientists to an understanding of local worlds and contexts. Bioethicists on both sides of the disciplinary divide have sought to resolve this paradox. Anthropologists Koenig and Marshall, for example, agree that morality has universal dimensions, such as justice and fairness, but these are expressed differently in different cultural settings (Koenig and Marshall 2004). Arthur Kleinman, also a medical anthropologist, similarly argues in favour of a bioethics that attempts to define universal standards. While knowledge gained from empirical research about local worlds helps relate ethical deliberation to local contexts, he notes that local worlds can be “utterly unethical” (Kleinman 2004:73).

In describing the local worlds of Canadian breast cancer groups, I have tried to provide sufficient detail, nuance and social context to allow the reader to understand and fairly assess their competing discourses. While I do not shy away from ethical judgement, I take the view that any narrative, including my own, has embedded assumptions. The positioned researcher has a responsibility to seek out and direct attention to these assumptions (Charon and Montello 2002; Haimés 2002). To this end, and because in any study using discourse analysis the amount of material available is vast, I have adopted recommended techniques to counter the tendency a researcher may have to inadvertently favour material that supports her theories or values (Carabine 2001: 206). To offset this potential for selection bias, I have sought out, collected and analysed information that challenges my expectations. I maintain a focus on the issue of pharmaceutical company funding in the breast cancer movement, not on my personal views. I adopt a distancing technique introduced by Susan Greenhalgh and refer to my activist self as “SB,” or

“Sharon,” reserving “I” for my ethnographer’s voice (Greenhalgh 2001). I also include exchanges in my interviews in which interviewees challenged my perspective on pharmaceutical company funding issues.

### 2.5.2 Ethics Approval, Consent and Engaged Research

The study proposal was developed in accordance with the Tri-Council Guidelines that were in effect when the data collection began in 2007 (Canadian Institutes of Health Research, Natural sciences and Engineering Council of Canada and social Sciences and Humanities Research Council of Canada 1998) and with Dalhousie University’s policy on the ethical conduct of research involving humans (Office of Research Services 1999; Office of Research Services 2009). The proposal was approved by the Dalhousie Research Ethics Board in March 2007. The consent form sent to individuals was refined over time and varied slightly depending on the participant. I discussed the purpose of the research with each potential participant (group representative or individual) through a variety of means, from initial telephone or e-mail communications, to full discussions, and finally to signing the consent form. The consent process explained the purpose of the study, the methods, potential risks and benefits, and methods for protecting confidentiality and anonymity. The right of the group or individual to limit participation in some way (e.g., by refusing access to certain files, or declining to respond to a question) was made clear, as was the option of withdrawing from the study altogether.

All participants were informed that I hoped to publish the findings and that, although pseudonyms would be used (except where participants indicated they did not wish to be anonymous), I could not guarantee complete anonymity. Ultimately, however,

I decided to anonymize all names because the mix of actual names and real names was confusing and the use of one individual's real name sometimes undermined the anonymity of another interviewee with whom she had interacted. I made an exception to this rule in the case of a particular dilemma -- cases where an interviewee had written a key text which I cited and asked her to reflect on. Because the citation required attributing the text to the author by her actual name, it was impossible to incorporate these reflections without revealing the interviewee's name as well. In these instances, I asked the interviewee if she was comfortable being identified with respect to those reflections. If she was, I tried to include the comments in such a way that the context would not reveal her identity if she was quoted speaking on other topics. In my biographies of three groups, as well as in the narrative of Chapter 5, I have changed the names of the organizations, as a further means of preserving the anonymity of the participants. To distinguish anonymized from actual names, I have italicized the anonymized names; for actual names (of individuals or groups) I use plain text. The use of pseudonyms was consistent with the objective of my project, that is, to focus on structures, systems and processes rather than individuals and personalities. I did, however, use the real names of pharmaceutical companies, drugs and government entities.

## **2.6 OVERVIEW AND PRESENTATION OF RESULTS**

In this chapter I discuss my three main research goals and the methods I chose to realize them. I summarize the discussion in Table 1. These are: to conduct a holistic analysis of actual groups and their relationships with the pharmaceutical industry, using

ethnographic methods; to identify changes in these relationships over time, using Actor-Network Theory and methodologies derived from Foucault's theories (discourse analysis, archaeology, genealogy analysis and periodization); and to assess the implications of PAG/Pharma alliances for macro-level ideals, such as democracy and justice, using a local level analysis of macro-level actors. I present these results in Chapters 3, 4 and 5.

The results of my study of actual groups appear in Chapters Three and Five. Chapter Three comprises close-up biographies of three PAGs that fall along the continuum of PAG/Pharma relationships, from "no pharma funding" to "completely funded by pharma." This chapter serves to highlight the diversity and central themes in the discourse over pharma funding and its potential to affect advocacy in relation to breast cancer drugs. In chapter 5, I construct a chronological narrative of the breast cancer movement in Canada, from the perspective of the participants in PAGES, and over the 21 year period of the movement's evolution from approximately 1990 to the present. This chapter takes a mid-range perspective of the struggles over pharma funding and includes macro-level actors. The chapter concludes with a "socially constructed breast cancer pharmacopoeia" that summarizes the social influences on three treatments used to treat breast cancer, as revealed in the chapter's narrative.

Results of my diachronic analysis appear in all three chapters. Chapter's Three and Five, as outlined above, are both chronological narratives. Chapter Four comprises three overlapping historical narratives that depict the origins of three policy landscapes that shape the contours of patient group advocacy in contemporary Canada. Based on my historical research I describe the evolution of competing discourses in Canada over three contentious questions: government-funded healthcare, pharmaceuticals/the regulation of

pharmaceutical companies, and the place of civil society groups. This analysis helps interpret the events of Chapter Five, in which I use periodization to show significant breaks in the nature of the PAG/Pharma alliances, as revealed in my analysis.

The results of my analysis of macro-influences analysis appears in Chapters Four and Five. Chapter Four explains the development and changes of selected macro-level structures related to healthcare, pharmaceuticals, and civil society groups, while Chapter Five incorporates a discussion of actors from these structures at the local level, along with accounts of ways in which these structures continued to evolve, over the twenty-one year span of the chapter's narrative.

## **CHAPTER 3      BIOGRAPHIES OF THREE GROUPS**

### **3.1    THREE GROUPS, THREE STANCES ON PHARMA FUNDING**

In the last chapter I discussed Faye Ginsburg's methodology for studying the divisive issue of abortion politics as a researcher whose own sympathies clearly lay with one side of the debate (Ginsburg 1998[1993]). Following Ginsburg's rationale, one of my goals in this chapter is to understand, and fairly portray, the perspective of activists within organizations whose views on pharma funding are different from mine. As is the case with the abortion debate, the issue of funding from the pharmaceutical industry is contested and highly divisive within the community of patients' organizations. "Pharma funding" is also an issue on which I, as a researcher and activist, hold a point of view which is in sympathy with one perspective on the issue (that of refusing pharma funding); I therefore sought methodological strategies to ensure my own views did not interfere with my ability to represent the views of research participants with whom I disagreed.

In order to avoid stereotyping the perspectives of women whose views she did not share, Ginsburg developed a "life stories" approach: she assumed the women were active agents in their decisions and used lengthy quotes and multiple voices to show how the activism of women in the right-to-life movement grew out of and was an integral part of each woman's life experiences. In this chapter I adapt Ginsburg's approach to my study in which I have defined groups, not individuals, as the actors of interest and hence the unit of analysis. I tell the "life stories" of three selected groups in the movement: how they began, the members' internal struggles as the groups evolved (particularly with respect to the issue of pharma funding), and the distinctive identities the groups had developed by the time I concluded my research. Drawing from ethnographic data, I



depict the groups from the inside, with a particular focus on why and how the decision-makers in each one made the decisions they did about pharma funding.

This chapter also serves to identify empirical and theoretical issues that are relevant to the decisions groups make about pharma funding. To this end I have chosen to profile three “critical cases” from the numerous groups that emerged as Canada’s breast cancer movement developed (Snow and Trom 2002). The first group, which I call *Critical Advocacy to Prevent Cancer* (all group names in this chapter are pseudonyms), developed a policy that prohibits the group from accepting any funding from the pharmaceutical industry. I was a co-founder of this group and the views of its members align most closely with my own. A central concern of the group’s advocacy is to reduce toxic substances in the environment as a means of preventing breast cancer, a “green” emphasis that has become more pronounced in recent years. The second group profiled in this chapter, *Down-home Peer Support and Education*, defines peer support and advocacy to improve information and other services for local women with breast cancer as its main focus. This group concluded that pharma funding was an inherently divisive issue that created tensions in the group which were unresolvable. In order to remain inclusive of all women with breast cancer, *Down-home Peer Support and Education* arrived at a case-by-case policy on pharma funding, in which each case was brought to the board for discussion. The third group, the *Patients, Know Your Rights! Working Group*, was a national ad hoc committee comprised of six to eight volunteers<sup>10</sup> from local organizations across the country. The Working Group was initiated by a provincial breast organization in central Canada. It was wholly funded by the pharmaceutical company Astra Zeneca and was created for the sole purpose of developing a Canadian breast

cancer patients' bill or charter of rights. None of the groups is necessarily "typical" of breast cancer groups in Canada; rather, they are archetypes on a "No-Maybe-Yes" continuum. Two groups are extreme cases, while the third instance illustrates a conscious effort to embrace and internalize the ambivalence that many members of patients' groups feel about the pharma funding issue.

Much as the perspectives of Ginsburg's "pro-choice" and "right-to-life" activists developed out of their life experiences and identities, I assume that the position that a *group* holds on pharma funding is shaped by key events within the group's history and is part of the group's coherent and continually evolving identity narrative. Maren Klawiter's concept of a "culture of action" (Klawiter 1999) is useful for conceiving of groups as actors with multi-faceted identities. Klawiter theorizes that health advocacy groups have distinct cultures which are manifested in a group's modes of behavior, values, tacit knowledge, and the way the organization frames the issues around which it mobilizes. Cultures of action are fluid and are shaped by external forces as well as internal bargaining.

Neither of the groups at either end of the "Yes-No continuum" had a position on pharma funding at the outset. The third group existed from the beginning in a relationship with the industry, yet this relationship was far from static. Like Ginsburg and Klawiter, I assume that groups are active agents whose members created their culture of action, including the group's position on pharma funding, through a process of engaged debate and in recognition of external pressures, as well as pressures within the organization. To show the interplay of these forces, I trace each group from its beginnings to the present, drawing from accounts of women who were active in the organization at different points

in its evolution, and from texts, visuals, group websites, and organizational files relevant to how the group dealt with the issue of pharma funding at different points. Within each group, I assume that the views of members are neither homogeneous nor static. Thus, in each of the three narratives, I present multiple voices to show the way in which members discuss, sometimes disagree, and struggle to resolve their differences. The polyphonic voices expose pressures external and internal to the group that influenced their decisions or constituted turning points. Because the chapter's focus remains within the three groups, these narratives do not provide a coherent account of pertinent historical factors external to the groups; this is the goal of Chapter Five. Nor does Chapter Three provide a macro-level view that captures the social and political environment in which Canada's breast cancer groups function; this is the goal of Chapter Four.

Chapter Three does, nonetheless, introduce a variety of actors, within and outside each group. Table 2 itemizes and briefly describes the human actors in the three group narratives, while Figures 4 and 5 visually depict the relationships among the actors in two of the three group histories.

*Critical Advocacy to Prevent Cancer*, the subject of the chapter's first biography, is an urban organization based in a large city in central Canada; its members oppose pharmaceutical company funding not only for itself but for the movement as a whole. Founded in 1991, the organization is part of the breast cancer environmental movement (Ley 2009); in 2001 the group developed a Corporate Contributions Policy to guide decision-making internally and to explain its position to others. The second narrative features the story of *Down-home Peer Support and Education*, a provincial organization on the east coast founded in 1995 and dedicated to improving breast cancer care and

support for patients in that region. The group has come to recognize pharmaceutical funding as an irreconcilable issue among its members and has therefore decided to evaluate these opportunities on a case-by-case basis. The third group, *Patients, Know your Rights* is a national working group of volunteers founded in 2003 that spent three years developing a charter of rights for breast cancer patients while wholly funded by the pharmaceutical company Astra-Zeneca.

### 3.1.1 Group A: *Critical Advocacy to Prevent Cancer*

*Group history, activities, and background on pharmaceutical issues. Critical Advocacy to Prevent Cancer* began in 1991 when five women living in the same Canadian city, all of whom had had breast cancer, decided “to end their isolation and move the disease from the private to the public sphere.” From the beginning, *Critical Advocacy to Prevent Cancer* defined itself as a new type of breast cancer group in Canada, while acknowledging the influence of an American group founded the previous year, *Breast Cancer Truth-Tellers*. It was not a support group; its goal was to provide women living with breast cancer a voice in cancer policies. Its founding members were drawn to the emerging theory of environmental health scientist Devra Lee Davis, who had begun to challenge epidemiological evidence about cancer causality, suggesting that more cancers than previously thought had<sup>11</sup> environmental origins (Davis, Hoel, Fox and Lopez 1990). Davis’s theory came to the attention of the four founders when she was profiled in the *New York Times Magazine* in December, 1991 (Wright 1991). Davis had begun to make waves with a provocative argument that research by two leading cancer epidemiologists, Sir Richard Doll and Richard Peto, had underestimated the percentage

of cancers that could be prevented by public health measures. In a monthly discussion session that pre-dated the launch of the group, the four women agreed they wanted the new organization to push for greater attention to determining the environmental causes of breast cancer. Over the next two decades, *Critical Advocacy to Prevent Cancer* would become part of a loosely organized international network of breast cancer groups now referred to as “the environmental breast cancer movement” – health activism aimed at redressing the historical imbalance between disease treatment and disease prevention in breast cancer (Ley 2009).

The group held its public launch in April 1992 in a downtown church basement. Fifty people, including members of the media, came out to hear the founder of a patient-centred breast cancer group from Vermont describe the sudden emergence of breast cancer activism in the United States, and to talk about launching a similar political movement in Canada.

In March 1993, the group staged its first large educational event and waded into controversy, holding a public debate on the pros and cons of the newly launched Breast Cancer Prevention Trial, a Canada-US clinical trial to determine whether the treatment drug tamoxifen would be effective as a breast cancer preventative (Fosket 2004; Ley 2009). The speakers were a prominent local oncologist who was also a leading advocate for the trial, an American physician from an American feminist health network that opposed the trial, and a female professor from a local university who also had reservations about the trial. The group’s sponsorship of the event was consistent with its developing commitment to environmental advocacy; that is, feminist opponents of the trial argued that researchers and cancer policy makers were prepared to study cancer

prevention using a pill while underfunding research into causes of the disease. This critique engaged long-standing feminist concerns about the medicalization of healthy women's bodies; women with breast cancer added a dimension of "embodied knowledge" to these familiar concerns, since tamoxifen's side-effects were well known to women taking the drug. The debate, which drew an audience of 400 people and garnered national media coverage, cast doubts on the wisdom of using a toxic drug as a means of preventing cancer, and drew critical attention to the clinical trial, which was actively recruiting participants across Canada. Such public discussions of controversial questions about breast cancer became a signature activity for the group, with speakers often chosen to catalyze debate about how to prevent the disease.

For early members, participation in *Critical Advocacy to Prevent Cancer* was a process of discovery that challenged their received understanding about breast cancer.

The first public meeting was two years after I had been diagnosed .... I saw an ad in the paper that appealed to me because it didn't look like a support group; it looked like a political group that was going to do something.

... I had no idea, really, I didn't know what was going to happen, and I went with an open mind to see. And I learned a tremendous, tremendous amount. I remember that I wanted to go to other meetings. I saw a bunch of bright, interesting women who wanted to do something. [...] I heard a lot about 'slash, cut, burn, poison,' I mean, things I had never even thought about. ... I was always amazed. I was taught [in the group] to be an activist, taught to think and not to trust. (laughs) I don't trust anything now, it's terrible!  
(Interview with *Georgina*, 2007)

*Sara*, another of the early members, is a self-described Depression baby who was hooked, like *Georgina*, after attending the first public meeting of *Critical Advocacy to Prevent Cancer*. Unlike *Georgina*, who refers to herself as an "apolitical hippy" prior to

her breast cancer diagnosis, *Sara* had been involved in political organizations since joining the Peace Club in high school:

I was terribly impressed with all the young women – how knowledgeable they were, how gung-ho and sure in what they wanted to do. It made it easier for me to get involved. I never went to college as a young woman ... I was 50 or something when I enrolled in university courses. So for me, to be in close contact with women who had that kind of know-how, was very, very encouraging! (Interview with *Sara*, 2007)

In November 1993, *Sara* was one of the members of *Critical Advocacy to Prevent Cancer* to attend the National Forum on Breast Cancer, a national policy meeting sponsored by Health Canada which included women with breast cancer as full participants, along with researchers, oncologists, and policy makers from the government and the large cancer charities. The Forum, she recalls, showed her the breadth of this new movement in Canada. She also recalls her shock in talking to a speaker from the UK, an international expert on the particular treatment she had been given after her diagnosis:

I had been on tamoxifen and I had a very bad reaction -- blood clots in my legs -- and my doctor had to take me off the drug. When the keynote speaker talked about tamoxifen, I wanted to ask a question in front of everybody but I didn't have the nerve. So I went up to him afterwards and I asked, "When I was on tamoxifen, if I had only taken half the dose would it have been effective?" He said, "I don't know"! So I asked him, "How was the dose arrived at?" And I will never forget his answer. He said: "Random!" (laughs) You're on your own, it seems. It didn't give me much confidence -- not only in tamoxifen, but in general – in how these doses are arrived at. (Interview with *Sara*, 2007)

In early 1994, *Critical Advocacy to Prevent Cancer* found itself at the centre of another political storm, when a local oncologist was implicated in a high-profile research fraud case involving breast cancer clinical trials that had international press coverage. The group decided to call a meeting where patients could discuss what had happened.

We thought [it was a good idea], just to let [his] patients air some of their personal fears, because they had been involved in falsified statistics. And it was a rather political event. ... There was a lot of energy flowing in many directions. It was quite horrifying to find that a [prominent American researcher] was the head of the whole thing ... I mean, it's such a demystification process! And I was pretty old to start to be demystified. ... But it's really hard to believe, when you find out that people have done something like that, and it also makes you very, very cautious. It makes you want to tell everybody that if they're going to be in a [research] protocol, to make sure that they are in the best protocol available to them.

And also then, of course, we started finding out that the drug companies were the ones funding a lot of these things. And what were they trying to find out? How to sell more pills! More chemicals! And we also found out that they were the same ones making the chemicals that were poisoning us in the first place. So it was just sort of an ongoing revelation of information. And what to do? How do you get this information out? [Georgina, 2007]

*Critical Advocacy to Prevent Cancer's* initial budget came from individual donations at the first meeting and from selling memberships at \$20.00 each. By January 1993, the group's minutes record a budget for the previous year of \$2,000, raised from memberships, donations and small fundraising events, such as a yard sale. The same month the federal government refused an application for Charitable Tax status -- which would allow *Critical Advocacy to Prevent Cancer* to issue tax receipts for donations -- on the grounds that the group engaged in political advocacy. With the help of a sympathetic lawyer working *pro bono*, *Critical Advocacy to Prevent Cancer* appealed the decision, emphasizing its educational mandate and, in February 1993, the application was granted. The incident was prescient, however, of the group's location on the ill-defined boundary between non-profit educational work and political advocacy.

*Critical Advocacy to Prevent Cancer* had no office in its start-up years. Its directors held business meetings in each others' homes and monthly public meetings for



members at the same downtown church where it held its launch. The occasional larger events were held in university venues. In January 1995, however, with its previous year's receipts up to \$5,500, *Critical Advocacy to Prevent Cancer* accepted an invitation to share office space with another women's health advocacy group, *Learn from Drug Tragedy*, which had been founded in 1982 by a mother and daughter harmed by the drug diethylstilbestrol (DES). *Learn from Drug Tragedy* worked to educate the public about DES and its effects (which included an elevated risk of breast cancer) while pressuring the federal government for stronger drug safety regulations. Because of its origins, *Learn from Drug Tragedy* had a tradition of critiquing the pharmaceutical industry; *Critical Advocacy to Prevent Cancer's* informal affiliation with that organization, combined with its ongoing opposition to the tamoxifen prevention trial (which continued to recruit participants until 1998) were two early expressions of the group's critical stance *vis à vis* the industry and its commitment to discussing drug harms as well as benefits.

Discussions about the science of clinical trials and the pharmaceutical industry informed *Critical Advocacy to Prevent Cancer's* early policy stances on public issues, although questions of industry funding were not a focus of the group's internal decision-making in its start-up years. By 1995, however, references to industry overtures began to show up in the organization's minutes. In May 1995, the minutes of a board meeting record a discussion of "three overtures from different [pharmaceutical] companies in the past month." One, described in detail, involved a visit to the group's office by a woman who said she was representing a client, but wouldn't reveal who the client was. A series of leading questions suggested that she wanted to galvanize the group to lobby to have the drug Taxotere® (docetaxel) included on the provincial drug formulary as a treatment

for breast cancer. When she repeatedly refused to say whom she represented, she was asked to leave the office.

In January 1995, the group accepted a different overture, however, from the San Francisco-based biotech company Genentech, which was recruiting patients in the US and Canada for clinical trials for the new breast cancer treatment, Herceptin® (trastuzumab). The invitation came through the auspices of the U.S. group, *Breast Cancer Truth-Tellers* and concerned a meeting outside Washington, DC, organized and paid for by Genentech. Borrowing a page from AIDS activists, the American group had demanded that the company make the drug available on a compassionate basis to women who might benefit from it. The company had rejected the request, prompting *Breast Cancer Truth-Tellers* to stage a demonstration at the company's headquarters in December, 1994<sup>12</sup> The company responded by inviting representatives from several activist groups to a meeting to air their concerns. *Critical Advocacy to Prevent Cancer*, through its links to *Breast Cancer Truth-Tellers*, was invited to the meeting. With encouragement from *Breast Cancer Truth-Tellers*, in January 1995 the group sent a representative to Washington and to a subsequent follow-up to the meeting in San Antonio, in April 1995. A May 1995 entry in the board minutes suggests some misgivings about the decision, and an internal call for the group to begin thinking about a policy (“What is *Critical Advocacy to Prevent Cancer*'s stand on flying off on drug company junkets?”). Similarly, a March 1996 entry notes a discussion of “drug companies as a problem *versus* as an easy target for bashing.” The interaction with Genentech was seen as different from using pharmaceutical company grants to run organizational programs; rather, the purpose was to address a difference of perspective

between activists and company representatives – arguably, exactly the type of policy consultation the group was established to promote. Nonetheless, accepting travel funds from the company was a source of discomfort; the exchange highlighted the financial and power differences between the group and the industry as well as the contradiction between accepting travel funds from the industry while attempting to speak for patients on drug policy questions.

Drug company-sponsored events involving breast cancer patients' groups were becoming a routine occurrence and the phenomenon began to generate discussion not only within *Critical Advocacy to Prevent Cancer* but in the breast cancer and women's health communities. During this same period, government funding for community-based groups was being cut back. *Critical Advocacy to Prevent Cancer*'s minutes reflect concerns about both developments. A July 1996 entry reads: "Government funding very tight and getting tighter. Governments are very cautious about giving, especially to new groups. Core operating funds are practically impossible to get from governments and foundations." (*Critical Advocacy to Prevent Cancer* minutes, July 1996).

The federal government had, however, named breast cancer as a priority area in health policy, and committed \$5 million over five years to breast cancer research and a variety of other breast cancer projects. *Critical Advocacy to Prevent Cancer* and other patient-centred groups had demanded that women with breast cancer be included in decision-making. These efforts succeeded; now, the groups were under continual pressure to send representatives to sit on committees that selected which research projects to fund, to discuss policies about mammography screening, and consult on other breast cancer-related programs. Although they were evidence of successful advocacy, these requests

began to generate resentment: the group was struggling to survive financially with little help from the federal or provincial governments, yet it was regularly urged to contribute members' volunteer time to government committee work. A board member's comment, recorded in the minutes, notes: "I'm getting fed up with these government bodies telling us our participation is so important when they are doing so little to help us survive."<sup>13</sup> (*Critical Advocacy to Prevent Cancer* Board Minutes, 1996).

Despite the concern about government funding cuts to community groups, *Critical Advocacy to Prevent Cancer's* annual revenues had gradually increased over the years. By 1996 the group had an annual budget of \$25,000 and had moved from its shared office with *Learn from Drug Tragedy* to a large, one-room office in the same building, where it remains today. The group was able to purchase an office computer, pay its executive director an \$8,000 honorarium, and hire a part-time administrator to answer the phone and take care of routine office work, such as filing and sending receipts for donations. The organization's money came mainly from memberships, from small personal and corporate donations (although never from the pharmaceutical industry), occasional larger donations when someone died ("legacy donations"), and community fundraisers (a local Girl Guides group held, and still holds, an annual walk-a-thon).

The group continued to mount large educational events, often bringing in prominent controversial authors and speakers from the U.S. These included the popular surgeon Dr. Susan Love and a series of sessions which highlighted the growing body of science suggesting that certain chemicals in the environment could enter the body and mimic the hormone estrogen. Because estrogen is known to promote the growth of a majority of breast tumours (i.e., the "estrogen-receptor positive" tumours), Devra Lee

Davis and other researchers proposed what they called the “xenoestrogen hypothesis”: that exposure to these chemicals contributed to the rising incidence of breast cancer in industrialized countries since the 1950s (Davis et al 1993). Chemicals identified as estrogen-mimics included the pesticide DDT, certain industrial chemicals, notably polychlorinated biphenyls (PCBs), and phthalates, softening agents used in plastics and cosmetics. Davis was a panelist at the group’s second major event, along with physician and cancer epidemiologist John C. Bailar III (a veteran voice for cancer prevention from within the cancer establishment<sup>14</sup>), and San Francisco cancer activist Judy Brady.<sup>15</sup> Other events, including talks by the author, ecologist and cancer prevention activist Sandra Steingraber, and cancer prevention advocate and toxicologist Dr. Samuel Epstein, kept the organization in the media, promoted a counterdiscourse on environmental links to cancer, and solidified the group’s reputation as one that did not shrink from controversy.

In the mid-to late 1990s *Critical Advocacy to Prevent Cancer* was awarded a number of federal and provincial government grants. The group is located in a province that, unlike most other provinces in the 1990s, had a program to provide community groups with a health-related mandate with a small basic stipend to support its core operations. As recently as 2007 when I spent time with the group, this remained the organization’s largest single source of revenue -- \$15,000 annually which provided base revenue for the office and part-time administrator. In theory, at least, the organization can spend the money as it pleases. The office administrator felt, however, that there was an implicit assumption that at least some of her time would go towards providing an information service to the community. Thus, although *Critical Advocacy to Prevent*

*Cancer* does not feature an advertised support service,<sup>16</sup> the office administrator stays on top of the various services in the city, listens sympathetically to callers, and directs them to the service that seems most appropriate.

That's my responsibility. If somebody calls and says, "I think I have a lump in my breast, what do I do?" then I would say, "Oh you have to go to a GP, and you have to fill out this form, and you have to get a mammogram," and [I would explain] where you would go for your mammogram, where you would find a GP if you don't have one. That type of thing. And Sharon, there are about 100 questions, different types of questions that come in. I feel like we have to give the best information we can, so I have to do research ... I get the information by reading, by talking to people, by calling around, by talking to women who've been through treatment -- what they tell me. (*Interview with Cora, 2007*).

Because the service is not one that the group actively promotes the office is not inundated with such calls – *Cora* estimated she received about three requests for information a week, typically when someone who was recently diagnosed and found the group's name in the phone book or on the Internet – the time required to research each one can be significant. On one of my days in the office I observed *Cora* spend four or five hours of telephone and internet research to determine whether any agency in the city would provide a woman undergoing cancer treatment with transportation from the suburbs to appointments at the hospital, as she was feeling unwell and could not afford a taxi (no such service existed).

*Saying "No" to "Bucks from Big Pharma"* By 1996, a discourse on the issue of funding from the pharmaceutical industry had begun to circulate within Canadian breast cancer groups and other women's health organizations. Notably, in May that year, a long-time women's health activist, Anne Rochon Ford, organized a public panel discussion in

Toronto titled “Ethical Issues in Women’s Health: the Delicate Business of Funding from Drug Companies” Rochon Ford had co-founded a Toronto-based breast cancer organization and knew first-hand the developing discourse on pharma funding in the breast cancer community. As a sequel to the panel discussion, in 1998 Rochon Ford wrote a booklet, titled *A Different Prescription: Considerations for women’s health groups contemplating funding from the pharmaceutical industry*, in which she used a hypothetical breast cancer organization as the framework for critically examining the circulating arguments in favour of accepting funds from the pharmaceutical industry. I describe this panel discussion and booklet in more detail in Chapter 5; here, I simply note that they informed the decision at *Critical Advocacy to Prevent Cancer* to create a “no pharma money” corporate funding policy.

With the exception of the two trips funded by Genentech in 1995, *Critical Advocacy to Prevent Cancer* had rejected overtures from pharmaceutical companies throughout the 1990s. An event in late 2000, however, prodded the group to develop a formal policy. That fall *The Hub*, the national umbrella organization of breast cancer groups of which *Critical Advocacy to Prevent Cancer* was a member,<sup>17</sup> published a diary-form booklet with funding from the drug company Janssen-Ortho Inc. The board of *Critical Advocacy to Prevent Cancer* discussed the corporate sponsorship of *The Hub*’s booklet at its October meeting. In addition to finding out what product(s) the company manufactured members of the board decided to write to *The Hub* to “point out the conflict of interest” in the booklet’s sponsorship. The board’s decision to articulate a formal policy was a means of clarifying its own thinking on the subject which in turn

would provide a basis for debate with *The Hub* and other breast cancer organizations from across the country who were also members of *The Hub*.

*Deirdre* was President of *Critical Advocacy to Prevent Cancer* at this time and her past experience positioned her to provide the group with leadership on the pharma funding issue. She had been active on women's health issues related to menopause in the 1980s and early 1990s. Her knowledge of the menopause community, which included attendance at conferences of gynecologists and GPs whose patients were mid-life women, helped shape her views on pharmaceutical company funding to health advocacy organizations long before a breast cancer diagnosis in 1998 led her to join *Critical Advocacy to Prevent Cancer*. As a voice critical of how hormone therapy had been marketed to menopausal women, she had been offered money by drug companies to fund a newsletter she edited, "and turned [the offer] down, thank god!"<sup>18</sup> She reflected that she could not have joined a breast cancer group that took funds from pharmaceutical companies.

I think I just saw so much of the bad side of the pharma companies going to the [international and North American] menopause meetings – there was obviously so much money floating around that it turned me off. I became cynical hearing the kinds of claims they would make. They had no proof that hormones were going to make life just a paradise for menopausal women. Their advertising was unrealistic, the kind of expectations that women had as a result of the advertising were unrealistic. I think if they hadn't been quite so avaricious I could have lived with them. But there were, and there still are, some companies that comport themselves in a more or less honest way.  
(Interview with *Deirdre*, 2007)

Through her extensive work in the women's health community, she was a long-time friend of Rochon Ford's, whose booklet on pharma funding of women's health groups she jokingly dubbed "Anne's screed" when I interviewed her. When she and the



other women on the board of *Critical Advocacy to Prevent Cancer* decided they needed a formal policy, she recommended they read it to prepare for their discussion (Table 7 summarizes arguments in the booklet).

The group's board members also read a second background document, the Corporate Donations' Policy adopted in 1999 by *Breast Cancer Truth-Tellers*, an organization in the United States with which *Critical Advocacy to Prevent Cancer* had a long-standing, amicable relationship. Indeed, the policy *Critical Advocacy to Prevent Cancer* adopted in March 2001 (Appendix A) was almost identical to that of *Breast Cancer Truth-Tellers*. Key points in both documents included:

- A statement of the group's mission, that is, advocacy, education and coalition-building related to the primary prevention, diagnosis and treatment of cancer; within this mandate, the group's advocacy to eliminate environmental carcinogens is paramount
- An assertion that the group's credibility is fundamental to its work which, at its core, involves providing unbiased information;
- An assertion that funding from a corporate source with a vested interest in cancer prevention, diagnosis and/or treatment creates the potential for real or perceived potential corporate interference (conflict of interest) and undermines its political legitimacy by threatening the group's credibility.
- An assertion that the group's educational work on environmental links to cancer, and its advocacy to eliminate environmental carcinogens precludes any association with companies that endanger environmental or occupational health through a disregard for environmental or workplace regulations.

Based on these criteria, seven categories of corporations are specified as off-limits as funders: pharmaceutical companies, chemical manufacturers, biotech and agribusiness companies, oil companies, tobacco companies, private cancer diagnosis and treatment facilities, and companies that develop and market cancer-related technology. The policy specifies that this list is open to modification and that it does not mean the group will exhaustively research every donation. The group posted the statement on its website, including an explanation that the policy “aims to reconcile the need to ensure the long-term financial health and longevity of the organization with the desire to avoid potentially real or perceived conflicts of interest related to corporate giving.”<sup>19</sup>

Adopting a formal policy has been good for the group, says *Deirdre*, for reasons that were both pragmatic and political:

*Deirdre*: I think it’s important for people who look at our website to see the policy. I think it’s important for when we’re looking for speakers or organizing events to be able to show them the policy. The fact that it’s down there in black and white, on the one hand, explains why we’re such a small group, and explains why we can’t afford to pay a lot of money for speakers or those sorts of things.

And I think people have a, most people have a grudging respect for that kind of integrity – it’s certainly rare enough. And I just find it unbelievable that so many groups, particularly breast cancer groups, believe that they are not influenced! I don’t know how they can serve two masters like that. (*Deirdre*, Interview, 2007)

Within the group, the decision itself was not controversial although details took some time to hammer out. *Cora*, the group’s administrative secretary, newly-hired at the time, recalled that maintaining the integrity of *Critical Advocacy to Prevent Cancer’s* information service was one reason for the group’s stand against taking pharmaceutical

funds, but a greater concern was that such money would undermine the credibility of their advocacy and education work, which was often critical of the status quo.

We were ... concerned about taking funds from any group that was in some way profiting from breast cancer. We said we wouldn't take money from pharmaceutical companies because that would be a conflict of interest for us, in the sense that we might subtly be swayed by whatever medications they were making. We would feel that we are getting money from them and we can't bite their hand -- we can't bite the hand that feeds us. That implies a *conscious* decision [that we would promote their products] ... but it was more of a worry that sort of unconsciously we would be swayed. And also, since we'd been fairly critical of certain preventative pharmaceuticals [we thought] 'how can we then turn around and take money from *any* pharmaceutical [company]?' Because it opens us up to criticism that we're hypocritical. (Interview with *Cora*, 2007)

Thus, the policy has become a badge of integrity that distinguishes *Critical Advocacy to Prevent Cancer* from the majority of breast cancer organizations that do take funding from pharmaceutical companies. *Martha*, who joined the board in 2000, shortly before the policy was adopted, agreed that the policy is a point of pride and has become part of the group's identity.

We all agree on [the policy]. A few people are tougher, but we all have the same position. We all feel the same way. I certainly do -- although some people express themselves in a way that sounds more hard-line. You have to be clear and clean, it's a matter of integrity. .... We can hold our heads high. .... I can be proud to be in such a group. (Interview with *Martha*, 2007)

As a volunteer in a hospital, *Martha* saw parallels to the gifts drug companies give to physicians.

*Martha*: It's not just [*Critical Advocacy to Prevent Cancer*], it's how the pharma companies woo the doctors -- it makes me sick. You wonder why [certain] things are being done -- would things be done differently if it weren't for the pharma-sponsorship of events and gifts?

Sharon: Do you see that sort of thing in the hospital?

*Martha*: Oh yeah!! The holidays they go on! ... I can't say if [the money] makes a difference to the way things are done but I suspect it does. For example, at [the hospital where I work], you see events and speakers sponsored by pharmaceutical companies. You get a piece of paper and it says, "sponsored by ... [XYZ drug company]." I can't help thinking it has an effect on patients, on how the doctors make their decisions. (Interview with *Martha*, 2007)

Two other board members, *Zoë* and *Marilyn*, hold down the softer end on the continuum positions on the pharma funding issue. *Zoë*'s husband, a prominent medical researcher, has received pharmaceutical funding for some of his work. She understands *Critical Advocacy to Prevent Cancer*'s concerns but knows the high cost of medical research and the large role that industry funding plays in that area. For *Marilyn*, attending meetings where the group "hammered out its policy" was her first encounter with concerns about pharmaceutical companies and conflicts of interests. She, like *Martha*, works in a hospital setting; but, in contrast to *Martha*, her hospital experience, including work on a project funded by the pharmaceutical industry, moderates her view towards pharmaceutical company funding of research, although she thinks the policy is right for *Critical Advocacy to Prevent Cancer*.

I do know that pharma gives money to research to do good things; so in a way it's a two-edged sword. ... I think [the policy] sets us apart in the eye of the public. ... I think it's more of an issue of respect for where we're coming from. We're not tainted, or couldn't be tainted by the potential of bucks from big pharma.

I see it as, we can tell the public, "This is who we are" and be clear with that, and, hopefully, they see that in a positive light. I would think, especially, with [*Critical Advocacy to Prevent Cancer*'s work] on the environment: How can we say 'keep things clean' when the drugs we take pollute, like anything

else? ... It's that same issue, it pollutes everybody's water. All these chemicals pollute. (*Interview with Marilyn, 2007*)

At the other end of the spectrum, *Diane* and *Georgina*, two board members who self-identify as the most militant on the issue of corporate funding, see their role as policing the others, to ensure that *Critical Advocacy to Prevent Cancer* doesn't drift from the policy. *Diane*, self-employed with a small business, has little trouble drawing the lines in the sand:

I tend to be very reactionary about this particular thing [laughs] so I have less trouble than some of the members who see shades of grey ... (*Interview with Diane, 2007*)

*Georgina* takes a similar hard-line view:

I think [the question of corporate funding] comes up every now and then when we get broke. And we always have to re-affirm that you can't play it both ways. And you have to have a very strict policy! There is just no exception to it -- there is just no corporate money tainting, whatsoever! (*Georgina, Interview, 2007*)

Since *Critical Advocacy to Prevent Cancer* adopted its policy, overtures from the pharmaceutical industry have been rare. *Cora*, from her vantage point running the office, recalls a very few in her tenure, including one invitation to sit on a consumer advisory committee.

...I just tend to dismiss them. I say, "No, I'm sorry that doesn't interest us because we have a policy." And they don't go further and we don't explain. But I can tell you it doesn't happen often at all, maybe three times since I've worked here in six years. (*Cora, Interview, 2007*)

For several years around the time of adopting the policy, *Critical Advocacy to Prevent Cancer* tried to bring other groups and agencies around to its way of thinking on issues related to pharmaceuticals and pharmaceutical funding. In these efforts, the group

not only promoted the idea that breast cancer organizations should resist funding from drug companies but raised alarms about “the growing influence of the pharmaceutical industry in dictating [health] policy.”<sup>20</sup> In July 2000, *Critical Advocacy to Prevent Cancer* sent a letter to the president of McMaster University to protest the university’s decision to accept funding from Eli Lilly Canada to establish a chair in women’s health, an initiative that reflected the group’s solidarity with *Learn from Drug Tragedy*. The letter read, in part:

Our concern about Eli Lilly stems from their manufacturing and marketing of DES in spite of data-based questions about the carcinogenic nature of the drug and its failure to prevent the miscarriages for which it was widely prescribed. We are even more concerned because this pharmaceutical company has refused to acknowledge the adverse effects suffered by the women who took this drug and by their daughters and sons. The company has also been strongly resistant to any form of recompense, whether to individuals harmed by the drug or, more broadly, to the community of those at risk because of the drug.

We cannot help feeling cynical about Eli Lilly’s claim of being committed to the pursuit of women’s health. McMaster’s acceptance of the funding for the new chair lends support to their claim, in spite of the company’s record.<sup>21</sup>

In another example, a federally funded provincial agency which had the mandate of disseminating breast cancer information throughout the region published a full-page advertisement in its bulletin announcing that three pharmaceutical companies (Roche, Zeneca and Novartis) had sponsored the organization’s bulletin.<sup>22</sup> The board of *Critical Advocacy to Prevent Cancer*, which had participated in the agency as a community partner over the years, decided to write a letter “expressing outrage.”<sup>23</sup> *Critical Advocacy to Prevent Cancer* subsequently engaged *Learn from Drug Tragedy* in its protest efforts,

with the two organizations hoping to build “support for a broad-based coalition of women’s health organizations that would object to the [agency’s] policy.”<sup>24</sup>

A more sustained target for education was *The Hub*, the national umbrella breast cancer organization, the group whose acceptance of pharma money had prompted the formulation of the policy in the first place. Initially, these efforts took the form of trying to present *The Hub* with counterarguments to what *Critical Advocacy to Prevent Cancer* saw as the national organization’s developing closeness to the industry. In early 2001, *Critical Advocacy to Prevent Cancer* sent a copy of its newly-minted corporate donations policy to the national group, but received no response. A year later, *Critical Advocacy to Prevent Cancer* made a similar effort “to inform [the national group’s] board members about the issues” with respect to direct-to-consumer advertising of prescription drugs or DTCA.<sup>25</sup> Canada had long had a ban on such advertising, a policy which the industry was trying to overturn. When *Critical Advocacy to Prevent Cancer* learned that members of *The Hub*’s board had participated in an industry-funded public panel that presented consumer advertising of drugs as an important form of consumer education, the organization sent the national group a package of information critical of advertising drugs to the public.<sup>26</sup>

By February 2002, word had begun to circulate in the community that *The Hub*’s board was divided over the question of pharmaceutical company funding.<sup>27</sup> That same month, the president of *The Hub* resigned over ethical concerns about an agreement that organization had entered into with Ortho-Biotech. Ortho-Biotech, a division of Janssen-Ortho, that was marketing Eprex® (epoetin alfa) a drug to combat anemia, to cancer patients suffering from chemotherapy-induced fatigue; the agreement between Ortho-

Biotech and *The Hub* required the organization to publish articles about anemia in its newsletter in return for three-years of funding.<sup>28</sup> In September 2003, the *Critical Advocacy to Prevent Cancer* board decided to send a letter to three local breast cancer groups in other parts of the country, “explaining our concerns, asking for their reaction, & suggesting that we might ask for copies of the minutes of ... board meetings where the Ortho-Biotech offer was discussed.”<sup>29</sup> None of the member groups responded; in December, however, the board received a letter from *The Hub* expressing its displeasure about *Critical Advocacy to Prevent Cancer*’s overtures to other members.<sup>30</sup>

The clear difference of opinion on pharma issues between the board of *Critical Advocacy to Prevent Cancer* and *The Hub* presented dilemmas for *Critical Advocacy to Prevent Cancer*, which had been a founding member of *The Hub* and still saw benefit in some of the national group’s activities. In the fall of 2002, a member of *Critical Advocacy to Prevent Cancer*’s board who had attended one of the national group’s workshops reported at a board meeting that the workshop was “worthwhile and interesting”<sup>31</sup> Another member expressed a similarly positive reaction to meetings she had attended, saying that she had signed up to be involved in activities on breast cancer prevention and “was gratified to find that ‘prevention’ was seen much as *Critical Advocacy to Prevent Cancer* sees it, i.e., primary prevention.”<sup>32</sup> The frosty reaction to *Critical Advocacy to Prevent Cancer*’s attempt to intervene over the Ortho-Biotech issue and the President’s resignation left a lasting ambivalence about its membership in *The Hub*. *Critical Advocacy to Prevent Cancer*, in any case, was undergoing a process of redefinition which moved its centre of gravity away from the Canadian breast cancer



community, shifting its allegiances to Canadian and U.S. activist organizations with an environmental focus, the growing “green breast cancer movement” (Ley, 2009).

One example was *Critical Advocacy to Prevent Cancer*'s membership in a coalition of like-minded American and Canadian organizations called *The Coalition to Prevent Cancer without Drugs*, which began in September 2001.<sup>33</sup> All members were concerned about conflicts of interest involving the pharmaceutical industry; to underline the fact that no member groups accepted funds from the industry, the coalition added to its name the tag, “A coalition of independent health organizations.” Most, including *Critical Advocacy to Prevent Cancer*, had testified at a public FDA hearing held in 1998 to assess whether the results of the breast cancer prevention trial warranted approving the drug tamoxifen as a preventative for women classified as at “high risk” of breast cancer. All had opposed approving the drug for the purpose on the grounds that -- for healthy women -- the drug's risks cancelled out its potential benefits. Members included several “green” breast cancer groups (i.e., groups with an environmental perspective on cancer prevention), feminist women's health organizations, an American chapter of *Learn from Drug Tragedy*, and a consumer health organization. The *Coalition to Prevent Cancer without Drugs* viewed itself as a “counter-campaign” to the advertising campaigns of pharmaceutical companies.<sup>34</sup> In mid-2001, the *Coalition* was awarded a \$200,000 grant for two years from an American foundation that supports environmental civil society groups; the money enabled each of the member groups to hire someone part-time for two years to work at the local level. With its stipend, *Critical Advocacy to Prevent Cancer* hired *Linda*, an energetic young woman taking a Master's degree in public health. Following the *Coalition to Prevent Cancer without Drugs*' mandate, *Linda*'s work

straddled two areas: pharmaceutical policy, especially a concern about the failure of regulatory agencies to pay sufficient attention to adverse drug events (as reflected in a perceived trend to promote drugs for disease prevention, and the inadequate monitoring of adverse drug reactions); and promoting the precautionary principle as the basis for policies governing the use of toxic substances to the environment (including human health).

Hiring *Linda* enabled the organization to step up its advocacy in relation to pharmaceutical policy issues.<sup>35</sup> In regular articles in *Critical Advocacy to Prevent Cancer's* newsletter, *Linda* discussed such Coalition issues as the FDA's decision to add a "black box warning" to the label of tamoxifen,<sup>36</sup> and the marketing claims and price of Arimidex® (anastrozole), a newly approved AstraZeneca drug.<sup>37</sup> At a World Conference on Breast Cancer<sup>38</sup> meeting in Victoria, in June 2002, she spoke about the Coalition's work and DTCA in Canada. Reflecting the Coalition's environmental interests, *Linda* wrote an article in the *Critical Advocacy to Prevent Cancer* newsletter on the precautionary principle<sup>39</sup> and worked on projects to promote the precautionary principle as a way to practice true disease prevention. As a counter to the popular Run for the Cure breast cancer events, she organized a Prevention is the Cure march.<sup>40</sup> She wrote letters to support regulatory initiatives that would reduce carcinogens in the environment, including a proposal in the provincial legislature for regulations to restrict pesticide/herbicide use in the province.

In 2003, the Foundation funding for the *Coalition to Prevent Cancer without Drugs* ran out and *Linda's* status shifted to that of a volunteer and member of the board. Although she continued in this capacity for several years, she began fulltime employment

at a university and could not devote the same amount of time; nor was the Coalition able to continue its conference calls and meetings. Pharmaceutical company funding and drug policies continued to be preoccupations of *Critical Advocacy to Prevent Cancer*, however, as reflected in newsletter articles up to 2007.<sup>41</sup>

*Critical Advocacy to Prevent Cancer*'s membership in the *Coalition to Prevent Cancer without Drugs* prompted a major project that the group undertook in 2004 on the phenomenon of "pink marketing," a promotional practice in which a company pledges to donate some of the profits from the purchase of its product(s) towards the breast cancer cause. The company's goal is to boost sales by aligning its product with a cause popular with its target market (King, 2006). *Breast Cancer Truth-tellers*, an American member of the *Coalition to Prevent Cancer without Drugs* and the same group whose Corporate Donations Policy served as a model for *Critical Advocacy to Prevent Cancer*<sup>42; 43</sup> had initiated a project called Think before You Pink, which encouraged the public to ask questions about pink marketing campaigns, such as, How much money from the purchase goes to breast cancer? To what breast cancer organizations does the money go and what programs does it support? In the fall of 2004, *Critical Advocacy to Prevent Cancer* invited the executive director of the American organization to speak about the American experience with cause marketing. In the months leading up to the lecture, *Critical Advocacy to Prevent Cancer* hired *Celine*, a local university student, to research cause marketing in Canada, a project the group called *Profits in Pink*.<sup>44</sup> The project had a profound impact on the organization and ultimately broadened the scope of *Critical Advocacy to Prevent Cancer*'s corporate donations policy to include companies engaged in pink marketing.

We really became aware of what [cause marketing] was. We took that up as one of our issues for about a year, and we were vociferous against cause marketing – *some* aspects of cause marketing, not all – we were saying [to recipients of cause marketing funds], ‘you should really be more open about where your money is coming from.’ Because what was happening was, companies like Yoplait were saying, “We’re giving money every time you buy yogurt, we’re giving money to this organization” but they weren’t saying how much. Then, when *Celine* went to the organization that was receiving the money, they would say, “We can’t tell you [how much goes to a breast cancer organization]; that’s privileged information -- we’re not allowed to tell you”! So we were encouraging them, generally speaking, to be more open about the money they were getting and what it was being used for: What kind of [breast cancer] research, for example? (*Interview with Cora, 2007*)

*Celine’s* 26-page report, *Profits in Pink: Breast Cancer Cause Marketing in Canada*, attracted national media attention. Her analysis was frankly feminist and critical of the companies involved:

This is just a peek behind the pink façade but it reveals a plethora of pink ribbon bruises and blues. The current context of breast cancer cause marketing in Canada is lacking in transparency, accountability, a feminist agenda, and a public health perspective. Corporate interests are ‘pinkwashing’ away the political issues that become clear with a little probing. Unfortunately our purchases cannot sweep away the disease, no matter what breast cancer cause marketing would have us believe. What we can do is sing our pink ribbon blues, to corporations and to breast cancer charities, loud and clear.<sup>45</sup>

Although drug companies rarely made overtures to *Critical Advocacy to Prevent Cancer*, calls from pink marketers were an ongoing occurrence. In one instance, a women’s clothing manufacturer who was a friend of one of the board members asked if the company could put the group’s logo on their clothes in return for donating some money to the group.

We discussed it for a long time with them and finally said “no” we would not allow our logo to be used. And we said, “If you want to give us the donation without using our name or saying that the sale of these clothes has anything to

do with breast cancer, that's fine." So they gave us a \$1,000 donation.  
(Interview with Cora, 2007)

Having ruled out cause marketing as a fundraising strategy, *Critical Advocacy to Prevent Cancer*'s discomfort with market-related fundraising began to extend to yet another type of funding known as third-party fundraisers -- projects where someone outside the group offers to hold an event that will raise money for the organization.

And that's when we really thought, you know, "we can't afford to even look like we're involved in getting funding from *anybody* who's using our name to sell stuff."

We get a lot of people calling us who want to raise money, but we can tell from the kind of questions they ask us that it's not particularly *Critical Advocacy to Prevent Cancer* they're interested in; they want the breast cancer cause-marketing angle. So we have a policy that, if we go along and partner with them, we have to know that they're into *Critical Advocacy to Prevent Cancer* above all other breast cancer [causes], and why; and we also say that we either have someone who speaks at their event or we give pamphlets out at the event.... And also, they're not supposed to keep part of the funds. It has to be a total donation, though they can cover their costs. (Interview with Cora, 2007)

*Georgina*, one of the strongest supporters of this position, joined the group in its formative years and has remained active. She links her position on funding issues to her self-identification as a life-long socialist, albeit politically disengaged until she joined *Critical Advocacy to Prevent Cancer*. A teacher by training, she sees the group's role as a slow, steady process of educating the public, much as she herself was slowly educated in breast cancer issues.

I don't want *any* cause marketing. I don't want our name associated with anybody. Like I said, I'm not a capitalist. For a year, people [on the board] -- good people -- talked about galas, about making a big splash. They would say, 'Well if we're doing something, let's make a big splash.' I don't want galas in *Critical Advocacy to Prevent Cancer*! I don't want [us] to be a big

splash, I want education. ... And we do make a splash! We do it in our own quiet way. And quietly we are. It took a long time, quietly. (Interview with *Georgina*, 2007)

Yet for *Liz*, a part-time staff member whose responsibilities include fundraising, this relentless creep of sponsorship prohibition was becoming self-defeating.

No cause marketing, no pink stuff, no pharma, no companies that produce carcinogens—basically, I mean, I support all of that. ... But trying to figure out how we could creatively work around that? It was a bit scary.... It almost makes it *impossible* for people who want to support us to actually support us! It's like biting off our nose to spite our face. ... It's like a horse by committee, or a camel that keeps adding rules until the thing has two humps. (Interview with *Liz*, 2007)

As *Liz* saw it, such rigid rules arose from a sense of wanting to remain true to the group's history and ideals but hobbled the organization by lumping well-motivated giving together with giving that was exploitative. Deeply committed to the organization, she also expressed a frustration arising from her responsibility as a fundraiser.

There's this sense of responsibility, of honouring the past, of honouring you and Lanie and the work of all the founders ..., and it's palpable. At meetings, you can feel it. You can sense the pride that brings the people who are there to the room, to the table. And it's great! It's what makes the organization so strong. People really, really, really care.

I think a challenge for *Critical Advocacy to Prevent Cancer* now and in the future is to ... figure out the place of that caring and the values of the organization and trying to be as clear as possible about not blurring that line. Saying, 'Ok, we can make a decision about, whether we want to take this or that, and it's not dishonouring anybody, and it's not dishonouring the organization. We know who we are as an organization so we don't have to worry about making iron clad

policies -- because if we make decisions one by one, we'll be ok. We know who we are and it'll be alright.'

And there's a lot of concern, as there is in most organizations, about the future: 'Who will be on the board in five years?' and 'How will they interpret these rules?' And I get that, I do. But I think it sometimes stands in the way, it sometimes makes it harder for the organization to grow. (*Liz*, Interview, 2007)

The cause marketing project, while it garnered the group a lot of media coverage and brought the group to a deep understanding of cause marketing, turned out to be controversial and divisive within the larger breast cancer community, a fact that was driven home when *Celine* presented her results at an international conference in Halifax in 2005.

And the feeling in the room when I presented my results on 'What's the situation of breast cancer cause marketing in Canada now' was really divided. So that you had half of the room where people were *extremely* upset, and the other half of the room, people were coming up to me afterwards ... and saying, 'Oh, I want to hug you', and 'You should go on CBC with this,' and 'This is so amazing,' and really saying a lot of positive things. (*Celine*, Interview, 2007)

At the same conference, delegates from *Critical Advocacy to Prevent Cancer* met women from California involved in a Safe Cosmetics campaign. The American women subsequently invited *Critical Advocacy to Prevent Cancer* to join their coalition. *Celine*, who was on a committee to promote *Critical Advocacy to Prevent Cancer* at the time, argued strongly that the group's focus

*Critical Advocacy to Prevent Cancer's* decision to concentrate its activism and education on the evidence for links between cancer and the environment, with a special focus on toxic substances in cosmetics, began in the spring of 2006. *Georgina* recalls the

decision as a turning point for the organization, defining *Critical Advocacy to Prevent Cancer* as a breast cancer group that focuses nearly all of its attention on prevention and, in particular, on toxic ingredients in cosmetics. Part of the appeal of this project was that – unlike the contentious cause marketing project -- getting the toxic ingredients out of cosmetics was motherhood. The campaign for safe cosmetics was also a way to engage young women, provoking them to think about the connections between environmental toxins and cancer, and provided a vehicle for teaching activist strategies aimed at changing government regulations. Finally, choosing a single focus for its work allowed the group to use its limited resources effectively:

I thought it was possible to do the whole gamut, but it's not. It's much better to have a focus. ... [I]t was *Celine*, one of the younger people who said, "Choose one thing and go for it." And I was resistant -- but it's right to take one thing. ... And now our name is associated with the environment and prevention. And now the rest of the world is looking in this direction. (Interview with *Georgina*, 2007)

At the same time that she believed the group's single-issue approach was the right one *Georgina* recognized the motivations that push many patients' groups to demand new treatments:

When you're first diagnosed, you're interested in everything, but you're also interested in new medications that are coming out. It's something to remember, it's important to remember in terms of the whole prevention thing, which is that when you're newly diagnosed you just want to get better. And so it's very simple that this [concern about drug treatments] is the focus. You're reading, and you're seeing your friends who aren't doing that well and maybe trying to figure out which medications were helping them. (Interview with *Georgina*, 2007)



The organization's thrice-yearly newsletter reflects its shift in emphasis. Beginning in the fall of 2006, the *Critical Advocacy to Prevent Cancer* newsletter began devoting about two-thirds of each issue's content to articles on cancer and the environment. Articles include critical appraisals of Canada's regulatory efforts with respect to environmental health hazards,<sup>46</sup> announcements of the group's environmentally related events and projects,<sup>47</sup> film and book reviews,<sup>48</sup> and interviews with environmental health researchers.<sup>49</sup> These articles maintain the group's hallmark skepticism about taken-for-granted medical knowledge, as do the occasional feature articles about controversial detection and treatment issues.<sup>50</sup> The regular feature, *News Briefs*, continued to provide a round-up of the latest breast cancer research findings, including news about treatments, lifestyle research and health care policy issues.

The group now strives to emphasize its unique place in the Canadian constellation of breast cancer groups, without dismissing the importance of the treatment-related work of other groups. A short Q & A item published in the group's *Bulletin* in the Fall of 2006, explains:

... While applauding the accomplishments of other breast cancer organizations, *Critical Advocacy to Prevent Cancer* is concerned that over 95% of the funds raised for research into breast cancer are devoted to improvements in screening and treatment, leaving very little for research into the causes of this disease. *Critical Advocacy to Prevent Cancer* strives to put the spotlight on the reasons why breast cancer develops and why more and more women are being diagnosed. Our hope is that, one day, breast cancer can be stopped before it starts.

With the movement away from treatment-related breast cancer issues, the composition of the group's board -- its decision-making body and the small group that does most of the work -- has also evolved. Whereas the five founding members were all

in their 40s, and had all been diagnosed with breast cancer within the past few years, by 2007 the majority of board members had not had cancer; they ranged in age from women in their 20s to retirees in their 70s and 80s.

Despite pulling back from its earlier engagement in pharmaceutical policy issues, *Critical Advocacy to Prevent Cancer* continues to make its opposition to drug company funding a point of pride. An article in the *Critical Advocacy to Prevent Cancer* Newsletter in 2007 states:

[*Critical Advocacy to Prevent Cancer* is], so far as we know, the only breast cancer group in Canada that has a clear policy disallowing donations or contributions from pharmaceutical, chemical, oil, and tobacco companies, biotech and agribusiness, and any other facility that in any way profits from cancer-related diagnosis or treatment.<sup>51</sup>

I attended a meeting of the group's *Campaign Against Toxic Make-up* Committee in June 2007 and the Corporate Donations Policy was still a subject of active debate. Seven members gathered around the food-laden dining room table at the president's home to evaluate a recent downtown demo, a follow-up to one the group held in the fall. The ultimate goal of the campaign, undertaken in partnership with the Women's Studies program at a local university and funded by the provincial department of education, is to have the federal government prohibit cancer-causing ingredients in cosmetic products.

"I'm still mad that we are the ones that have to find out if a product is safe or not," says *Georgina*.

"A self-regulating industry does what it wants," adds *Celine*.

The project's interim strategy is to publicize the fact that the ingredients in products are secret, sometimes toxic, and largely unregulated, and to have all ingredients listed on the label. Discussion is energetic and ranged from the event's organization to

the weather and the media coverage. More questions and ideas follow. Did anyone take film shots for the blog? How many hits have we had to the website? Someone points out that at the last demo they had national coverage, but media coverage this time was only local. An analysis of likely reasons follow: in the fall the government was bringing in new regulations which provided a news hook; a trash can for dumping toxic cosmetics was an effective visual in the fall event; and a local academic who is sympathetic to the group agreed to be a media contact and spoke on the group's behalf for a national story on the public broadcast station.

“Is the key to media coverage having a scientist available to speak?” I ask.

“Not necessarily” responds *Georgina*. “They want a name that flutters.” *Deirdre*, the group's former president and an internationally recognized women's health activist, would have carried enough weight, but she was out of town.

Talk shifts to the group's efforts to build a national coalition to publicize its campaign for regulations prohibiting known and suspected carcinogenic ingredients in cosmetics. Three local groups have signed on – an allergy group, a women's health group and a consumer protection group. A recent national conference on cancer prevention yielded a list of sympathetic organizations from other parts of the country. A woman from the West coast has been especially enthusiastic. She has sent e-mails to people all over British Columbia and set up a Canadian page linked to a like-minded group in the U.S. – this despite having cancer which, she has learned since the conference, has spread to her liver and hip. On the Prairies an allergy group is interested, and a small breast cancer group will demonstrate on street corners if they are given enough advance notice,

although they don't want to become formal partners. I mention several groups on the east coast that have held events on environmental health.

“Do any of them take drug company money?” asks *Georgina*.

“One does.”

“Then, no,” she says flatly, citing *Critical Advocacy to Prevent Cancer's* corporate donations policy.

*Brenda*, the President, disagrees. “We'll have a lonely existence if we don't talk to other groups,” she says. “We need to reach out, to tiptoe towards them.”

This sparks a discussion on how to apply the group's Policy on Corporate Contributions, now six-years-old (see Appendix A) to the question of recruiting partners for the *Campaign Against Toxic Make-up*. In addition to prohibiting donations from certain categories of companies which could undermine its credibility, the policy also states that the group will “not officially support any organization or event that accepts funding from sources unacceptable to *Critical Advocacy to Prevent Cancer*.” The disagreement about whether groups that accept funds from such corporations should be invited to participate in a proposed national coalition of groups opposed to toxic ingredients in cosmetics hinges on divergent interpretations of this clause.

“We should absolutely stay with that policy for ourselves,” says *Brenda*; but if other groups agree with the goal of the project she thinks it's counterproductive to exclude them from the coalition. Besides, she adds, the policy has not precluded involvement with other groups in the past. *Critical Advocacy to Prevent Cancer* sent delegates to an international breast cancer conference in 2005, for example, even though the organizers of that conference accepted funding from drug companies.

*Autoethnographic Interlude.* Celine, who developed the materials for the campaign, supports this conciliatory approach: “*Critical Advocacy to Prevent Cancer* could be a positive example to other groups,” she argues. Deirdre reminds everyone that they have already tried to bring other groups around to their position on corporate donations and failed. As Sara put it, “the support was not forthcoming.” The group then considered resigning from *The Hub*, but has maintained its membership, despite ambivalent feelings based on the group’s acceptance of drug company funding

“What do you think, Sharon?” asks Georgina, pointedly.

Deirdre looks uncomfortable, and gestures to me to stay silent. I don’t understand what’s going on. When I ask for an explanation, I’m finally told that the group remained a member of *The Hub* despite the board’s disagreement with its funding policies because they knew I had been one of its founders and a member of its first board. This revelation startles me. Although I remain a member of *Critical Advocacy to Prevent Cancer*, and a resource, particularly with respect to the group’s early years, I withdrew from the group’s decision-making structure when I moved to another city in 1999. I assure them that the group’s board should not feel bound by concerns about my views. Additionally, I remind them that my own involvement with *The Hub* was long prior to that group’s decision to accept money from the drug industry. My statement doesn’t seem to solve the debate at hand which arises in part from the difference of opinion among those around the table about how the group should handle tensions with other organizations; the discomfort also involves complicated questions of identity which arise from a loyalty to the early activists who built the organization and the movement and the group’s ongoing transformation.

“It’s important to have the conversation [about corporate influence],” *Celine* insists. *Deirdre* heaves a long sigh: “but it just goes ‘round and ‘round.”

*End of autoethnographic interlude.*

As of this writing, *Critical Advocacy to Prevent Cancer* is still a member of *The Hub*. While the group maintains some contact with the wider community of breast cancer organizations,<sup>52</sup> its primary network has shifted to the environmental-health activist and academic communities, including the David Suzuki Foundation, which formed a partnership with the organization in January 2010. The group remains staunchly committed to its policy to reject funding from the pharmaceutical industry and selected other corporations. In mid-2010, the organization’s website boldly proclaimed, in a banner across the bottom of the screen “WE DON’T TAKE PHARMA MONEY!” followed by a hot-link to the corporate contributions policy.<sup>53</sup> As a green breast cancer organization, *Critical Advocacy to Prevent Cancer* sees pharmaceuticals as one more class of chemical pollutant. Board members accept that the organization’s policies, including the corporate donations policy, are not shared by the whole breast cancer community but, unlike the focus on cause marketing, they see their campaign for a clean environment as “motherhood” and one that few breast cancer organizations actively oppose.

### 3.1.2 Group B: *Down-home Peer Support and Education*

*Down-home Peer Support and Education* was founded in 1994 in a mid-sized community on the East Coast when members of a local support group decided, as one of the founding members put it, they wanted “to discuss things in a different way”:

There were obviously all the personal stories and issues, but there were a group of people who were saying, “You know, this happened,” and “That wasn’t right!” and “Why did it take so long?” and “This is happening.” (Interview with *Jenny*, 2007)

In the previous three years, a number of patient-centred “action groups,” including *Critical Advocacy to Prevent Cancer* had started in other parts of the country and breast cancer conferences were being designed with survivors in mind. When members of the support group heard that a conference for survivors was taking place in Toronto, they applied for funds from a local cancer agency to send two of their members. Instead, the agency decided to fund two nurses to attend.

And we really thought that was wrong, because it was a conference very much for survivors. . . . We felt that if there were two people going, certainly a survivor or a patient could have been *one* of the ones chosen. And that was just one incident that was maybe the straw on the camel’s back. A lot of people had been saying that, “you know, we’re getting to the point where we’re coming here and we’re talking about how we feel and so on, but some of us are really interested in trying to make some changes in the system.” [We wanted to] bring some issues to the attention of the government, or the Department of Health or the hospital, or whatever. (Interview with *Jenny*, 2007)

The result was *Down-home Peer Support and Education*, a group whose mandate, as described on its website, was to be “a voice for survivors.”

Initially, the group didn’t think much about money, let alone money from the pharmaceutical industry.

We were probably a little naïve, or not really sure what it was exactly that we wanted to do. And so really, at the beginning, it was more about doing mission statements and trying to figure out what we wanted to do and who we wanted to be. And, as you know, in groups like this these things move pretty slowly -- so that all took quite a while.

We kind of didn't need anything in terms of funding because we weren't really doing any work! We were meeting, we would write letters to the Minister of Health, or we had the Minister of Health come and speak with us. We might write a letter to the newspaper. That was more the type of thing that we were doing. (Interview with *Jenny*, 2007)

When *Down-home Peer Support and Education* did get its *raison d'être* sorted out, one of its goals was to promote awareness of breast cancer and of the needs of people in the community who were affected by the disease. As the group gained local recognition, organizations and agencies with health-related interests began to approach them to collaborate on projects related to this goal. In collaboration with local community and university groups, for example, they began mounting small educational projects including two one-day workshops on breast cancer and the environment, the first in 1996 and the second the following year. Another early project, *Jenny* recalls, was a breast cancer patients' needs assessment, for which Health Canada provided funding. Then the Canadian Cancer Society asked the group to be a partner on a project to examine the breast health needs of women of African heritage living in the province. The group and its partners issued reports on these two projects in 1997 and 1998 respectively. When a provincial task force on cancer care was established in 1998, *Down-home Peer Support and Education* was invited to be part of it, a sign of the group's growing credibility in the cancer community. Around the same time, *Down-home* vocally protested a shortage of oncologists at the local cancer clinic; four new medical oncologists were subsequently hired.

In addition to the funds provided by established agencies for collaborative projects, individuals gave small personal donations. Periodically, when a group member died, the group would receive "in memory" or legacy donations of a few thousand



dollars. For the most part, these projects and events evolved in tandem with the group's gradually expanding financial and human resources.

One particular project, however, began modestly but unexpectedly mushroomed, exerting pressure on the group to seek ongoing funding for a salary. In 1996, a web-savvy board member volunteered to put up a brochure website, describing the group and its activities. Within the site she incorporated a web-based *Chat Space*, where patients could post questions, raise cancer-related issues, and discuss them with one another. The *Down-home Peer-Support, Education, and Advocacy Chat Space* was easy to use and was one of the first such websites for breast cancer patients anywhere. Within a few years, recalls *Jenny*, the hits on the group's site "exploded." From one or two messages a month in the year after its December 1996 launch, postings and visits accelerated dramatically in the spring of 1998, reaching 5,611 hits that April. Local women logged on to talk; so did women from the four corners of the globe. The site continued to grow in popularity: in April 1999 it logged 18,917 visits and by the spring 2003 the monthly tally of hits was about 22,000. *Down-home Peer Support, Education and Advocacy* became an international phenomenon and attracted the attention of academic researchers (e.g., Bayers 2004). For the group's board, however, the *Chat Space's* success created internal tensions. The work to maintain it outstripped the group's volunteer person-power and its cyberspace profile began to overwhelm the organization's hands-on presence in the local community.

There were a few years there where we just, we couldn't keep up. [The *Chat Space*] really started to kind of dominate the group, which caused some big issues in the group. And we needed some money because [the web mistress] just could not stay on top of all the work that it was generating. ... And one of the things that, right from the beginning ... made *Fiona* [the web mistress] so busy was moderating it to make sure that it wasn't being spammed. ... If people came on and said, "Oh, the

miracle drug!” we would take that off. We had a policy that, “You can’t come here and just say whatever you want to say.” ... If someone said, “The cure for cancer is blah, blah, blah,” it would come off. Or, “You should read my book!” -- We would always take that off. (Interview with *Jenny*, 2007)

The first time *Jenny* recalls the group discussing pharmaceutical company funding was when they were looking for money for the web site, in 2000. Based on a consensual understanding about the purpose of the *Chat Space*, and with strong leadership from the web-mistress, members began to articulate a policy that defined the *Chat Space* as outside the reach of pharmaceutical company funding.

[The *Chat Space*] was very much *Fiona*’s baby [and] she was very against [funding from the pharmaceutical industry]. She would say, “Newly diagnosed people come here, they don’t want, they don’t need to be seeing Astra Zeneca, and this and that dominating the site.” One of the reasons the site is so popular is because it is women talking to women. It’s very non-commercial and it’s very grass roots. It’s a safe place. And that was really important, especially to [the web mistress]. And of course we all agreed, we all went along with her. That’s exactly the presence that we wanted to have.

But it did make it a lot more difficult to find funding. Because, yeah, it would have probably been a lot easier if we would have been happy to [accept a corporate sponsor], we probably could have found people interested in funding it. (Interview with *Jenny*, 2007)

In addition to the supportive messages to those newly diagnosed or suffering a relapse, the *Chat Space* was a rich source of lay knowledge about living with breast cancer. Experiences with treatments, including drug treatments, were a common theme of shared understanding among *Chat Space* participants. A participant from Florida took this informal exchange of lay knowledge a step further. Her oncologist had prescribed the drug tamoxifen but had not warned her about the drug’s many side effects affecting quality of life (e.g., hot flashes, weight gain, loss of libido). A frequent visitor to the *Chat Space*, she prepared a questionnaire asking women taking tamoxifen what side-effects, if

any, they suffered, and what information their physician had provided about side effects when prescribing the drug. The web-mistress created a page for the questionnaire and 200 women taking tamoxifen responded. The woman who initiated the survey then compiled the responses into a report which was posted on the *Chat Space* and sent to cancer specialists. Unexpected side-effects from the drug were clearly a frequent concern.

Board members who wanted to keep the website free of industry funding saw the survey as validating their position:

I think it was a pretty common thought among our board members that the pharmaceutical industry was part of the problem. And so why would we take money from them? And I think a lot of people felt it would make us unlikely to speak out. For example the survey about tamoxifen was cool, it really was! [The woman from Florida decided,] “I’m pissed off and I’m going to find out [about the side-effects and the information given to patients] and I’m going to interview all these people.” And I guess there was some thought, “You know, if we were taking money from – who makes tamoxifen? It’s AstraZeneca isn’t it? – then, would we feel completely at ease being critical about tamoxifen?” (*Jenny*, Interview, 2007)

In general, however, *Jenny* didn’t believe funding from the pharmaceutical industry had to have a silencing effect:

Frankly, I don’t have an issue with that. If I take your money it doesn’t mean I’m not going to say anything ... You know, I don’t think that has to be the case. (Interview with *Jenny*, 2007)

For some board members, however, a national breast cancer fundraising organization, known as “*The Pink Foundation*” was a more palatable source of funding. *The Pink Foundation* holds an annual breast cancer run in locations across Canada every October raising millions of dollars each year, and disperses a portion of the money raised

in each community to local organizations and projects. Yet even this source met with mixed reaction from *Down Home's* board members.

... the whole pharmaceutical issue was really a topic of conversation.<sup>54</sup> There were people on our board that were against taking money from *The Pink Foundation* because *it* gets money from pharmaceutical companies. So it really was a big issue at our board. We discussed it quite a lot, actually. Then we had a couple of members draw up a policy, and our policy in the end was -- because we all couldn't agree -- was that we would look at it on a case-by-case basis. Which really wasn't much of a policy! (laughs) But we were not going to get consensus on it. (Interview with *Jenny*, 2007)

In the end, the group agreed to apply to *The Pink Foundation* for funds to hire the web-mistress to maintain and moderate the *Chat Space*. At the same time, the board concluded that they needed an office and a part-time paid staff person to carry out the day-to-day work at the local and regional levels, and to apply for grants.

Because we had kind of grown a little bit, and were more involved, and a lot of it was through the web site, but through many other avenues also. And often we would be asked, "Oh, we need a board member to sit on such-and-such a committee, we need..." you know, representation here and there. And we really didn't have people who could do that. Either people were not wanting to get that involved or they worked full time and they just couldn't do those kinds of things. (Interview with *Jenny*, 2007)

In early 2001, the group hired *Jenny* one day a week for six months to write grant applications.<sup>55</sup> Two of her initial applications were successful: a request to *The Pink Foundation* to support the *Chat Space* and an application to Health Canada for a grant to develop the *Web of Support*, a provincial network of breast cancer groups and resources. *The Pink Foundation* continued to support the *Chat Space* until mid-2007. The provincial *Web of Support* project was funded through a federal program called a Community Capacity Building grant.<sup>56</sup> In 1993, the federal Department of Health and Welfare (renamed Health Canada that same year) had declared breast cancer a national health

priority and launched a national program called the Canadian Breast Cancer Initiative (CBCI) which committed \$20 million over 5 years for breast cancer research and \$5 million to a variety of projects designed to improve health and community services for breast cancer patients. The CBCI was renewed for another five years in 1998 and in 2003 was renewed again, “indefinitely.”<sup>57</sup> From the outset, a small portion of the Initiative’s money was dedicated to supporting the creation of networks of breast cancer organizations across the country. The structure included a national office in Ottawa with a salaried executive director and a volunteer board made up of survivors from each province and the territories (*The Hub*); in addition, the project involved the gradual creation of regional networks in each province and territory. In 2001 *Down-home Peer Support and Education*, located in the only province still lacking a network of breast cancer organizations and services, was well-positioned to create one. The group has continued to receive funding, with the latest grant extending to 2012.

With \$26,000 in federal grant money from the CBCI’s Community Capacity-Building Component, *Down-home Peer Support and Education* was able to increase *Jenny*’s hours and, along with representatives from other parts of the country, she became part of a Health Canada-funded<sup>58</sup> national Community Capacity Building Committee.

Locally, she was the group’s point person for the provincial *Web of Support* project.

And that was what [the government] wanted done, they wanted a [provincial] network -- which was a great project for me. I got to know many different people all across the province -- people on dragon boat teams, and support groups, so, yeah -- everybody, really. [But the project] had all kinds of problems: money and -- mostly money! And then the money just kept decreasing. (Interview with *Jenny*, 2007)

The federal funding to create the *Web of Support* began with one-year grant in 2001 -- money that the group was told from the outset would be cut back by 25 per cent annually. The federal government's plan was to provide seed funding through its regional funding offices to establish a national system of interconnected networks which would become self-sufficient within five years. To *Jenny*, the idea that these programmed funding cuts would act as a fundraising incentive was ludicrous.

*Jenny*: Yes, Yes! That's why they cut the money. It's an 'incentive'! It was the incentive to find money elsewhere! [laughs] And it was funny, I was telling somebody at Health Canada that this had exactly the opposite effect. All of these projects all over the country just ceased to be; because, really, there is no other money out there [for a support network].

Sharon: Does the *Web of Support* have any funding now?

Actually, we got some funding – we were going to close down the project. And strangely enough, as soon as we said that, the government found some more money. So yeah, we have some money to do that this year. ... but it didn't really get enough money to do what needs to be done, it's a shame.

You know, it seemed like there was a time when it felt like things were going to get better, and people were recognizing that these things are important, that supports in the community are available and the information's there and there and there is a community for people when this happens to them! And it seems like this has gotten lost again. Or people think that that has been done, you know: "the house was built and now we can go away!" But it doesn't work like that. Or people say, "You have to run more like a business." Well, hello, who is our clientele? Sick people! It doesn't make any sense to me. It really, really doesn't. (*Jenny*, Interview, 2007)

The group continued to attract money for specific one-time projects; for example, participants on the *Chat Space* donated money to compile and print a book from their own experiences<sup>59</sup> which *Down-home Peer Support and Education* made available online and distributed free to libraries in the province; and the local hospital serving women and

children funded the group to purchase a selection of books about breast cancer which were placed in libraries throughout the province.

The issue of pharmaceutical company funding resurfaced at *Down-home Peer Support and Education* on several occasions between 2003 and 2006. In 2003, the group sent two delegates to a national workshop initiated by *Helping Hand*, an Ontario breast cancer group, to discuss disparities in the way breast cancer patients' needs were being met across the country. The result was a project funded by the pharmaceutical company Astra Zeneca to develop a Canadian charter of breast cancer patients' rights. In this case, the Ontario organization had already secured pharmaceutical industry funding so *Down-home Peer Support and Education*'s decision involved deciding whether to be part of a national collaboration for which pharma funding was a *fait accompli*. The group did become a partner through the participation of one of its members, *Thora*, but another member, *Jenny*, withdrew after the first meeting. I discuss this project in the next section of this chapter as the group, *Patients, Know Your Rights!*

*Pharma Funding and the Unrestricted Educational Grant.* The existence of industry "unrestricted educational grants" was a happy discovery that one member credited to a fundraiser who worked for the group for a year. By 2005, the group had reached the point where board members agreed they needed an office and a paid staff member. They also knew their federal grant money would continue to shrink under the government policy that pushed groups to become self-sufficient. They group applied for a grant to hire a fundraiser through a federal program called the Human Resources Skills Development Program (HRS DP). The successful applicant was a young man named *Keith*.

... he thought we were crazy not to go after the unrestricted educational grants. And he got us a lot of unrestricted educational grants, small amounts for various projects that we want to do. So I think we're a lot more open to that, but again it would have to be "no strings attached." Luckily a lot of them [drug companies] seem ok with that. They don't expect you to stick their logo everywhere if they give you money. (*Ruth*, Interview, 2008)

Another board member, *Meredith*, felt that leasing the office and hiring a fundraiser had contributed to moving the group towards a business model, a transition she opposed and which she felt was dividing the board. The office and the fundraiser were linked, she said: to apply for an HRSDP grant to hire a fundraiser they needed an office, so they found an office ("it was a cart before the horse thing"). The government provides funds to pay a salary but the organization is expected, by the time the grant expires, to prosper to the point where the group can pay the salary itself.

*Down-home Peer Support and Education* has an annual fundraising dinner and auction at a hotel and *Keith* approached a number of pharmaceutical company representatives about buying tickets for a corporate table at \$500 each. Four or five companies agreed, said *Thora*, "...and they didn't even send reps, they just said 'Here!'" Of the board members I spoke to, this instance of company largesse elicited the same ambivalence and mixed reaction as the issue generally. For *Ruth*, a large amount of money would set off alarm bells but selling tables at a dinner was a different matter:

...for them [pharma companies] \$1,000 is chump change. That's what our fundraiser said, too, you know, their regional sales rep is authorized to give that amount of money for a charitable cause, without even going back to headquarters and saying "Is it ok for me to do this?" (Interview with *Ruth*, 2008)



*Meredith*, the board member who was least comfortable with this increased openness to the industry felt the group had to make decisions about drug company funding “with our eyes open.” She favoured having an office, but it was important to her that the group not break faith with the members who had built the group’s foundation and she thought “taking pharma money or not might make the difference in how we grow.” She felt the board had ceded control of the decision-making to the fundraiser, who eagerly pursued funding from these sources; indeed, once the HRSDC grant ran out, his job depended on finding enough money for the group to continue to pay him. To her consternation, the board had no way of knowing what he was saying or promising to companies.

For *Jenny*, however, selling tables at a fundraising dinner was unproblematic:

[It’s] just an easy way to get money ... And I think at a dinner -- who’s going to be offended? It’s different than on a web site where people have just been diagnosed, and are upset, and are coming for support. (*Jenny*, Interview, 2007)

*Thora*, however, mused that the group might have to come up with “more creative ideas,” like a flower campaign. She summarized the group’s ongoing ambivalence as perhaps an irresolvable tension:

If, in order to continue our work, we have to resort to that, or whatever, if we have to -- but it’s mixed because some women of course feel very strongly that these drugs they are receiving are keeping them alive, right? There’s always that mix, [the drug companies] are doing some good; but then there’s the chemicals and the toxins and things like that. It’s never a comfortable relationship because of that. And of course the price of drugs, and the fact that they don’t have them in poor countries -- it’s a whole Pandora’s Box, right? So I don’t know if there will ever be any clear perspective on it, because of that. (Interview with *Thora*)

In 2005, the group accepted another overture to participate in a pharmaceutical industry-funded event, a public education evening. A local oncologist (whom some of the women in the group knew as their cancer specialist) approached the group to say Astra Zeneca had invited him to give a public talk on breast cancer at the provincial Art Gallery, one of five such events the company was sponsoring in different cities across the country. The group's role would be to take on some of the organizational and hosting responsibilities ("the scut work" as *Meredith* put it). In exchange they would receive \$1,000 of the total \$5,000 that the company had budgeted for the event. In accordance with the group's "case by case" policy, this offer went to the board.

*Ruth*: And we debated about that for quite a while! (laughs) And then we decided, 'Well, ok, that's not compromising.... We're not endorsing their products, we're not giving them our blessing or anything.' And that sort of opened our eyes to something known as an 'unrestricted educational grant.' (Interview with *Ruth*, 2008)

In order to ensure that the group was not endorsing the company's products, they set out certain conditions. *Thora*, who was directly involved in the discussions with the physician, explained:

They had a PR [public relations] firm that took care of all of [the planning]. They took care of booking, they took care of the ads. But we took care of all the RSVPing, and hosting, having the volunteers there to greet people and to introduce the speaker -- basically, to say what it was all about. And at the talk, we didn't even mention the funder. That was just part of the agreement, that we wouldn't mention Astra-Zeneca, or thank them. ... We just told them -- that was our stipulation -- that [their sponsorship] wasn't even going to be brought up at the talk.

They [Astra Zeneca] didn't get involved at all. I mean they literally were totally hands-off, which was nice to see. And we made it very clear that it was an "unrestricted educational grant" ...because we didn't want people to think we were doing it just for [Astra Zeneca], basically, so they didn't have signage [i.e., publicity signs], they didn't have brochures -- they didn't have anything there.

That's why [members of the public] RSVPed to us, because we didn't want [the company] to have the contact information for the breast cancer patients and their family members. (Interview with *Thora*, 2008)

Members of the group were satisfied that the talk was not promotional in nature.

[The oncologist] told [Astra Zeneca] he wasn't promoting their product. So when he did his talk, he was talking about *all* adjuvant therapy. That was his deal, too, that he would not endorse, he would not talk about one particular product; he would talk about all products. . . . He was very honest. We were quite impressed. (Interview with *Thora*, 2008)

For members of *Down-home Peer Support and Education's* board, receiving a share of the money was not the sole, or even the main, benefit of participating in the event. As part of the *Web of Support* project, the group was initiating a series of its own educational talks, organized in-house. When members of the public called the group for details of the evening, they were able to ask if they would like their name added to the group's own list for promoting events. The event also raised the group's profile, associating its name with a well-advertised, successful evening (about 50 people attended) at an attractive downtown venue.

For one member of *Down-home Peer Support and Education*, however, the event created a liaison with the drug company that was not entirely comfortable.

Now, AstraZeneca thinks they can ask us for things on a regular basis. They've come up with a website that promotes [the drug] Arimidex® that's very warm. They wanted [*Down-home Peer Support and Education*] to link our website to theirs. We said "No, let's step back." (Interview with *Meredith*)

The following year a radiation oncologist known in the community for his interest in mind-body-spirit healing retreats approached *Down-home Peer Support and Education* and invited the group to participate in a similar event, with sponsorship from another

major drug company, Pfizer. Once again, the board discussed the project and members agreed to go forward.

It has to be passed by the board. We sort of say, ‘This is coming in, this is how much, this is what they want us to do.’ The board will want to know, ‘What do they expect in return?’ And that would depend ... if they expected a lot in return, of course we would turn it down, I think. Of course, I can’t speak for [the other board members], but that’s the impression of the board that I get. You know, we’re very leery about taking pharmaceutical money and being associated with any pharmaceutical company. (Interview with *Cindy*, 2008)

For this second event, two other specialists were added to the agenda, an oncologist and a plastic surgeon. This time the session took place at the local cancer centre and drew 150 people.

And it was the same deal: they paid for it, they did the promotion, our job was to book the room and to do the promotion as far as calling people, and getting the ad ready, although they paid for all that. And we didn’t actually deal with the drug company at all, because it was all done through [the radiation oncologist], because he was the contact person for it all. His main thing was to talk about the body-mind-spirit connection for cancer patients. So he dealt with all that. So again, there was a budget for AV, there was a budget for the ads, honorariums for two of the speakers. The plastic surgeon didn’t get anything, but they [the two oncologists] got maybe \$500 I think it was. And again what was left over we got, as payment for that, and I think it was around \$1000. And again, they weren’t advertised as the sponsor or anything like that. And it was a really amazing turnout, people loved it! And we got more names, because they RSVPed to us again, right?

So again, it was a really good opportunity for us .... But again, it always causes anxiety, dealing with a pharma company, because we know that perception is there, and we’re not all comfortable in doing that. And so there’s always restrictions around what we want, we have to make sure it’s an unrestricted grant, and that they have no dealings at all. (Interview with *Thora*, 2007)

Although members of *Down-home Peer Support and Education* took pains to establish conditions for their participation and were satisfied that both company who sponsored talks did not use the occasion as an opportunity to directly promote its

products, their deliberations did not consider -- and members of the group were probably not fully aware of – the intricacies of drug approvals, or drug promotion strategies and institutional safeguards designed to control pharmaceutical company claims about their new therapies. I discuss this knowledge gap and its significance more fully in Chapter 5; at this point, I use the example of the two sponsored talks as a preliminary exploration of the question, “If the companies aren’t able to advertise their products at these events, what do they want from us?”<sup>60</sup>

In 2005 and 2006, when *Down-home Peer Support and Education* held its two public education events, Astra Zeneca and Pfizer, the two companies that funded these talks, both had competing entries in a new class of breast cancer drugs known as *aromatase inhibitors*, as did a third company, Novartis (Chapter 5 Supplement). Like tamoxifen, these drugs reduce the woman’s exposure to her endogenous estrogen but by a different mechanism. Whereas tamoxifen blocked the ability of circulating estrogen to enter the tumour, aromatase inhibitors are designed to eliminate the production of estrogen in post-menopausal women almost completely (Love and Lindsey 2010). Theoretically, then, their effect in reducing breast cancer recurrence might be expected to exceed that of tamoxifen; however, side effects would still be expected and might be more severe than tamoxifen’s. Clinical trials are the means to determine whether these expectations for benefits and risks will be borne out. Given the extraordinary success of tamoxifen – by the late 1990s, the drug had become the best-selling anti-cancer treatment on the market – the prospect of an even better drug was generating excitement on both the therapeutic and financial fronts. Astra-Zeneca’s patent on tamoxifen expired in 2001, so prices for this old standard would inevitably drop; in order to justify their inevitably

higher price, the new class of drugs would have to demonstrate a significantly improved ratio of risk to benefit.

Despite this competitive environment, in these new-drug sweepstakes all three companies had a common interest in gaining awareness and clinical acceptance of the new class of drugs as “better” than their predecessor, tamoxifen; it was a project of translation in which all three companies had the same stake. A public information session at which an oncologist talked to patients about adjuvant therapies for breast cancer – especially new developments -- could thus serve the interests of all three competitors, even if no specific brand names were highlighted. Indeed, surveys of physicians show that they want “unbranded ‘unproduct-specific’ information” to give to their patients (Cassels, 2003:4).

At the time of the public information sessions in which *Down-home Peer Support and Education* was involved, all three drugs were in various stages in the process of generating clinical trial results and were passing through the drug approval process. Astra Zeneca, the company that developed tamoxifen had also developed the first aromatase inhibitor, Arimidex® (anastrozole) and was ahead of the competition in generating clinical trial results (Baum et al, 2002); Novartis was not far behind however, with its entry, Femara® (letrozole) (Goss et al, 2003), while the third company, Pfizer, was close on the heels of its rivals with a large international study of Aromasin® (exemestane) (Coombes et al 2004).

In the oncology literature, the clinical trial results of the three drugs were generating both excitement and controversy. The three studies cited above each had a similar design in which postmenopausal women with estrogen-receptor-positive tumours

were treated first with tamoxifen then randomly switched either to an aromatase inhibitor, or continued through the five-year course of tamoxifen. By March 2004 when the early results of the third study appeared, each of the three novel drugs had been shown to significantly lower the risk of a recurrence compared to the standard treatment of a five-year course of tamoxifen. These findings fell short of demonstrating the superiority of aromatase inhibitors over tamoxifen, however, because all three trials had been halted before their intended completion date on the grounds that withholding the more effective therapy would be unethical to women in the standard treatment group. While the practice of stopping a trial early is based on ethical considerations (volunteers in a clinical trial should not be denied a treatment that is clearly superior to the one administered in the arm to which they are randomized), the appropriate criteria for stopping a trial are a subject of debate in the ethics literature (Cannistra, 2004; Meuller, Montori, Bassler, et al, 2007). The use of *surrogate end-points* is a particular concern, and all three trials of aromatase inhibitors used the surrogate end-point of a cancer recurrence as the basis for stopping, rather than a true end-point: improved overall survival and/or quality of life. Early stopping thus precluded gathering evidence of long-term benefits and toxic effects of the newer therapy compared to tamoxifen. The most important questions remained unanswered. Do aromatase inhibitors reduce mortality as tamoxifen has been shown to do? If so, does their impact on mortality exceed that of tamoxifen? Did the prolongation of disease-free survival come at the expense of reduced quality of life?<sup>61</sup> Without answers to these questions, the research and treatment communities were divided: enthusiasts of the new treatments eagerly recommended that the newer drugs be adopted into standard practice, while more cautious voices argued that the results constituted early findings

only and could not be the basis for shifting standard practice away from a proven treatment like tamoxifen.

Stopping a trial early for apparent, rather than real, benefit may seem counter-productive; yet, as one group of ethicists point out, most parties to a clinical trial benefit from this practice:

For example, truncated trials that report a large treatment effect tend to be published in the most prestigious medical journals, which enhances the careers of the *investigators* and increases the likelihood that they will receive grants. *Funding agencies* have an interest in stopping trials early to minimize research costs. *Pharmaceutical and for-profit sources* that financially support trials are interested not only in controlling costs but also in the publicity and market share that result from reporting a trial stopped early for apparent benefit. *Medical journals* are interested in these trials because of publicity and citations, which result in increased journal impact factor, prestige, and advertising revenue. And *patients and their advocates* are motivated to stop a trial early when the experimental intervention is promising in order to hasten delivery of the intervention to clinical practice. All of these motives may affect investigators' decisions and encourage an inappropriately early stop to a trial. (Mueller et al 2007:880, italics added).

Yet the results of a trial that is stopped early are difficult to apply to clinical practice. An editorial that accompanied the publication of the Coombes et al study reflected on the dilemma of evaluating aromatase inhibitors, given that trials for all three of the new drugs were stopped before meaningful results were available:

The weaknesses of the [Coombes et al] study are the immaturity of the data in terms of overall survival and safety .... Will the study show a survival benefit with longer follow-up? The answer is uncertain. The hazards of death could be disproportionate over time ... The results of these three trials at median follow-up of only 30 months does not allow us to conduct a useful risk-benefit analysis, which is an integral part of making appropriate treatment decisions. Although the short-term toxic effects of aromatase inhibitors have not been particularly worrisome ... the long-term consequences of estrogen deprivation in postmenopausal women remain a concern. Particular attention



will need to be paid to bone and cardiovascular health, cognitive and sexual function, and quality of life. ... Considering these three important trials, what should clinicians do? Many more years will be required to fine-tune the risk-benefit assessment of adjuvant aromatase inhibitors.... (Piccart-Gebhart 2004).

The state of scientific uncertainty provided an ideal environment for companies to engage other actors in a translation that would emphasize the potential benefits of the drugs and minimize their risks. Indeed, the existence of ambiguous research results sets the stage for treatment recommendations based on “our ignorance of the future” rather than our “certainty of the present”, and on “hope that these therapies might have led to a survival advantage” rather than on “the facts” that would have been available if the studies in question had been allowed to run their course to maturity (Cannistra 2004: 1543-4). Importantly, from the perspective of patient activism, a typical way of dealing with such scientific uncertainty in medicine is to turn the decision over to the patient, via a discussion of “treatment options”:

The implication is that patients will know the right answer, despite the fact that their physicians do not know how the new treatment will affect important measures of clinical outcome. In this regard, it is legitimate to consider whether the results of the letrozole ... [trial] might unfairly tantalize patients with the prospect of prolonged PFS [progression-free survival], in the absence of a known survival benefit, and with the possibility of treatment-related toxicity. (Cannistra, 2007: 1544)

From this perspective, systematically informing patients’ organizations of a promising new treatment option for their disease builds on the construct of the modern patient as “knowledgeable” and “informed,” while systematically ensuring ignorance of the key facts.

What patient would easily refuse the prospect of prolonged progression-free or disease-free survival under these circumstances, and how many would be

able to understand the uncertain and oftentimes tenuous relationship between PFS, OS [overall survival], and QOL [quality of life], when data regarding these important outcomes do not exist as a result of early study closure?” (Cannistra, 2007: 1544)

The problem is not that patients are naïve, or too unsophisticated to understand the science, it is that the science has not produced the answers necessary to make an informed decision. In fact, as the above discussion suggests, disseminating such early trial results to patients (and clinicians) could more accurately be characterized as using the clinical trial as an “information inhibitor” – a means of fashioning ignorance, not knowledge (Drug Trials should not be Information Inhibitors, 2011).<sup>62</sup> A “patient information session” in the wake of clinical trials that were stopped early begins to make sense as a marketing strategy. Even the most cautious presentation of the science to a lay audience is unlikely to include a discussion of surrogate endpoints or clinical trial stopping rules.

In July 2004, Health Canada awarded Arimidex®, the aromatase inhibitor made by Astra Zeneca, the status of “NOC/c,” -- meaning conditional approval-- as a treatment for early breast cancer in post-menopausal women who had already been treated with tamoxifen (Health Canada NOC database:Arimidex®). The acronym NOC/c stands for “Notice of Compliance with Conditions,” meaning that, on the basis of early clinical trial data, the drug meets the conditions for approval (i.e., safety and efficacy) and the company can begin marketing it for the specified indication; but, because the results are preliminary, the company must continue to monitor results and submit them to the agency. Femara® was awarded NOC/c status for extended adjuvant therapy on April 1, 2005 (Health Canada NOC database: Femara®) and on May 12, 2006, Pfizer’s

Aromasin® gained its NOC/c approval from Health Canada for early breast cancer after two-to-three years of tamoxifen therapy (Health Canada, NOC database: Aromasin®).

As Piccart-Gebhart predicted, assessing the three drugs in relation to tamoxifen, and in relation to one another, has proved to be a long-term project. As new clinical trial data emerge, reviews of the data from the three novel agents continue to appear in the literature (e.g., Berry, 2005; Rugo, 2007; Aydiner and Tas 2008) with some incorporating a cost-effectiveness analysis that weighs the gains that aromatase inhibitors offered in disease-free survival, against the substantial increase in cost over tamoxifen (Imai, Kuroi, Ohsumi et al 2007; Hind, Ward, De Nigris et al 2007).

The treatment information sessions for patients raise ethical issues on another count, namely, such events could be viewed as a means of circumventing restrictions intended to control the venues in which drug companies can ethically communicate drug trial information. An article published in the *Canadian Medical Association Journal* two years prior to the event which *Down-home Peer Support and Education* hosted (Chepesiuk, 2003) describes limits to the kinds of “educational” publications and projects that pharmaceutical companies should sponsor. According to the criteria the author lays out, pharma funded public talks about treatments would appear to be out of bounds.

The author of the article, Ray Chepesiuk, is Commissioner of the Pharmaceutical Advertising Advisory Board (PAAB), an independent body set up to oversee pharmaceutical company advertising materials (Lexchin 1997a<sup>63</sup>). Because inappropriate use of prescription drugs can harm the user’s health and even cause death, claims about these products are controlled, with the particular safeguards dependant on the means of communication. Chepesiuk classifies drug-company sponsored claims about drugs in to

three categories: first, advertising materials, which are regulated by law under the federal Food and Drugs Act and are assessed by PAAB before reaching their audience; second, published scientific articles reporting on drug trials, in which claims are controlled through the outside evaluation of peer review; and third, materials which are described as “educational,” which are exempted from PAAB review and which are often said to be “supported by an unrestricted educational grant” (Chepesiuk, 2003). Chepesiuk flags this third category as open to abuse and cautions physicians to exercise care if asked to contribute to such unmonitored materials. Since 1996, Chepesiuk explains, PAAB has exempted educational meeting reports from review in order to enable *physicians* to receive timely information about therapies at accredited continuing education meetings; but to qualify for the exemption, PAAB requires that the process be, “truly independent of the sponsoring company” (2003:421). According to Chepesiuk, an event sponsored directly by the company or by a firm acting as an agent of the company would not meet the requirement of independence. He also warned that use of the phrase “supported by an unrestricted educational grant” is no guarantee that the requirements necessary for an exemption from PAAB review have been met. He states:

I have ... seen reports based on preliminary trial data, incomplete scans of the literature, unfair comparisons, suggestions for off-label uses, and inappropriate descriptions of safety measures. (Chepesiuk 2003: 421).

Chepesiuk’s cautionary article raises a number of red flags about the educational event in which *Down-home Peer Support and Education* was involved – and the four similar events held in other parts of the country. First, educational events about pharmaceuticals sponsored by drug companies, when compliant with PAAB guidelines, are meant to provide *physicians* with timely information about new products, not patients

or members of the public.<sup>64</sup> Second, such events are not considered acceptable if the sponsoring pharmaceutical company is involved in organizing the event, either directly or through the efforts of a firm the pharmaceutical company has hired. In this case, the pharmaceutical company hired a PR company to organize the event, which violates of the requirement of independence. Thus, despite the group's efforts to ensure the drug company was not using the talk for promotion, the event would not likely have met PAAB's criteria for the exemption from a PAAB review.

*Down-home Peer Support and Education* provides peer support for breast cancer patients facing or undergoing treatment so that members of the staff and board take calls from newly diagnosed women who want to discuss particulars of their diagnosis with another woman who has been through the treatment experience. These discussions were not an area where group members worried that pharmaceutical company funding would influence the treatment information they gave to patients, however. As one member of the board explained, the group observed a strict boundary that put medical expertise outside its purview and rendered such conflicts of interest academic:

We provide peer support if you call the office, but it's not, if someone were to ask me if I should be taking this drug, I would say, "Hon, I have no idea. That's between you and your oncologist." I might give them the website of Dr. Susan Love, because they will answer more medical-type questions. But I never, ever, ever, nobody at *Down-home Peer Support and Education* would...we would never, ever give information that was at all medical in nature.

We would never tell somebody to take a particular drug or to take a particular therapy. We would say, "Now you need to talk this over with your oncologist." And if it was someone who really didn't have any idea what was going to happen, we might say, "Now you might have radiation, you might have chemotherapy, it's going to depend on your path [pathology] report." That kind of stuff; it would be very broad, very broad. And even at that we would say, "Now I'm not a medical professional and I can't give you anything resembling medical advice, but, as a

general rule...” and then go on. ... And we’re very careful about that. (Interview with *Ruth*, 2007)

This did not mean, however, that the group disavowed any expertise about drugs or other aspects of treatment; indeed, exchanging information about drugs and their effects is a major theme on the group’s online *Chat Space*. Members make a distinction, however, between medical advice and exchanging accounts of their treatment experiences, particularly side-effects:

...it tends to be more like, “My doctor has prescribed Taxotere®, I’ve been taking it for three weeks and my fingernails have gotten all thick and smelly and what do I do about this? Has anybody else ever had this happen?” And somebody else will -- with any luck quite a few people will -- write in and say, “Omigod yes, isn’t it disgusting! I wore white gloves to bed at night with hand cream!” Or something like that; and it’s about side-effects of drugs, like “Did your joints ache with Arimidex®?” And you’ll get 80 responses saying, “Omigod! Did they ever!”

And lots of moaning and complaining about how doctors never tell you about the side-effects of drugs. And it’s supposedly because then you’ll get [the side-effects], you’ll psych yourself into getting them if you know what they are. And so sometimes [patients] look at it as a conspiracy to hide the possible side-effects and not tell you the whole picture so you can make an informed decision: “OK, for the little tiny bit of additional protection I’m going to get from this drug, am I willing to put up with not being able to walk up the stairs?”

There’s that kind of conversation on the *Chat Space*, yeah. And here [in the office], too, for that matter! Among the ladies on an education night -- afterwards they’re drinking tea and eating cookies and moaning and bitching about drug companies. (laughs) It’s not unusual! (Interview with *Ruth*, 2007)

The group’s advocacy work has not, to date, involved engaging in advocacy in relation to pharmaceuticals, a fact that *Ruth* attributed to happenstance more than an active decision.

We were stronger in advocacy at the beginning, before I joined *Down-home Peer Support and Education* -- and then all the attention went to the *Chat*

*Space*, the *Chat Space* was the main project. The provincial [focus] and advocacy sort of went by the wayside and I'm actually trying to revive it. (Interview with *Ruth*)

The group's first step in this return to advocacy was to raise awareness within the cancer treatment community of the post-operative risk of lymphedema for women who had had breast cancer surgery. They successfully lobbied the CEO of the local cancer treatment centre to give women a bracelet coloured hot pink to wear when they are admitted for other types of surgery as a quick reminder that medical staff should not put an IV in the arm at risk from lymphedema, take blood from that arm, or perform any intervention that might risk infection and provoke lymphedema. *Ruth* did not rule out the possibility that the group would advocate to have a new drug put on the provincial formulary, but thought the circumstances would have to be unusual.

No, I can't [envision advocating for] a drug that wasn't available unless it was an absolute miracle drug, and nobody's come up with that. ... And if that came along that would be very interesting. That I could see getting involved in, I would be so fascinated. But so far, the cancer drugs they've come up with are just more of the same, and I can't, I haven't met one yet that I'd advocate for. That is not to say that one isn't going to come down the pike. But I suspect the next big cancer drug is going to come from university research, or some other source rather than a pharmaceutical company. They have too much of a vested interest in the drugs they already have. (Interview with *Ruth*, 2007)

*Meredith* agreed that the group might revisit drug policy advocacy at some point, although she viewed the subject as a complex one that might be beyond *Down-home Peer Support and Education's* political- and person-power:

We didn't want to do single-person advocacy – we didn't want to say, “Someone needs this drug.” Our advocacy has to involve a policy that benefits any breast cancer patient, and it can't cost money. The lymphedema project was the kind of advocacy we do. It didn't involve any money except the cost of a stamp. One of our members sat down with the CEO of the hospital district to explain our case and she succeeded. No glory, no credit. It doesn't involve a \$3,500 a week drug.

Drugs are not the focus of the advocacy committee although we may have to look at that issue eventually. I would love to have those drugs covered, but I don't think we have that power any more. We have a very active, hands-on board of 12 so we have to choose our issues. We don't know if that's our area. If sad stories in the media don't get the government to pay for the drugs, how likely are we to do it? Also, if they spend that kind of money on a drug for you, that's less money to pay for care for someone else. There's a fixed amount of money to go around. Maybe if a drug is really beneficial for breast cancer patients, like Herceptin® was and is – maybe we should go to the drug company. I think with Herceptin®, although it's officially case by case in [our province], I think it's a done deal. The [provincial formulary] policy is set. ... Only eight per cent or so of women with breast cancer benefit from Herceptin® and I think, if the drug will help someone, they get it. (Interview with *Meredith*, 2007)

In 2007, a number of significant changes reconfigured *Down-home Peer Support and Education*'s funding sources in ways that reverberated through the organization. The regional office of *The Pink Foundation* that had funded the group's *Chat Space* project told the group that, because its mandate was to represent the Atlantic region, its priority was to provide seed funding for projects on the East coast. *The Pink Foundation* would therefore no longer fund the *Chat Space*, which was well-established and no longer local (although many women in the region used the *Chat Space*, they were a minority of all users). Furthermore, *The Pink Foundation* didn't see the need for a full-time web-mistress to monitor the site when other sites, including that of *The Pink Foundation*, were outsourced to professional managers who oversaw many sites at once. A spokesperson for *The Pink Foundation* reasoned that the *Chat Space*'s maintenance could be outsourced to a professional web-service company for much less money than the group was paying its web mistress. *The Pink Foundation* was, however, prepared to fund a website featuring breast cancer news, events and information specifically for women in the East coast region – an internet extension of the group's other major project, the *Web*



*of Support*. This website to announce regional breast cancer events had already been set up in a rudimentary version in 2000 as part of the *Web of Support* project. Unlike the group's *Chat Space* it involved on-going liaison with breast cancer groups throughout the region and constant posting of information. In the eyes of *The Pink Foundation*, managing a sit for the *Web of Support* could therefore merit a salary.

In June 2007 *Fiona*, the web-mistress, was let go and the *Chat Space* was administered, on an interim basis, by volunteers on the board while the group looked into outsourcing possibilities. Meanwhile, the group applied for and received funding from *The Pink Foundation* to hire one of its other members to work in the office and maintain the network of breast cancer groups in Atlantic Canada that had been initiated with government funding. *The Pink Foundation's* decision to terminate its support of the *Chat Space* brought the issue of funding, including pharmaceutical company funding, to the fore once again and marked a shift in the group's culture of action away from the *Chat Space* and back to its local roots. The termination of the web-mistress's employment had internal shockwaves (the web-mistress left the organization, a fact lamented in web postings by some of the long-time members and regulars on the *Chat Space*). The question of whether the group should move to a more "professional" model divided the board, which hired a facilitator to help the group through an organizational crisis.

By late 2007, however, *Down-home Peer Support and Education* had found a corporate financial angel, in the form of a large regional drug store and grocery store chain. The fundraiser left the group to follow career opportunities elsewhere. Shortly before his departure, however, the two chains had approached him to propose a partnership in which they would provide the group with an annual donation of \$40,000 –

a large sum for *Down-home Peer Support and Education*. The board entered into discussions and decided they were comfortable with the terms. In return for the money, among other things, they would help the pharmacies design women-friendly centres to fit and sell breast prostheses. Board members liked the concept of an active collaboration with the company that tapped into the group's expertise as survivors.

They said, "You know, we don't know anything about this. ... Help us design these centres." And we can do this without compromising ourselves. We are breast cancer survivors, we've had experience [with breast prostheses].

They do want their name on things. We have no problems with having their name on things because they're not a pharmaceutical company, so we don't feel compromised by that. And there are certain things they would like us to do; they want us to do more road trips. Like, we'll go and we'll talk in other towns, we'll address a support group, we'll give a public presentation.

(Interview with *Ruth*, 2007)

Three years later, with core funding in place, the issue of funding from pharmaceutical companies remained an open one, but no longer seemed so pressing. *Down-home Peer Support and Education* continued its leadership role in the provincial network and the partnership with the drug store chain continued; indeed, the group had moved to an office above a store of the sponsoring drug chain in a neighbouring community. The larger, welcoming space, situated in a new building that also housed many physicians' offices, had free parking. Many more women dropped in to chat or to use the resource center (named in honour of *Ruth*, the group's librarian, who died several months before the move). The on-line *Chat Space*, meanwhile had been discontinued altogether. Use had dropped off and maintaining the archives proved to be too much work for volunteers. (Reasons for the decline in the *Chat Space*'s popularity were unclear and were probably multiple. *Thora* speculated that social media like Facebook had taken over the role of the *Chat Space*. Other cancer organizations had since instituted chat

spaces for breast cancer patients.<sup>65</sup> In addition, comments from *Chat Space* participants at the time the web-mistress was let go reflected the on-line community's distress at losing the person who had initiated the project and maintained its distinctive character. *Down-home Peer Support and Education* had started a Facebook page but it didn't seem to fill the same need. "Now people are saying they want the *Chat Space* back!" said *Thora*, when we spoke by phone in early 2011.)

### 3.1.3 Group C: "*Patients, Know your Rights!*"

*A Pharma Partnership* In June of 2003, at the invitation of the Ontario-based breast cancer organization *Helping Hand*, a dozen women from breast cancer groups across Canada attended an advocacy workshop in Ottawa to "to find out what the landscape looked like across Canada" for breast cancer patients (interview with *Thora*, 2007). The invitation was extended by the then-president of *Helping Hand*, a large breast cancer group in Ontario set up to provide telephone peer support and information; the workshop was funded by Astra-Zeneca, the UK-based pharmaceutical firm which makes the breast cancer drugs tamoxifen<sup>66</sup> (Nolvadex®) and the aromatase inhibitor, Arimidex®. As discussed in the last section, aromatase inhibitors were a new class of treatment drug which was generating considerable excitement in the breast cancer research community and Astra Zeneca was the first of three companies to position its entry in the marketplace as an adjuvant treatment (i.e., for early stage cancer). Based on results of the pivotal clinical trial called ATAC, which had been halted early and published in 2002 (Baum, 2002), the FDA had granted Arimidex® "supplemental approval" in 2002 (a provisional status based on early clinical trial results and comparable to NOC/c approval in Canada); and Health Canada awarded Arimidex®

NOC/c status in July 2004. A skeptical mind might reasonably construe this overture to the breast cancer community in 2003 as part of AstraZeneca's strategy for marketing Arimidex® in Canada. I explore this possibility in the following account of the four-year history of *Patients, Know your Rights!*

The pharmaceutical company hired a Toronto-based public relations firm, Courtney-Rainey Group, to take care of the logistics. By the end of the meeting, a Working Group of participants from five provinces had been struck and was given the task of developing a Patients' Bill of Rights for Canadian breast cancer patients. I refer to this committee as *Patients, Know Your Rights!*

Three years later, a document had been drawn up and approved by the members of *Patients, Know Your Rights!* Renamed from the legal-sounding "Breast Cancer Patients' Bill of Rights" to the "Canadian Breast Cancer Charter of Rights," the document was launched at a national breast cancer conference in Montreal in May 2006 (Appendix C). By this time, several of the original members of the *Patients, Know Your Rights! Working Group* had left; several others had joined the group. I interviewed two of the original participants, *Thora* and *Jenny*, and two women who did not attend the first meeting but who joined soon after, at the request of attendees from their region who felt they would be more suitable representatives.<sup>67</sup> Several other members of the *Patients, Know Your Rights! Working Group* declined to be interviewed, however. My discussion of the project is thus based on the perception of a subgroup of those participants directly involved in the project and may not reflect the views of all *Patients, Know Your Rights! Working Group* members.

Beginnings of *Patients, Know Your Rights!* *Thora* and *Jenny*, two women who attended the invitational advocacy workshop, both told me in separate interviews that the plan to create a Patients' Bill of Rights or Charter had not been clearly articulated to participants in advance. They diverged, however, in their assessment of the meeting overall and whether this lack of clarity mattered. *Thora* (who remained with *Patients, Know Your Rights!* for the duration of the project), felt that knowing the workshop agenda in advance would have allowed her to better prepare for the meeting:

We really had no idea that the outcome was to be to start on a Charter [of Patients' Rights]. It was just something that Carmel [the Ontario-based organizer] brought to our attention basically by the afternoon of the second day that we were in this brainstorming session and whatnot. And it was quite interesting, although at the time, as I say, we weren't really prepared for it. [Interview with *Thora*, 2008]

For *Jenny*, however, the lack of transparency raised the spectre of a hidden agenda:

... the bottom line is, we got there, and it was clear that it was already decided what was going to come out of this meeting, it was the Breast Cancer Patients' Charter of Rights. ... It just really turned me off because no one said when we were invited, "Oh, we're going to be working on a Breast Cancer Patient Charter of Rights." It was billed as an advocacy workshop [i.e., more broadly, with no specific outcome]. It was all kind of predetermined. ... It felt just a little off, you know? ... I didn't like being invited to a meeting where there's a predetermined outcome. Like, "Why do you need *my* opinion [then]? Just do what you want to do." (Interview with *Jenny*, 2007)

*Jenny* was not alone in feeling that disclosure about the purpose of the meeting was inadequate at the outset. *Samantha*, who attended on behalf of the national breast cancer organization, *The Hub*, described her reaction in similar terms:

We were invited to a meeting under different pretenses than what it was actually for. It was one of these meetings where the outcome had already been predetermined -- which was offensive. And they wanted to spend money

on this particular thing, which we considered to be a total waste of time and money. (Interview with *Samantha* 2008)

Following the initial workshop, *The Hub* decided to withdraw from the project because, as *Samantha* said, “We discovered it was not what we signed on for.” As discussed below, lack of support from *The Hub* eventually proved to be a major hurdle for the project.

The fact that the project was to be sponsored by a pharmaceutical company *was* disclosed at the initial meeting; however. Participants differed in how they reacted to this sponsorship. *Thora*, who attended as a representative of *Down-home Peer Support and Education*, was initially wary of Astra Zeneca’s involvement, but quickly felt assured that the drug company would not interfere:

[Astra Zeneca] paid for us all to come up. I don’t remember that they were there. That was important for me because -- being part of *Down-home Peer Support and Education* -- we had that controversy going [at the provincial group level] about pharmaceutical companies. So if I wasn’t comfortable, I was going to back out. I just had a comfort level from the very beginning, because they [people from Astra Zeneca] were not part of the discussions, or any of the decisions. They just supplied the money. (Interview with *Thora*, 2008)

For *Jenny*, however, the drug company’s presence was obvious and potentially compromising:

We all had our lovely little gift baskets from Astra Zeneca. Now, I’m not saying I don’t like a gift basket, who doesn’t? And they were lovely -- all these young women who are the PR [public relations] for Astra Zeneca are very lovely women and friendly and showed me a great time. ... But really, is the drug company trying to get us to advocate a patient charter of rights to be telling women that they are entitled to get whatever drugs they want or need, no matter how expensive it is? Is it going to bankrupt our health care system? I just think it’s a really complicated issue. I don’t know -- the whole thing

didn't sit well with me. It was just a bit too complex and I don't feel like those issues were really addressed.

I asked her if the questions were raised.

Some people raised those kinds of issues. I raised [the fact] that I really didn't like that I had come there and, why would we *as a group* not be deciding what kind of efforts we want? Because my understanding was that this was what the meeting was going to be about. That we, as a group, would talk about our experiences. And we would say, "You know, maybe *this* would be a very good thing." But no, it was, "*This* was what was going to be done." Well then, why wasn't that said up front? It was a little bizarre. I didn't think it was the way to do things. ...If you're going to bring all these people together, maybe *we* have some ideas -- maybe we have something that is better than what Astra Zeneca came up with! I don't think it was appropriate for them to be steering people quite so much. (laughter) (Interview with *Jenny*, 2007)

Despite her discomfort, *Jenny* was not opposed to pharmaceutical company funding *per se*.

I don't feel that because someone gives you money that you have to toe any kind of line. And I have never, ever seen -- when I think of other groups I know that take pharmaceutical money in the form of Unrestricted Educational Grants -- I think there are ways that you can do it without compromising yourself. I'm not saying you should, but there are things that are needed and if you can't find the money anywhere else -- which I think is ridiculous, that *we can't* find the money anywhere else -- I'm not sure I'm against it, in certain circumstances. You know, if something needs to be done, it needs to be done! (Interview with *Jenny*, 2007)

What did bother her was that she felt she was silenced when she questioned the appearance of a pre-set agenda:

... I brought up that I really didn't like this, and I felt that nobody wanted to hear that. You know, that I shouldn't be saying that. And I'm very much the type of person that [thinks], "Why shouldn't I say it? It's a perfectly legitimate question." There's no way I should feel like I'm being rude -- just because you gave me shampoo?

It comes back to that whole thing – just because someone gives you money, I don't feel that gives them the right to tell you what to say. It gives them the right to never give you money again if they don't want to. (Interview with *Jenny*, 2007)

*The Post-workshop Process* The workshop concluded with the creation of a Working Group made up of women who supported the idea of the Charter. *Thora* was among those who continued, while *Jenny* and *Samantha* both withdrew, *Wendy* and *Martha*, neither of whom had attended the workshop, joined *Patients, Know your Rights!* soon afterwards, when participants from each of their local communities sought someone to take their place. *Wendy* replaced *Leona*, a paid employee of the cancer care centre in her province who withdrew because she herself had not had breast cancer. She thought the document would be useful to patients but that it should be developed by women from within the community of survivors. *Martha*, by contrast, replaced a *Sue*, a workshop participant who was cool to the project because she didn't believe the proposed document would have any teeth. *Sue* thought, correctly, that *Martha* might support a patients' rights charter. *Martha* eventually became the group's chairperson and a passionate advocate for the document. Thus, a six-person working group that emerged from the initial meeting stressed regional representation, with members drawn from breast cancer organizations located in provinces from Nova Scotia to British Columbia. In hindsight, the process of forming *The Patients, Know your Rights! Working Group* tended to gloss over objections raised at the workshop – all of which resurfaced later to dog the project -- and thus may have contributed to subsequent difficulties.

While some misgivings were evident from the initial meeting, members of the six-person working group who carried the project forward did so based on their tacit knowledge of regional disparities in services for women with breast cancer and a sense



that such disparities were unjust.<sup>68</sup> For *Thora*, the first day-and-a-half of discussion reinforced her existing understanding, acquired from her experience in the regional group, and provided a solid rationale for the Charter project:

... [The organizer] had brought women from across the country to kind of brainstorm as to what was needed, what was missing. What we were able to see was that, from province to province, it was just so different -- the coverage, and care, and access to treatment and access to support. What one doctor or one surgeon said was different from what a doctor would say in a different province, and it was a real eye-opener! Because we knew there were differences, but we didn't realize how great the difference was at times.

I know people who have lived in one province, been diagnosed and come home, for instance to Nova Scotia, and had such conflicting information from oncologists and ended up totally confused and wondering what to do: "Should I follow the doctor in British Columbia? Should I follow the doctor in Nova Scotia?" And you can see really how that would cause so much stress for the patient. So I knew first hand....

(Interview with *Thora*, 2007)

From her vantage point as a member of a support and advocacy group on the Prairies, *Wendy* similarly saw such knowledge as expertise acquired in any patient-run organization. Like *Thora*, she felt that the workshop discussions reinforced and enriched her local knowledge of these disparities in services which in turn provided the foundation for a Charter of Rights for patients.

*Wendy*: As a support group, we saw the same thing that they saw at *Helping Hand*. Sometimes -- not through carelessness or lack of understanding -- there's huge differences in the treatment and in your options, in how everything happens. So we were aware of this. And, like I said, in some instances we could tackle the problem, and in some instances we didn't know how to make a difference.

[Our provincial cancer care organization] feels the same way. Sometimes they are contacted by women and of course they become aware of the differences. So when *Helping Hand* contacted them ... the person who went

to the first, original meetings thought, “Ok, this [project to create a charter] is a good thing!”

(Interview with *Wendy*, 2008)

The patients’ charter was to address these disparities at two levels: for the individual patient in conversations with her medical team, and at the societal level, as an advocacy tool that the patients’ community could use to demand policy changes. An oncologist who worked with the group underlined the utility of the charter or bill of rights as a communications tool between a patient and her doctor:

*Thora*: [He] saw the need for this, to try to get the standard of care synchronized across Canada. And he saw it as a really important document that every patient should have in their hands, to read before they go to their doctor, and [to] sit down and say, you know, “What are the resources?” “What can I tap into for support?” “How long should it be between this appointment and when I get surgery?” Because when you’re newly diagnosed you don’t know what to ask. So he saw it as a really important document just for communication between the patient and the doctor. (Interview with *Thora*, 2008)

Shortly after the initial meeting, the working group began regular discussions by conference call and e-mail. The member from Quebec had been instrumental in developing a patients’ rights charter for breast cancer in her province and the Quebec document served as a starting point for the group’s discussions.

There was a lot of talk about, “What is quality of care “What is timely care?” and getting caught up on a lot of details of what was different from province to province. We decided we really couldn’t put a time frame on treatments. You know, the clinical guidelines say you should have treatment within a certain time frame. So we would get a draft and we would show it to the medical consultant. We wanted the doctors to be onboard too. The idea wasn’t to be against the doctors, it was something that patients and the doctors could work together with. And so he would go over it and say, “No no, no!” or “Yes, add this.”

And then we would discuss it as a group. ... And that's basically how it became word-smithed, between that document from Quebec and feedback from the group. Because we all kind of know, as people who had been through breast cancer, what we want people to have in front of them.

(Interview with *Thora*)

*Martha*, who became the *Patients, Know your Rights! Working Group's* chair, recalled Astra Zeneca as very much in the background during this period. The public relations (PR) and communications company, Courtney-Rainey Group, handled the logistics of setting up teleconferences every two or three weeks. "We were really almost unaware that Astra Zeneca was sponsoring the project at this point," she recalls. As the group's point person in dealings with Courtney-Rainey, *Martha* found the arrangement, "very professional." She felt reassured that the PR company, as intermediary, kept the pharmaceutical sponsor at a distance; in addition, the group's contact at Courtney-Rainey enthusiastically supported the project and maintained regular contact with the *Patients, Know your Rights! Working Group*.

By late fall 2003 they felt ready to send what *Martha* called "a more or less finished draft" out to other groups across the country in order to "test out the waters locally and get some feedback." To the dismay of members of the *Patients, Know your Rights! Working Group*, not everyone agreed with the draft Charter. Indeed, objections from the community precipitated an unanticipated crisis within the Working Group and generated a delay of almost a year. *Thora* describes the response this way:

Some people figured it was a waste of time because there are patient charters in every hospital and that should be enough. Another criticism was that a patients' charter wouldn't have any teeth. And we still have that problem, right? ... And I think, because there was a pharmaceutical company sponsoring it, it was hard for people to buy into it. It sort of put a damper on it. Instead of people coming on board to help make changes [to breast cancer treatment] in Canada, it became an issue of, "There's a pharmaceutical

company sponsoring it, so really, do we believe it?” Which was too bad, really. (Interview with *Thora*, 2007)

The first objection stemmed from the fact that patient charters and patients’ bills of rights have been a growth industry both in Canada and internationally since the 1990s. In addition to the charters in many hospitals, provincial governments across Canada have introduced bills at various times to articulate patients’ rights and responsibilities; a few countries, notably France and the U.K., have national Charters (Vogel, 2010a). The plan to develop yet another charter or bill of rights for patients in Canada thus raised the question: why invest time and resources to produce yet another? Furthermore, once produced, what claim to legitimacy would this charter have over others?

A related concern was the fact that the *Patients Know Your Rights! Working Group* was an ad hoc structure of volunteers created for the sole purpose of developing a patients’ charter. Once the document was ready, new patients would only make use of it if an organization or agency made a point of promoting it. The *Patients Know Your Rights! Working Group* members I interviewed had hoped *The Hub*, as the community’s national voice would take ownership of the charter; however; the national group declined to be the host organization. In part this was because the president of *The Hub* at the time thought existing hospital charters were sufficient. As discussed below, however, other reasons likely came into play as well.

The second objection, that the charter would have “no teeth” is a common objection to such documents (Vogel, 2010b). Statements of patients’ rights vary in content and in force. The majority are voluntary guidelines which assert policies based on moral maxims, such as, “the right to participate in decisions affecting care,” and “the right to individual dignity and privacy.” These assertions may be backed up by

institutional mechanisms for filing complaints, such as an ombudsman. Documents that assert entitlements to goods and services (e.g., limits on waiting times or a right to particular medical tests or treatments) are rare and, when included, are tied to structural and economic constraints (Smith 2002: 10). In Canada, numerous attempts to enshrine patients' entitlements in law have been unsuccessful, according to Lauren Vogel: bills in Alberta and Ontario were defeated and a provincial Health Council in Nova Scotia rejected the idea of a bill of patients' rights as legally too complicated. A section of Quebec's *Loi sur les services de santé et les services sociaux* (Act concerning health and social services), passed in 1990, includes a statement of patients' entitlements, both moral and material, but material rights are restricted to those which the individual's chosen institution has the resources to provide (Vogel, 2010c). The initial version of the Patients' Rights Charter included material rights as well as moral rights (in particular, the right to certain medications) but the final document included only moral rights.

The Working Group struggled with the question of what a breast cancer patient could do if she felt the rights spelled out in their document were not being respected or met; they could not think of an agency to which the patient could appeal to give the document force, or even a way of reaching patients before they made their treatment decisions.

If a woman was diagnosed, and the standard of care wasn't being met, what recourse did she have to have that corrected? You know, we didn't solve that. That was, I think, one of the faults of the Charter, that it didn't develop a mechanism -- aside from the Canadian Cancer Society information line -- but everybody recognized that that wasn't the ideal way to go. And also, the political landscape had changed in terms of services being offered to women. Increasingly, women's surgeries became shorter and shorter and women were being discharged so fast that there was no way, if you had a [hospital] visiting

program, that you could get through to people [to give them a copy of the Charter] before they were even out of hospital. (Interview with *Martha*, 2007)

A third objection to the document related to pharmaceutical company sponsorship and to the question of material entitlements, in particular to two mutually reinforcing claims included in a draft of the document circulated to other groups in late 2003 and early 2004. Section I, Items 2 asserted that patients have “the right to the highest standard of care ... regardless of cost” and Section I, Item 8 made the claim, “You have the right to have all costs associated with your breast cancer diagnosis and treatment covered under medicare [sic]” In fact, neither of these claims corresponded to the realities of Canada’s health care system. For one thing, the treatment guarantees under the Medical Care Act and the Canada Health Act which define Medicare in Canada have always recognized fiscal limitations. Second, Medicare does not include specific coverage of pharmaceutical drugs except for hospitalized patients, an omission that policy makers have grappled with since the Medical Care Act was introduced in 1966 (Armstrong & Armstrong, 2008). Medicare does, however, cover essential treatments and procedures carried out in a hospital. Because older, cytotoxic cancer drugs have been administered by infusion in-hospital, they have in fact been covered. More and more, however, cancer drugs are available in capsule form, to be self-administered at home by the patient. The coverage of these drugs becomes a case-by-case negotiated decision under provincial formularies and private drug plans. If the Charter was designed as a lobbying tool, it could conceivably be used to rally patients to demand rights they did not yet have in law; and this may have been the intention initially (recall that the original meeting was labeled an “advocacy workshop”); the final document, however, was framed as an educational

document, in part to help patients communicate with their doctors and, also as a basis for advocacy at the political level.

A further point of interest in the *draft* patients' rights document is that a glossary of terms included the phrase "adjuvant treatment," illustrated with two examples: tamoxifen and Arimidex® -- both drugs made by Astra Zeneca. Tamoxifen was indeed an approved adjuvant treatment in Canada at this time, and had been for many years; at the time the draft patients' rights document was circulated, however, in late 2003- early 2004, Health Canada had not yet approved Arimidex® as an adjuvant therapy for breast cancer. This approval was granted in July 2004 (Astra Zeneca 2004; Health Canada NOC Database: Arimidex®). Thus, embedded within the generally uncontroversial claims to moral rights, the document included a number of material claims that are part of a contested discourse on the direction of Canadian health policy.

*Autoethnographic Interlude.* At this point, my own prior engagement with the issue as a member of the community became an unexpected factor in the narrative I was researching. In February 2004 I had received a copy of the draft document from *The Hub* as one of many breast cancer survivors throughout the country on that organization's large electronic mailing list.<sup>69</sup> I was not at the time aware of the *Patients, Know your Rights! Working Group's* existence or history and I mistakenly assumed the document I received had originated with *The Hub*. In fact, *The Hub* was only one of many to whom the *Patients, Know your Rights! Working Group* had sent the document, in order to obtain reaction from the larger community. Alarmed by the document, I responded to the request for input with a letter which I e-mailed to *The Hub*; because of my

misunderstanding about the document's origins, I framed my objections as if that group and its board were responsible for drafting it (Appendix B).

My central argument was that, in encouraging breast cancer patients to demand that all aspects of their breast cancer treatments be covered under Canada's Medicare system, regardless of cost, the group was promoting an unrealistic sense of entitlement, abdicating its educational role (as I saw it) of encouraging patients to critically evaluate costs and treatments, and putting the country's system of universal health care at risk over the long term. I further claimed that the pharmaceutical industry "stands to benefit far more than patients from a document that claims patients have a right to disregard treatment costs." Finally, I wondered whether a pharmaceutical company had funded the project and contributed to framing the document. I urged *The Hub* not to risk losing credibility as an organization engaged in health policy advocacy work by releasing the document in its present form.

The group's executive director (whom I knew) responded in a friendly e-mail, pointing out that the group was "not the lead player in the project" and would be discussing issues related to the project at an upcoming board meeting. She added that she had forwarded my e-mail to *Helping Hand*, the lead organization, and to others who were directly involved (see full text of letter and response in Appendix B). By this indirect route, my letter found its way to the *Patients, Know Your Rights! Working Group*, whose members neither responded to it nor acknowledged receipt of it. When I began my research some years later, I had forgotten about writing the letter.

Against this backdrop, I was surprised to discover in the course of my interviews that the letter had in fact disrupted the work of the *Patients, Know Your Rights! Working*



*Group*, stalling the project for almost a year and contributing to one of the group's major failures – *The Hub*'s refusal to provide a home for the document once it was launched.

As one of the *Patients, Know Your Rights! Working Group* members told me:

*Martha*: I mean this isn't said in a blaming way, but [your letter] just stopped things cold in its tracks. Things sort of pattered along for the next year. ... But anyway, we kept [going] along and we had phone calls every so often discussing what would be the next steps. (Interview with *Martha*, 2008)

*Thora* also recalled the year after the draft was sent out to the community as discouraging.

When you're hit with things being thrown in, and having to defend, and look for organizations to work with, and all that, it's very time-consuming and it takes some of the wind out your sails. You kind of just sit there for a while until people say, 'Ok, come on, let's pick it up again, we can do it!' It took a little while, yeah... (Interview with *Thora*, 2008)

*Wendy*, the third member of the *Patients, Know your Rights! Working Group* that I interviewed believed that my letter was the main reason *The Hub* would not provide a home for the charter ("our biggest failure"), notwithstanding the then-president's belief that hospital-based patients' charters were sufficient. Another factor contributing to *The Hub*'s reluctance, she acknowledged, was the fact that the national organization had previously entered into a partnership with a different pharmaceutical company and had been badly burned:

*Wendy*: They went into this whole partnership thing and ... well, in the end, it made it look as if the [organization] was supporting this new drug that [the company was making] to help people with anemia. And of course, since then there's been a lot of literature that these kinds of drugs interfere with the chemotherapy. So this was a very bitter [experience] ... Now that's a specific drug company but it's certainly enough to make you nervous about *any* drug company. ... But what tipped it was your letter. (Interview with *Wendy*, 2008)

Like many of the women I spoke to who were open to drug company partnerships, *Wendy* was far from a cheerleader for the industry; indeed, she agreed with most of the points I had raised in my letter, which I recounted in our conversation: that costs for drugs placed on formularies had to be contained if a publicly funded system was to survive; that to achieve this, Medicare funding had to be restricted to drugs and procedures actually shown to have tangible benefits to patients; that drug companies would be only too happy to see Medicare replaced by a two-tiered system; and that Medicare's resources had to be distributed among all diseases, not allocated disproportionately to those which had organized lobby groups.

*Wendy*: It's not that we didn't have many of the same concerns. We don't want a two-tiered system. We don't want [that], any more than we want some stupid little company that's got nothing to do with us putting a pink ribbon on [its merchandise] and sailing along on our work, getting good will for no reason. (Interview with *Wendy*, 2008)

*Wendy* responded to my view that patients' groups should be challenging some of the price tags on these drugs with an emphatic, "I *totally* agree with that." She cited her own family's experience in trying to ensure that her brother-in-law had access to Tarceva®, a new treatment for lung cancer which cost \$5,500 for a round of treatment, only part of which was covered by the provincial drug plan. In her view, the problem of escalating drug costs began in the 1987, when the Progressive Conservative government of the day extended the patent protection of pharmaceuticals from 17 years to 20 years:

You're right about the two tiers, and the cost. It's formidable. And I can't help but curse [former Prime Minister] Brian Mulroney whenever [patients are hit with high drug costs] because when the talks about drugs were opened

under his administration,... he extended the time before generic drugs could be made.<sup>70</sup>

(Interview with *Wendy*, 2008)

*End of Autoethnographic Interlude.*

The version of the charter that was ultimately published, she pointed out, did not make the claim that “Everyone has the right to every new treatment regardless of the cost”; instead it said that patients have a right to “timely and accurate care by a health care team and optimum standard of care and best practices.”

*Wendy*: But that’s including prevention, screening, diagnosis, surgery treatment, and right to palliative care [i.e., not just drugs]. And it says “treatment by a suitably equipped and organized practice hospital or cancer centre, comprehensive coverage of costs by Medicare, and where costs are not covered, information on financial assistance.”

As for the potential systemic injustices that might arise from one well-organized disease group promoting its “rights”, *Wendy* explained:

We also don’t want to be seen as thinking we’re more important than anyone else. We simply have, as a group, a large chunk of at least short-term survivors, whereas lung cancer can’t say that. So we can organize first. ... We’re just a huge group. We have more people getting it and we have, thank god, more people who survive at least five years. So it makes us a better group to study for many things and it makes us a likely group to do this kind of work. (Interview with *Wendy*, 2008)

At the same time, *Wendy* was sympathetic to the decision of groups such as *The Hub* to accept funding from the pharmaceutical industry; if any moral blame was due for the industry’s growing role in the funding of patients’ organizations, she placed it on the federal government’s policy of systematically cutting back grants:

You can certainly see that the way the government treats them [i.e., *The Hub*] -- expecting them to do the work and cutting their funding -- they need funds from somewhere. ... And it's wrong that they spend all their time raising the funds and not doing the work that the funds are intended to let them do. (Interview with *Wendy*, 2008)

*The Patients Know Your Rights! Working Group Gets Unstuck*. In late 2005, Carmel, the executive director of *Helping Hand* who had organized the project brought the *Patients, Know your Rights! Working Group* together for a face-to-face meeting in Toronto. This meeting proved to be a turning point which enabled the members to break the psychological logjam precipitated by criticisms from the community. What most impressed the participants was the opportunity to meet a prominent activist from the European breast cancer community, Stella Kyriakides, who met with the group prior to speaking at an annual American Society of Clinical Oncology (ASCO) meeting in Florida. A clinical psychologist by training, Ms. Kyriakides was diagnosed with breast cancer in 1996 and became active in breast cancer issues as an organizer, writer and speaker -- first in her home country of Cyprus and then in Europe and internationally. In 2006 she was elected to the Parliament in Cyprus.<sup>71</sup> As a member and eventually president of the Executive Board of *Europa Donna* (a coalition of European Breast Cancer organizations), she was active in an initiative to promote high standards of breast screening and breast cancer treatment throughout the European Union.<sup>72</sup>

*Thora* recalls being “blown away” listening to Ms. Kyriakides describe her early activism in Cyprus, a much smaller country than Canada where breast cancer had not even been on the political agenda, and how, through *Europa Donna*, European women had together developed a cohesive vision to shape their advocacy and bring it to their Parliament. By contrast, *Thora* felt Canadian advocates “had no cohesion as far as what

everyone was working on.” For her, the story of breast cancer advocacy in Europe provided a context that helped make sense of the whole Charter project. *Wendy*, the member from the Prairies, also identified meeting Stella Kyriakides as a turning point, particularly in the way she underlined the group’s tacit knowledge as women with breast cancer as their source of legitimacy:

Everyone had a certain amount of hesitancy. We knew this was a good goal. We understood it, because breast cancer is the [particular] cancer we understand. We did not want to be seen as thinking our cancer was more important than anybody else’s. But... it was hard enough to get the breast cancer groups together -- we had no way of dealing with *all* the cancer groups. We were having a hard enough time keeping it coherent, representing everyone across the country. I think in our hearts we had doubts about how to proceed in the most ethical manner possible. And she was so clear. She said, “You want to arrive at the right decision. Who are you? You are breast cancer advocates. Do this wholeheartedly! Only good can come from that. This can grow wider, but it has to grow well from here.”

It really helped us. It helped us to erase our doubts and to focus and to go right ahead, strongly. Because I thought, “of course she’s right.” And I said to someone at the meeting, “You know what? Medicare started [small] in Saskatchewan. Of course this is right. This can be bigger, but we must do our job well, this is *our* step, this is the step *we’re* able to take. (Interview with *Wendy*, 2008)

*The pharmaceutical company’s presence becomes visible.* Despite the success of this meeting, in November 2005, that same fall a number of other changes transpired about which members of the *Patients Know Your Rights! Working Group* were markedly less enthusiastic. In each instance, the pharmaceutical company exerted pressure in a way that the members of the Working Group viewed as “not right,” despite the fact that the actions did not bear on the actual content of the Charter.

In September 2005, the Working Group was trying to finalize the Charter, including making changes to address the critical feedback from various external sources.

At one face-to-face meeting, the pharmaceutical company brought in an activist who was also a professional writer to help draft the changes and finalize the document; other members of the group did not realize until later that the company was paying her.

One member that ostensibly was a member of the Working Group -- and we were all volunteers -- her career was in organizing like this and in freelance writing, and she kept saying, "Well, I'll work with the Courtney-Rainey personnel to help with this and this." And she was doing it, and I understood why she would volunteer to do it, but it was *much* later that we found out, and *never* officially, that she was in fact being *paid* to do it, which made her an employee! Well, that did not sit well with us. ... We weren't being paid by Astra Zeneca. And I don't know if she was being paid by them or by Courtney-Rainey, it was never clear, but we didn't think it was right that it was happening without our knowledge.

And that's just a small point. But we *so* wanted to make sure it was all straightforward and above board so it could pass *any* scrutiny. That was critical to us... because we just needed it to be so transparent! And if there was a good reason for paying her for her good work, this [was] not a problem to us although it might have meant that she'd have to sit at the meetings without contributing. We'd need to have hammered that out. I do usually work where people are volunteers, and then you are at least -- you might be fumbling but you're on the same footing. ... So people know that when I say something it can't possibly benefit me. (Interview with *Wendy*, 2008)

In a second decision -- this one after the meeting with Stella Kyriakides -- Astra Zeneca replaced Courtney-Rainey Group with a different PR company, National Public Relations, without consulting with the *Patients, Know your Rights! Working Group*. This distressed the members of the *Working Group* whom I interviewed because they had established a congenial working relationship with Courtney-Rainey Group; losing the company's logistical support seemed like another setback just when they had renewed their focus. Secondly, rather than working with the newly hired company, the group found itself suddenly in a direct working relationship with an Astra Zeneca employee

responsible for patient-liaison, *James*, who members of the *Patients Know Your Rights! Working Group* described as “very hands-on.” *Martha* at this point had taken over as the Chair of the *Patients Know Your Rights! Working Group*. She first met *James* at the annual Breast Cancer Symposium in San Antonio Texas, sponsored by the American Society of Clinical Oncologists (ASCO) and held that year from December 8 to 10.<sup>73</sup> She reflected on the events of this transition period:

First of all they fired Courtney Rainey, which I think was a *major* mistake, because they had been doing a really good job of holding us together and keeping things on track. And they were really committed to [the project]. ... So that really left us in a quandary because we were dealing with *James*, from AstraZeneca, directly. And we had never, ever, dealt with Astra Zeneca in any way up to that point. The company was sort of in the background but we didn't know anything about it. So all of a sudden *James* starts organizing and changing the phone calls, and calling me. He said to me, “Look, we've let Courtney Rainey go and we've got to hire our own PR firm, and that will take” -- he gave me a timeline -- I think it was until basically the end of March to get the new PR company in place. (Interview with *Martha*, 2007)

This was just a few months before the official launch of the Charter, in May 2006, at a national conference of breast cancer research called *Reasons for Hope*.

*Martha*: So I think that was an adjustment for all of us, but at that point we were so determined to finish it that we put up with perhaps more than we would have otherwise. Although *James*, I have to say, I have a very warm spot in my heart for him because he was a nice guy, but he was like a bull in a china shop because he took such a hands-on role. That's never happened to me. Usually it's been the leader of the breast cancer group that's taken on the role. To my mind, he never should have been on the teleconferences. (Interview with *Martha*, 2008)

*Wendy* reinforced these sentiments:

*Wendy*: When they changed public relations groups, we were very uncomfortable with *James*'s hands-on attitude. And there were several times where he said he would phone someone, and I voiced this [discomfort] clearly. I said, “I think *Martha* should be the one to phone. *Martha*'s the head

of our group, she's chairing our group." You know," (laughs in exasperation), "It's not appropriate!"

Sharon: And he would agree?

Wendy: Well he would just keep trying to change things. He would say, "Well is it agreeable if I contact so-and-so?" (Interview with *Wendy*, 2007)

The group members' understanding about what was appropriate behavior for the pharmaceutical company hinged on their belief that the project's funding was awarded as an Unrestricted Educational Grant, a term with which most advocates were familiar, although not everyone agreed on its meaning. The women I interviewed from the *Patients Know Your Rights! Working Group* took the phrase to mean that the company would provide funding for a project, the broad lines of which both parties concurred with at the outset (e.g., a Patients' Rights Charter), but the group would make all the ongoing project decisions. As the May launch date of the Charter approached, tension escalated over the divergent understanding that the *Working Group* and the pharmaceutical company had of the Unrestricted Educational Grant. Prior to a final, pre-launch meeting, the draft document had included the acknowledgement, "supported by an unrestricted educational grant from Astra Zeneca Canada"; but Working Group members arrived at the meeting to find this phrase had been removed from the document circulated for final approval.

Wendy: Just before we were ready to launch we had one more face-to-face in Mississauga. At that time he [*James*] had removed the language about a non-directed [sic] educational grant. ... And of course we were shocked, we said, "No, no, this has to go back in!" And he said, "But it doesn't matter and our lawyers are not comfortable with this." ...

And that's when I, one of the few times I spoke up -- because I've always felt that I'm a better soldier than I am a general -- Anyway, I said to him, "No, no, do you realize that all this work is for nothing, the Charter will mean *nothing*, without that? People will simply be suspicious, this will be an Astra



Zeneca “something,” it will not represent people with breast cancer.”  
(Interview with *Wendy*, 2007)

Members of the group were genuinely perplexed by the removal of the Unrestricted Educational Grant phrase because, despite *James*' intervention in their operations, they felt that he and the company's previous representatives had not interfered with the most important aspect of the Charter, its content.

*Wendy*: I said, “You haven't interfered -- why would you be afraid to say that?” And certainly there was a lot of [discussion], *Martha* is a very capable speaker and so is *Thora*. And Carmel [the Executive Director of *Helping Hand*] is very determined. So there was no doubt that in that room there wasn't a single person that would let that go by.

Sharon: Why do you think their lawyers were uncomfortable? Did he say?

*Wendy*: Nope. He just said that they had said, “Oh, remove that.” But of course we were firm. And he didn't fight us on it when he saw that it would mean that the work would have gone for nothing and the Charter would become meaningless if it was an Astra Zeneca charter.

And I spoke frankly, I said, “You know, most of us have a real distrust for working with large companies, especially drug companies. We do not want to be seen as pawns, and we are not puppets to have our strings pulled.” And I said, “So the fact that you *have* done this in a way that could be documented [to show] that you were not directing things, it doesn't matter! Without that wording people will suspect, and rightly so, and it just will make it meaningless.”

And I think he understood what we were saying. I think he thought that we were being a bit overly fussy about it. But I think that he got it anyway. Whether or not he agreed, *we* all agreed and [felt certain] that there would be literally hundreds and perhaps thousands of individual people who had breast cancer who would agree [with our perspective]. So it was never brought up again. (Interview with *Wendy*, 2007)

*Launching the Patients' Rights Charter.* The launch itself took place in Montreal at *Reasons for Hope*, a conference held every two to three years to showcase Canadian research on breast cancer. Initiated by Health Canada in 1994, the project subsequently attracted a number of national breast cancer charities subsequently became partners, forming the Alliance which continued to hold grant competitions and scientific conferences until its administrative offices were closed at the end of March, 2010. The conferences were geared to researchers but the support of advocates was viewed as vital to maintaining public support for the research fund; breast cancer patients' organizations across the country were thus provided with one or two free entrance passes and travel and hotel costs were covered for several dozen survivor group members for the duration of the meeting.

The event was held at the end of an afternoon in the break before supper and was attended primarily by the several dozen women with breast cancer who were at the conference and by a smattering of journalists. Once again, the members of Working Group felt that *James*, the company representative, was too visible and hands-on -- he literally greeted people at the door and shook their hands, introducing himself as from Astra Zeneca. He did not, however, sit at the speakers' table or address the audience or the press during the actual launch ceremony. The ceremony consisted of short speeches by several members of the Working Group from different regions of the country and an oncologist who had been supportive of the group's efforts. They described the purpose of the Charter, how it was developed, and the hopes they had that Canadian breast cancer patients would take ownership of the document and use it to learn about and assert their rights. Printed copies of the Charter in French and English were available and a table of

hors d'oeuvres encouraged people to linger while members of the *Patients, Know your Rights! Working Group* spoke to the press.

*Martha* recalled the launch with some discomfort. *James* had recently been transferred to Canada from Europe before being assigned to the file and she attributed his high visibility to his lack of understanding of the political tensions within the Canadian breast cancer community:

*Martha*: It bothered me frankly that Astra Zeneca was there, and so blatantly in public sight. As you know, this [pharmaceutical company sponsorship] is a very hot issue and it was like throwing it in people's faces.

Sharon: Had you talked to him beforehand about his role?

*Martha*: Oh, yeah, yeah. But he had no idea what we were talking about, and what I was talking about. Because I guess in Europe they work very differently. ... He was quite used to taking a public role. And I explained to him the sensitivities. In fact he saw your letter. And I said, "This is the kind of thing that we want to be very cautious about."

Sharon: What did he say about the letter, did he comment on it?

*Martha*: He said, "You just have to deal with it." But it wasn't that easy to do. (Interview with *Martha*, 2007)

*Martha* also thought the new PR firm had some responsibility for reigning *James* in, "Because they should have known that if you've got an unrestricted educational grant, the PR firm takes a much larger role."

By the time the Charter was launched, *The Hub* had a new president. In a final attempt to bring *The Hub* on board as the Charter's home, the Working Group members agreed to have *James* approach *The Hub*'s executive director. She was sufficiently receptive to prepare a proposal, a three-year plan which would have involved Astra Zeneca providing *The Hub* with some financing for a different project. At this point,

*James* balked and terminated the negotiations, much to the chagrin of one member of the *Patients, Know your Rights! Working Group*, who felt they should have had a say in the disagreement.

*Wendy*: Certainly he has the right to turn them down flat about financing, because that's what *he* does. But he brought it to us and told us that it happened ... he turned them down flat before he told *us* he was turning them down flat. So that felt reasonably autocratic, you know... I don't know. It's up to us! ... If [Astra Zeneca] turned it down, I think we should assist *The Hub* in finding somebody [to fund their project]... We care about the Charter! [emphatic] (Interview with *Wendy*, 2007)

*Thora*, however, was more sympathetic to the company's perspective:

*Thora*: Astra Zeneca was a little miffed [to be asked for money] after *The Hub* had given them so much hardship over the Charter, so that they declined.... This is what happens, right? *The Hub*, for instance, really weren't open to talking about [the Charter] and finding out what it was all about. And when there's that cut-off of communication, it makes it really hard for future negotiations, which was really unfortunate. (Interview with *Thora*, 2007)

*Thora* attributed some of *The Hub*'s caution to a contentious atmosphere among Canadian breast cancer groups at the time the document was developed and launched. Not only had *The Hub* backed away from the Charter but a collaboration of organizations representing all cancers decided to develop its own patients' charter and so declined an overture to launch the breast cancer charter at one of its events:

*Thora*: I think it was a very political time three to four years ago. Breast cancer groups are -- they'll eat themselves, you know! They're very full of conflict at times. Sometimes the environment is very caustic like that. And it tends to go in waves, or cycles [...] Sometimes people work together and then at other times it's very difficult to get projects done together. Often you get groups that are keen to do something and others that don't and it just doesn't seem to work.

And it seems like that was a real time when there was a lot going on across Canada, in terms of breast cancer projects ... people were more inclined to do things that they felt were closer to home for the patient. This seemed more -- higher in the sky, perhaps, and they thought that it was a lot of time and effort for something that wasn't directly helping the patient today. ... It wasn't a support group. It wasn't changing a procedure in a hospital, or bringing women together. It was a document that some felt didn't have teeth. (Interview with *Thora*, 2008)

Once the Charter had been launched the *The Patients' Rights Working Group* experienced another frustrating lull, which *Thora*, *Martha* and *Wendy* attributed to a variety of factors. *Martha*, the group's chair, had a number of health setbacks which drained her energy and absorbed much of her time. The originator of the project, *Carmel*, from *Helping Hand*, took the reins as executive director at another cancer organization, and the member from Quebec retired from her activist organization. *James* (who everyone agreed was "a doer," despite his intrusive style), returned to Europe. Neither his replacement nor the new public relations firm took any initiative to contact the group. The few remaining members of the group were left in limbo. Without funds or clear direction they returned to the demands of their local-regional organizations.

*Thora*: ...because of the way the breast cancer industry [sic] is, you often have the same people doing all the work. And it was very draining for even those of us who were on the committee because we had so many other things we had to do. We didn't always get a lot of support -- not because they didn't believe in it sometimes, but because they did not have the human resources to put into it. The number of volunteers was really on the decline at that time. ...And so, unless it was something that was an absolute priority, it just did not get attention.

Sharon: Do you think that has to do with cutbacks in funding?

*Thora*: Oh, definitely, I'd say. I think it was just too -- people getting burnt out. Like, there's a cycle for that too, right? But of course, everyone's rallying for funding for a certain project and trying to do it the best that they can. ...and they just can't stretch themselves any further. (Interview with *Thora*, 2007)

Because the Working Group was an ad hoc committee created specifically to develop the Charter, it now needed an organization to take ownership of the document so that newly diagnosed women would be aware of it and so that its advocacy potential could be realized

*Thora*: Who was going to own it? Because the pharmaceutical company couldn't own it, that wouldn't be right. ... Or, originally we thought maybe *Helping Hand* would, or, actually, we thought *The Hub* would, because it was a national voice for breast cancer across Canada. But the president at the time was totally against the Charter. ... She was very vocal against it. Which was kind of a shame, you know ... because that's where I still think it should be, [where] we think it should be. (Interview with *Thora*, 2007)

*Who Controlled the Process?* The Working group's frustration over being absent from the negotiations with *The Hub* illustrates a larger dilemma posed by the drug company's sponsorship. Throughout the project's history were instances in which Astra Zeneca, the two public relations companies and *Helping Hand* (the lead group on the project), guided the process in directions that other members of the *Patients, Know your Rights! Working Group* – including *Martha*, the titular chair for much of the group's history -- did not fully support. While the Working Group members felt they maintained control over the Charter's content, they also acknowledged that many administrative and procedural decisions were made without their participation and were hence beyond their control. In retrospect, *Thora* dated the problems back to the very first meeting:

*Thora*: I do really think things should have been started [pause] ... better. I think they should have let people know what they had in mind before they invited them. They should have had representation from each of the provinces and ... the prep work should have been there.

Sharon: Before you went to that initial meeting?

Yes. I think we were all kind of surprised. We didn't really know, I mean, it was a natural procedure to see, "Ok, these are the problems, here's the solution" but it wasn't a solution that came from the committee members, it was something Carmel had already thought of because she had a contact in Europe who did it [i.e., Stella]. And so, it would have been nice to have known that, or to have seen some of the documentation from Stella, before we even went to the meeting. So, it's kind of 20-20 vision in hindsight that the prep work should have been there. (Interview with *Thora*, 2007).

This lack of control extended to other decisions, such as paying an activist who they thought was volunteering to edit the Charter, the switch in public relations firms, and *James*' sudden appearance a few months before the launch and his disappearance soon afterwards. A year after the launch of the Charter, *Wendy* remained puzzled by *James*'s role:

*Wendy*: Well, I just kind of think [Astra Zeneca] brought this guy in to tie down some loose details and maybe to extract themselves from some community projects. I mean I could be mistaken. But he came over, he pushed this [the Charter] through— he *certainly* seemed to get exceedingly involved – and then he was gone!

Sharon: Hmm.

*Wendy*: So, like -- I cannot tell. I don't know their corporate philosophy for this year, you know?

In mid-2007, more than a year after the launch of the Charter, members of the Working Group were not certain whether Astra Zeneca was still a player. *Martha* was

beginning to regain strength after some health problems that had required hospitalization and was ready to re-engage in activist work but was uncertain about the Charter:

*Martha:* In some ways I feel it's so remote now.

Sharon: Well it does seem a bit adrift. You're not meeting actively with your group now, are you? Or talking, you're not making plans?

No. Like, whoever replaced *James* is not making himself that visible. ...I was supposed to talk to him, and he was supposed to call me and he didn't. So I called him and I e-mailed him. He'd be the person who'd have to make a commitment to get us organized.

*Wendy*, however, felt it was now up to the *Patients' Know Your Rights! Working Group* to take the reins and move the project forward. She was encouraged that several other nation-wide cancer organizations – a lung cancer and a colorectal cancer group -- had adapted the Charter, giving credit to *Patients' Know Your Rights!* as their starting point.

Even more encouraging, in the spring of 2008 *Wendy* was able to claim, with satisfaction, that the charter produced by *Patients, Know Your Rights!* had served as a model tool endorsed by the *Canadian Cancer Plan*, a national initiative to combat cancer in Canada. The *Canadian Cancer Plan* had been developed over a period of years, beginning in 1999, by a broad coalition of cancer agencies and groups (I discuss the *Canadian Cancer Plan* in more detail in Chapter 5). An Action Group within the *Canadian Cancer Plan*, which was responsible for ensuring the patient's perspective was not lost and for improving the quality of life for cancer patients and their families, had endorsed the idea of a cancer patient charter. To *Wendy's* delight, this Action Group had not only modeled its Charter on the one developed by *Patients, Know Your Rights!* but



had presented the modified document at a series of cross-Canada workshops. As *Wendy* wrote in the newsletter of her regional breast cancer group:

... Our wish at the time of the launch ... was to encourage other cancer groups to develop a charter adapted to their needs and finally to have enough groups on board to be able to pressure the federal government with the tool to force them to act on our behalf and assure us of national standards. Now the federal process is backing this national team to develop a cancer patient charter based on our document. This seems like a dream come true. At the very least, this is a solid step in the right direction.

It appeared that the Charter would have a home after all, vindicating the *Patients, Know your Rights! Working Group's* years of work and their struggle to maintain control over the content. Shifting to a more cautious tone *Wendy's* article goes on to say that the vision of a patient-centred cancer care system has been articulated many times in Canada, by a succession of individuals and committees since the early 1990s, she concludes: "We must all stay alert and active so that this time words and vision are put into practice nationally to the benefit of all Canadians."

### 3.1.4 Summary and Analysis of the Group Biographies

These narratives provide a portrait of the world(s) of Canadian breast cancer groups over some twenty years of activism, particularly in relation to questions of funding and even more specifically, in relation to funding from the pharmaceutical industry. The accounts presented here have been constructed to highlight the ways in which overlapping and conflicting discourses on pharmaceutical company funding affects breast cancer groups. The narratives also provide a glimpse of the way breast cancer group members constructed their understandings of pharmaceuticals and pharmaceutical

companies as social worlds which are separate but which intersect with their own. In these accounts, I show these worlds from inside three breast cancer groups; in subsequent chapters I examine the factors and processes that contributed to the evolution of these worlds.

As noted in the previous chapter, discourses are multi-modal, multi-voiced, and serve multiple purposes. My analysis rests in particular on the critical analysis approach which examines these layered meanings to discover ways in which discourses serve to negotiate social interaction, to produce identities and subjectivities, and to express ideologies and control through the exercise of power/knowledge.

The narratives above sketch the very different trajectories by which each of the three groups developed a discourse about pharmaceutical company funding. The accounts also begin to articulate the layers of discourse found within the three groups and beyond: within other breast cancer organizations in Canada and within intersecting social worlds within the breast cancer arena such as the pharmaceutical industry, governments and foundations.

The board and staff of Group One, *Critical Advocacy to Prevent Cancer* have consistently viewed funding from the pharmaceutical industry as a conflict of interest that ultimately undermines the group's credibility and its mandate to speak critically about cancer medications and related policies. The "No Pharma Money" policy adopted in 2001 formalized this discourse with a public statement and a requirement that anyone joining the group's board or staff agree with the policy. Decision-making members do, however, differ in how passionately and/or how hard line they feel about this issue; thus, internal discussions about pharmaceutical and other sources of corporate funding are not

uncommon, but they centre on strategic questions such as how strictly to apply the policy, how far to expand it, and whether the organization should attempt to change the views and practices of other actors within the breast cancer arena. Several attempts to promote the policy to other organizations and agencies proved unsuccessful, leading *Critical Advocacy to Prevent Cancer* to embrace and promote the policy as one of the features of its group identity that makes it unique among breast cancer groups in Canada.

The twelve active group members who made up the decision-making core of Group Two, *Down-home Peer Support and Education*, by contrast, recognized conflicting views among themselves over funding from the pharmaceutical industry within a few years of the group's founding. Identifying the issue as potentially divisive internally and a possible threat to the group's hard-won credibility in the community, members of the board, through frequent discussions, shaped a discourse on this topic which *defines pharmaceutical company funding as presenting moral and practical dilemmas that are inevitable, ongoing and unresolvable but manageable through case-by-case decision-making*. The case-by-case policy forces the board to examine and discuss each proposal involving pharmaceutical company funding that comes before it, parsing the conditions and the diverse points of view of board members, and weighing the potential effects on the group's reputation as well as on the internal dynamics. Through repeated board discussions, and the leadership of members such as the web-mistress and the fundraiser, informal norms for negotiating the intra-group divisions were established and the discourse became nuanced to articulate common understandings and disagreements of when funding from pharmaceutical companies might be accepted or refused, and why. The case-by-case policy helped shape the group's external interactions

as well, allowing its board members to bargain with a drug company, making demands such as “no signage” at an event, requiring that all phone calls about an industry-funded event go through their office, and requiring that the funding be awarded as an “unconditional educational grant.”

The *Patients Know Your Rights! Working Group*, as a group funded from the outset wholly by a pharmaceutical company, developed its discourse on pharmaceutical funding following yet another trajectory of internal debate and external communication. A tension over industry funding was evident from the first workshop when one participant raised concerns that the industry’s funding contributed to the pre-set agenda, a concern which she felt others did not want to hear. Throughout the project, the discourse of discomfort over pharmaceutical industry funding resurfaced and subsided several times. Initially, participants who disagreed with aspects of the process simply dropped out of the group and were replaced. Those who remained or joined after the first meeting did so because they saw merit in the project; furthermore, they experienced their central activity in the Working Group – creating the content -- as independent of industry interference. The public relations agency that buffered members of the *Patients Know Your Rights! Working Group* from direct contact with the company aided participants’ conviction that the group decisions were made autonomously. Receipt of a critical letter from a member of the survivor community destabilized the internal discourse of autonomy and sowed doubt within the Working Group about the project’s value to patients; however, the powerful counter-discourse of a European activist reignited the group’s confidence a year later by emphasizing the project’s potential to benefit cancer patients. The group’s internal discourse of autonomy was challenged again when *James*,

a representative of the pharmaceutical company newly arrived in Canada, took charge of the administrative process, firing the public relations agency and making decisions the group members considered off-limits for the industry. This tension came to a head in the disagreement between the Working Group and *James* (speaking for the company) over use of the phrase “funded by an unconditional educational grant” on the published Charter. *James*’s eventual willingness to allow the phrase to stand provided the group with a visible badge of autonomy it could take to skeptics in the patient community; *Patients, Know your Rights!* Working Group members, meanwhile, were united in discursively separating the development of the Charter’s content from the company’s undeniable involvement in the administrative process.

Drawing from Irving Goffman’s theories about presentation of self, Jaworski and Coupland (1999:407-414) highlight the importance of discourse in the construction of identities. The narratives of the three groups illustrate different ways in which each organization’s discourse on pharmaceuticals, pharmaceutical companies and funding from the companies contributed to their group identities. *Down-home Peer Support and Education*, through its policy of case-by-case decisions, eventually incorporated the tension among group members over the topic of pharmaceutical company funding into the group’s survivor-directed, politically moderate identity as a democratic, cautiously pragmatic grass roots entity. In line with the group’s politically moderate stance, members of the board straddled a number of fences; for example, the group’s willingness to entertain pharmaceutical company funding for its projects and events varied along a continuum, from the Discussion Forum -- for which a deeply-felt moral responsibility to protect vulnerable women facing treatment decisions put any corporate involvement off-

limits -- to educational fora, where such funding was deemed acceptable as long as the event did not promote a company's product and the company's name was not in evidence, to social events, such as the fund-raising dinner, where overt sponsorship by a pharmaceutical company was seen as innocuous. Similarly, while a large amount of money from a pharmaceutical company was thought to be potentially too compromising to contemplate under any circumstances, \$1000 was seen as "chump change" to a pharmaceutical company and therefore unproblematic, provided the company asked for and received nothing in exchange. The formal processes and norms shifted over time with changes in the group's structure and new experiences; but a cautious pragmatism, guided by the group's primary commitment to serving the needs of local survivors, remained constant.

In contrast to *Down-home Peer Support and Education's* embrace of moderation and accommodation, *Critical Advocacy to Prevent Cancer* constructed an identity as an organization that resides in its strong stands, critical of knowledge claims dominant in the breast cancer patients' group community and in the broader breast cancer policy arena (in *Cora's* words, "we have the reputation of being shit-disturbers"). With its focus on cancer prevention, *Critical Advocacy to Prevent Cancer's* identity also differs from *Down-home Peer Support and Education's* survivor-directed concern with local patient care issues. Once the group adopted its policy on corporate funding policy, the critical discourse on funding from the pharmaceutical industry became part of the organization's distinctive identity, prominently displayed on its website and promoted as a badge of integrity and as a means of "explaining why we can't afford to pay a lot of money for speakers or those sorts of things." As well as defining the group itself, *Critical Advocacy*

*to Prevent Cancer* uses its skeptical stance to counter the identity claims about pharma funding, pharmaceuticals and pharmaceutical companies constructed by other entities in the cancer arena. Thus, the group has developed public discourses on the possibility of serious drug side-effects, the need for an environmentally based strategy of cancer prevention, and on the in/ability of groups funded by the pharmaceutical industry to take independent stands on issues related to pharmaceuticals.

Members of the *Patients Know Your Rights! Working Group* began the process of identity construction at their inaugural workshop in Ottawa. Each invited participant brought extensive local/regional experience and knowledge about patient needs from her work in community-based breast cancer organizations and had responded to an invitation to brainstorm about unmet needs in their community. An identity-building exercise based on these group experiences invited participants to address the problem of local/regional disparities in patient care through a national, collaborative effort to create a Breast Cancer Patients' Bill of Rights; the exercise met resistance, however, when some participants experienced the agenda as imposed by the host organization and/or the sponsoring pharmaceutical company. Nonetheless, a Working Group did form and when it functioned at its best, this sense of a national mission defined its core identity. The identity remained fragile, however, and easily destabilized by discourses from within and outside the group. Some of these related directly to the fact of the group's funding from the industry; others arose from unsettling aspects of the process which were only partly related to the industry's role.

Participants in the *Patients Know Your Rights' Working Group* understood that the project was funded by Astra Zeneca and were familiar with the critical discourse over

pharmaceutical company funding within the community. Participants who stayed with the process had a “comfort level” with the industry’s role (to use *Thora*’s words) and were able to defend the industry as the project’s funding source, as long as the project’s value to the community remained clear and the industry representatives maintained a distance they deemed “appropriate.” For *Jenny*, this distance was breached at the initial workshop and she initiated a “discourse of discomfort”; others became immobilized when they faced critical feedback from the community. The European activist’s powerful discourse in favour of the Bill/Charter of Rights shifted the balance back to the project but *James*’ unabashed visibility and assertive manner once again destabilized the group’s identity as a community-based committee independent of industry. The *Patients Know Your Rights*’ *Working Group*’s members then began an active struggle to maintain the integrity of the project, both in fact (by distinguishing between the content decisions and the process decisions) and in appearance (by insisting that the phrase “Funded by an Unrestricted Educational Grant” appear on the Charter).

Power/knowledge, ideology and control are interrelated themes that can be explored using critical discourse analysis (Foucault 1980). The three group narratives in this chapter reveal the ongoing struggles within each group to construct truths about the pharmaceutical industry and to use this knowledge to define the ethical boundaries of pharmaceutical company funding. *Critical Advocacy to Prevent Cancer* identifies as a breast cancer group that promotes cancer prevention by reducing exposure to environmental carcinogens. The group’s ideological stance is to question received understandings of breast cancer and, as one member put it, “to demystify”, “to be very, very cautious” and “to think and not to trust.” This ideology deliberately destabilizes sites



of power and profit within the cancer establishment, including pharmaceutical companies. *Critical Advocacy to Prevent Cancer* questions the widespread implicit faith in pharmaceuticals as the solution to the breast cancer problem. Although drugs are acknowledged to have some benefits, the *Critical Advocacy to Prevent Cancer* ideology constructs pharmaceuticals as aggressively marketed commodities that are potentially harmful to both cancer patients and (particularly) to healthy women, as well as being a source of environmental pollution. In constructing a critical discourse about pharmaceuticals, pharmaceutical companies and pharmaceutical company sponsorship of breast cancer organizations, *Critical Advocacy to Prevent Cancer* draws on knowledge from its members' lived experience with the adverse effects of drugs (much like *Down-home Peer Support and Education*) and from interactions board members have had with the industry outside the group proper. The latter include having "seen the bad side" of pharmaceutical companies as a former menopause activist, observing "the way companies woo the doctors" as a hospital employee, and learning from allies in the group *Learn from Drug Tragedy* about iatrogenic drug injuries resulting from unproven claims used to market a pharmaceutical product.

The group's policy of refusing funding from the pharmaceutical industry can be termed a manifesto that codifies *Critical Advocacy to Prevent Cancer's* ideology on corporate donations and the group actively promotes the manifesto's discursive power (Jaworski and Coupland 1999: 498-500). Since the policy was formulated in 2001, agreement with the policy has been a prerequisite for anyone interested in joining the group's board or being hired for a staff position. Having a written policy minimizes and simplifies any contact with the industry; it has not, however, eliminated internal

discussions about how far to extend the policy, for example, with respect to collaborating with other breast cancer groups, or accepting funds from corporations or individuals who may profit from breast cancer through cause marketing. Intra-group differences reside in how passionately and/or hard line members feel about the issue, and whether they believe they should proselytize to other actors in the breast cancer movement in the hopes of changing their views and practices. *Critical Advocacy to Prevent Cancer*'s attempts to bring other organizations around to its perspective on this issue have been largely unsuccessful and, in the years since introducing its corporate funding policy, the group has reoriented its social networks and communications to expand and strengthen alliances with organizations that share its views.

The discourses *Down-home Peer Support and Education* constructs are consistent with its identity as a survivor-directed organization with a moderate, cautiously pragmatic ideology based on principles of self-help (Bayers 2004). The group requires that a majority of its board members be breast cancer patients or former patients and values the knowledge of breast cancer drug treatments that are rooted in the patient's experience. The *Chat Space* and meetings provide venues for patients and survivors to share this power/knowledge. Group members drew a strong line, however, between these exchanges of lay knowledge and giving medical advice. As one member told me, "No one at *Down-home Peer Support and Education* would ever, ever do that." Despite such denials, members recognized that shared lay knowledge does have the power to disturb discourses constructed and sanctioned by actors with more formal status, including physicians and pharmaceutical companies as the results of the tamoxifen questionnaire posted on the online *Chat Space* dramatically illustrated. Participants who reported side-

effects of tamoxifen (a drug widely touted in the oncology community as “mild” or even as “having no side-effects” (Lerner 2007:239) also typically reported that their oncologist did not warn them of side-effects; yet the list of problems reported in the lay survey align closely with those listed in the drug’s Product Monograph.

Members’ views of the industry reflect an awareness of self-imposed silence as a form of political power (“A lot of people on our board felt that taking money [from pharmaceutical companies] would make us unlikely to speak out against them”<sup>74</sup>). At the same time *Down-home Peer Support and Education*’s context-dependant ideological perspective allowed for a positive view of small donations and grants that had enabled the group to co-sponsor educational events that they believed had been both helpful to patients and beneficial to the organization.

Unlike *Critical Advocacy to Prevent Cancer*, *Down-home Peer Support and Education* deploys its knowledge/power relating to pharmaceuticals and pharmaceutical companies internally. *Down-home Peer Support and Education* did not make pharmaceuticals and pharmaceutical companies a focus of its formal advocacy discourse: they neither advocated that specific drugs be put on formularies nor publicly critiqued drug company practices. Members did not rule out such actions in the future, but explained that they were a small organization and could only take on a few issues at once. One member laughed at the idea of their small, regional and mostly volunteer organization “taking on a multi-national drug company.” Views within *Down-home Peer Support and Education* about the motives of pharmaceutical companies in marketing their drugs and funding patients’ organizations incorporated experiences of other organizations, such as *The Hub*, as well as their own. They did not have the in-depth,

first-hand experiential knowledge of drug company malfeasance that some members of *Critical Advocacy to Prevent Cancer* reported. Even within the same interview, members of this group grappled with an ambivalence about the industry, as if group discussions had imprinted an “on the one hand, on the other hand” perspective. *Meredith*, for example, in our interview, at times expressed a hard-nosed realism (“I don’t think Pharmas are altruistic but they like you to think they are – they have shareholders, they’re out to make a profit”) but also mused, “It would be nice if we knew exactly what the Pharmas wanted from us.” *Ruth* opened our discussion with an emphatic “I have nothing good to say about corporations!” and later said she had “no problem” with taking money from a pharmaceutical company as long as the group was not expected to endorse their products; but there was an underlying note of caution in her attitude (“the jury’s still out” on whether a company might make unacceptable demands; and “It’s tough! We still debate the issue.”)<sup>75</sup> All five members from the group that I interviewed tended to distinguish between “acceptable” pharma funding (small amounts, given as unrestricted educational grants, with no possibility the group would be expected to endorse a product), although several mentioned that the group’s perspective had softened from its earlier days, when a number of board members, such as the web-mistress, were hard-line in their opposition to pharma funding.

With the hiring of *Keith*, a professional fundraiser who dealt directly with the industry representatives, the board of *Down-home Peer Support and Education* ceded some of its collective power/knowledge with respect to decisions and negotiations with the pharmaceutical industry. The fundraiser expanded the conditions under which the group would accept pharmaceutical funds by actively promoting the concept of

“Unrestricted Educational Grants,” which had previously been marginal in the group’s discourse. His receptiveness to funding from the pharmaceutical industry shifted the group to a more industry-friendly ground than it had been previously; at the same time, the fundraiser’s productive discussions with the drugstore and grocery chains provided the group with a stable source of funding that reduced the felt need for pharmaceutical industry funding. Unlike *Critical Advocacy to Prevent Cancer*, which expanded its prohibition of pharma funding to include other corporations that profited from cancer, pink marketers, and eventually even a local musician marketing her CDs, *Down-home Peer Support and Education*’s reservations about pharma funding remained isolated. The offer for funding from a pharmacy, for example was deemed unproblematic, because “they’re not a pharmaceutical company.”

The *Patients Know your Rights!* Charter is also a manifesto, one that expresses a particular ideology through particular rights claims for patients based on patients’ experiential knowledge of their needs; however a counter-discourse gained expression at the workshop, when some invited participants raised doubts about both the content and the process, destabilizing the workshop proceedings. *Patients Know your Rights!* Working Group members struggled to reconcile a critical discourse about corporate funding that was circulating in the community with their strong belief that the document would have a communicative and advocacy value that reduced regional and inter-regional disparities. In part, the struggles over the meaning of the document hinged on whether its corporate sponsorship undermined the legitimacy of a document which purported to embody the power/knowledge of patients. The discursive conflict resurfaced at key points

in the Charter's development, including the Working Group's successful fight to restore the written claim, "Supported by an Unrestricted Educational Grant" to the document.

*The Patients Know your Rights! Working Group's* members, through their three-year experience as partners with a pharmaceutical company, gained first-hand participatory knowledge of this partnership process. They were active in co-constructing the partnership with the pharmaceutical company and sometimes overruled the company in decisions, as in the question of the Unrestricted Educational Grants. Members of the Working Group were satisfied that company representatives did not interfere in the content of the Charter and defined the content as the most significant aspect of the project over which they needed to exercise control. *James'* "inappropriate" behavior was thus not seen as an exercise of power, but rather was framed as the annoying but ultimately harmless bumbling of someone "from away" who didn't understand local customs.

At the same time, members recognized many unsettling gaps in their knowledge about the process as a result of the pharmaceutical company's control over administrative aspects of the project: Why was the public relations company fired when Working Group members thought they were doing a good job? Why was a member of the activist community hired to work on the project without their knowledge? Why did *James* suddenly intervene in ways they considered "inappropriate"? Why were they not given the opportunity to negotiate with *The Hub* about providing a home for the Charter? In each instance, the company used its power as the funder to control key aspects of the process and, despite the *Working Group* members' willingness to challenge decisions with which they disagreed, they did not know why certain decisions were made, even though these decisions affected them directly.

Klawiter (1999) describes cultures of action as fluid and shaped by external forces as well as internal bargaining. The forgoing observations focus on three groups within Canada's breast cancer activist community and their internal bargaining over pharmaceutical company funding at a particular point in time: 2007-2008. They suggest the importance of discourses about the pharma funding issue in shaping distinctive cultures of action within the social world(s) of breast cancer groups. Missing from these narratives, however, is a consideration of the external forces that contributed to these cultural differences, the story of how pharmaceutical company funding became such an important issue within the Canadian breast cancer movement as a whole, and the often invisible connections between the funding patterns of pharmaceutical companies to PAGs and the efforts on the part of companies to move their latest drugs to market as quickly as possible. I examine these pieces in the next two chapters.

## **CHAPTER 4      THREE POLICY LANDSCAPES PRE-1991**

### **4.1    THREE INTERLOCKING POLICY LANDSCAPES**

In the previous three chapters I first problematized the issue of pharmaceutical funding to patients' groups with an introductory discussion, a set of questions I want my research to address, and an interdisciplinary review of the literature identifying gaps in the current state of knowledge. I highlighted three areas on which I want to focus: (i) the need for detailed accounts of how pharma funding fits into the daily practices of actual organizations, (ii) the need for diachronic accounts of how these practices evolved, and (iii) the need for critical analysis of meta-level influences. In Chapter 2 I set out the methods I use to accomplish these goals. My overall approach is to use ethnographic methods applied to a science and technology studies (STS) conceptual framework to provide a holistic account of the ways in which technologies (in this case cancer medications) are socially constructed. To analyse changes over time I use two complementary methodologies: an Actor-Network analysis to study the social negotiations among actors over the meanings of these technologies, and a form of discourse analysis to map competing discourses and how they interact and change over time. I use several chronological narrative approaches to present these unfolding struggles. In the last chapter I used a biographical "life story" approach to depict at close range the evolution of these struggles from inside three Canadian breast cancer organizations whose views of funding from the pharmaceutical industry fall along a continuum: one has developed a formal policy to refuse all such funding, one has an ambivalent case-by-case policy, and the third is an ad-hoc working group funded entirely



by the pharmaceutical industry. In this Chapter I shift my focal point from close-up to landscape. I narrate three interlocking political narratives that historicize contested issues underlying the present debate over pharmaceutical company funding to patients' groups.

As I point out in my literature review, a breast cancer movement did not form in Canada until the early 1990s (Kaufert 1998). This movement, and the discourse within it over pharmaceutical company funding, has roots in the previous decades, however. In this chapter, I draw from the tools of actor network and social worlds analysis to identify relevant actors and discourses in the policy arena in Canada that existed when the first breast cancer groups began to form. Using three overlapping historical narratives, I map the evolution of competing discourses in Canada over three contentious issues: government-funded healthcare, pharmaceuticals and the regulation of pharmaceutical companies, and the place of civil society groups, especially those in the health care sector.

## **4.2 GOVERNMENT-FUNDED HEALTH CARE IN CANADA**

### **4.2.1 History and Character**

Canada's system of universal, publicly funded hospital and medical insurance is a major actor in Canada and the breast cancer arena is no exception. Its terms shape the health care that cancer patients receive as well as health-related policies and structures. Arguments over the system's strengths and weaknesses permeate popular discourses and advocacy about health. Particularly significant for this discussion is the evolution of those aspects of the system most critical to determining the availability of drugs for cancer

patients. “Medicare,” or publicly funded health care is a legacy of Canada’s welfare state era. (I use the term “welfare state” to denote the era in Canada’s political-economic development in which a series of universal social programs were put in place and actively maintained; that is, the period from the mid-1940s and to the mid-1970s (Russell 2000). Although the term “welfare state” is often used today as a pejorative, in my analysis the era marked a high point for social justice in Canada. Not only did it give rise to universal, publicly funded hospital and medical insurance, the focus of this analysis, but programs of Unemployment Insurance, Family Allowance, and old age security augmented by the Canada/Quebec Pension Plan were all created in this period to provide the population with a social safety net.) Much of the following account of its development draws from an analysis by Canadian sociologists Pat and Hugh Armstrong (Armstrong and Armstrong 2008) and from a series of articles in the *New England Journal of Medicine* (Iglehart 1986a, 1986b, 1990, 2000).

Prime Minister Lester Pearson’s Liberal government introduced Canada’s publicly-funded health care program in 1957, using a provincial template, Saskatchewan’s public hospital insurance plan of 1947. The latter was the legendary brainchild of Tommy Douglas, the first democratic socialist to lead a government in Canada as premier of Saskatchewan. The essence of the original federal plan was that all Canadians are entitled to the same hospital care, regardless of ability to pay. Because health care delivery is a provincial responsibility under the Canadian constitution, the federal government could not impose the plan, but promised to pay half of all hospital expenses in any province that signed onto the plan; all ten provincial governments did so, enticed not only by the money but by the Plan’s undeniable success in Saskatchewan and

the enormous public support this generated. Saskatchewan, meanwhile, had taken the additional step of expanding its plan to include the cost of visits to a physician. In 1966 the federal government followed suit, passing the *Medical Care Act*. The decision to expand coverage drew from a Royal Commission Report on Health Services, published in 1964 and headed by former Justice Emmett Hall. The Hall Report, as it became known, provided evidence to support three claims in favour of a single-payer, publicly-funded, universal health insurance plan: substantial administrative cost-savings, medical outcomes that compare favourably with those under privately-funded systems, and assurance of the most equitable treatment across the entire population.

Significantly, the Hall Report argued that the country's health care needs would best be met if pharmaceuticals and other core services (home care, nurse care, ambulances, and eye and dental care) were brought under the single-payer umbrella. The government decided to proceed gradually, however, with the idea that other services could be added later. Public funding has yet to expand to cover these additional services and advocates of the public funding principle fault that decision as a political misstep (Armstrong and Armstrong, 2008: 20).

The single-payer system has always had detractors, making it a focal point of policy discourse since its inception. Provinces divide along lines of size and wealth; larger, wealthier provinces fear losing control of how they spend their money while smaller, poorer provinces welcome the guarantee of revenue to provide a basic, costly service to their populations. Nurses and other unionized segments of the affected work force have supported the plan, which ensures a large number of good jobs, particularly for women (Armstrong and Armstrong 2008). Many companies support the plan, which

relieves them of having to provide their employees with health insurance for core services (Iglehart 1990:562-3). Among voters, publicly funded health care quickly developed broad support because the system worked: as patients, they received good care at less cost than under a private plan. This strong voter support has meant that all Canadian political parties, from left to right on the spectrum, have ultimately endorsed single-payer health care, despite its origins in a democratic socialist party and despite opposition from companies and lobby groups that promote private enterprise.

Armstrong and Armstrong identify Canada's Parliamentary system as another actor that helped to usher in Canada's single-payer health care system (2008:16-17). They contrast Canada's system to America's, which grants more power to private interests with the means to launch pressure campaigns. Consequently, individual members of the U.S. Congress may well break ranks with their party even when a party platform is supported by a majority of the population. Armstrong and Armstrong argue that systemic political power dynamics -- and not an inherently more conservative collective identity -- account for the inability of Presidents Clinton and Obama to deliver a single payer system in the U.S. In Canada's system, by contrast, elected members of Parliament usually bow to party discipline rather than to demands of the local electorate or to private interest lobbying. Political scientist C.E.S. Franks cites features of Canada's Parliament that account for the "excessive" (Franks 1987: 110) party discipline that characterizes the Canadian House of Commons and restricts the contribution of individual members. These include the insecurity of the individual M.P.'s seat from one election to the next, the engrained use of patronage positions in the Canadian system to

reward loyal MPs when they lose an election, and the limited power of local constituency offices to select party candidates.

Private insurance companies were obvious opponents to the single-payer system because governments took over their role in insuring basic hospital and physician services; all provinces allow private insurance to cover areas not covered by their plans, however, and five allow additional private insurance for services that are covered (Armstrong and Armstrong 2008). Physicians have been divided. Some opposed the plan because they believed it undermined their professional independence; others saw the system as consistent with their professional obligation to treat on the basis of need and welcomed a plan that ensured they would be paid for their services regardless of a patient's financial means. Physician support for the single-payer system, individually and through the physicians' political advocacy organization, the Canadian Medical Association (CMA), is thus unstable and fluctuates depending on external factors.

*The Canada Health Act*, a significant addition to the 1966 *Medical Care Act* was introduced in 1984 to combat threats to the universality of the plan. A citizen's group, the Canadian Health Coalition, and a second Royal Commission, again headed by Emmett Hall, had warned the Honourable Monique Bégin, then the minister of Health and Welfare, that physicians were charging extra fees and provinces were spending their health care money on other priorities. With additional support from unions, health advocates and nurses, the health minister convinced the Liberal government under Pierre Trudeau to take on the physicians and the provinces, which they did with *The Canada Health Act*.

The *Act* set out five conditions for federal funding which strengthened and defined the public health care system. Each condition made explicit a value on which the system was based. To qualify for federal funding, the provinces and territories had to adhere to five principles:

- *Universality*, which affirms care as a right and promotes solidarity;
- *Accessibility*, which asserts that essential services provided must be similar for everyone and without user fees, although providers must receive “reasonable” compensation; having everyone use the same services also reduces the costs of collecting fees and gives everyone a vested interest in their quality;
- *Comprehensiveness*, which requires all hospitals to provide and pay for a specified menu of basic services -- another means to reduce administrative costs;
- *Portability*, which guarantees that coverage travels with the individual when s/he moves from one province to another, changes jobs or changes physicians; and
- *Public administration*, which asserts that the administration of a province’s health plan must be non-profit and responsible to the provincial or territorial government (Government of Canada 1985:5-8).

In 1986 the federal government demonstrated its willingness to use its power under the *Canada Health Act*: physicians in Ontario went on strike and the federal government withheld transfer payments to the province until the strike ended – a total of 23 days (Armstrong and Armstrong 2008: 28). The *Canada Health Act* was meant to address regional inequalities and to force compliance with the public system.

Since the mid-1980s, however, confidence in the system has declined. Health care costs began to rise and in 1987 the federal government responded by reducing its transfer

payments while giving up some of its areas of taxation to the provinces. Successive federal governments continued to cut spending for health (and other social programs) citing the need to balance the budget. The reductions in the federal government's direct share of federal/provincial health spending continued throughout the 1990s with a particularly sharp drop in 1996 when the federal government contributed only 15 per cent of the total spent by provinces.<sup>76</sup> As its direct contribution to health spending declined, the federal government lost much of its power to enforce the *Canada Health Act*. The system deteriorated and the public, as well as other actors, began to question the system's sustainability moving the debate about publicly funded health care to the fore once again. A modest restoration of funding began in 2001-2.<sup>77</sup>

Beginning with the election of the (then) Progressive Conservative<sup>78</sup> government in 1984 and continuing to the present, the Canadian government (under both the Conservative and Liberal parties) has moved away from the welfare state model, on which the health care system was based, towards a free market model which relies on markets to meet all needs (ibid:22-23). This radical shift in thinking about governance was in part a response to international pressures, notably the move to the right under Margaret Thatcher in the U.K. and Ronald Reagan in the United States. Nationally, the government was coping with a rising debt. The neo-liberal discourse which became dominant called for less government involvement in healthcare and other existing areas of government programming; its adherents rejected new government programs (such as pharmacare) as inappropriate and unaffordable. Pat and Hugh Armstrong sketch the two main competing discourses in this transitional period as follows: those favouring a reliance on markets and opposed to Keynesian economics blamed the crisis in health care

on programs and on dependent individuals and “promoted panic over the debt and deficit” to bolster support for their claims (ibid, 2008: 23). Those opposed to the free-market approach in health care and in favour of maintaining the publicly funded system (including the Armstrongs), point to research that “showed that the main causes of the federal government’s debt were the cuts to taxes for corporations and rising interest charges” (ibid 2008:23). Regional disparities in the provision of health care increased as cuts continued, undermining the ethic of equality.

By 1990, when the breast cancer movement in Canada began to stir, the federal share of direct transfer payments had declined from its high of fifty per cent to less than thirty per cent but had not yet reached the low of 14.6 per cent, two years after the dramatic budget cuts of 1996.<sup>79,80</sup>

#### 4.2.2 The Health Care System and Breast Cancer Treatment

From the introduction of Canada’s single-payer system to the mid-1980s, the nature of breast cancer treatments was such that the single-payer health care system served breast cancer patients well because most cancer care was carried out in hospitals, with follow-up by physicians and both services were fully covered by the single-payer system. The lack of a national pharmacare program, which has since become a concern of cancer patients (Anonymous 2009) had little effect on breast cancer patients prior to 1990, for several reasons.<sup>81</sup> First, although a research program had been set up in the United States in 1954 to systematically search for “wonder drugs” that would cure cancer, by the early 1980s, the search had yielded little success, with the notable exception of chemotherapy treatments for Hodgkin’s disease and certain leukemias and



lymphomas which affected mainly children and which comprise less than five per cent of cancers (Patterson, 1987: 196-7). Second, until the early 1980s, breast cancer was widely considered a local disease which meant that the basic treatments, surgery and radiation, were aimed at local control (Lerner 2001). Since both the latter were hospital procedures -- and end-of-life care was also at that time provided in hospitals -- cancer care was fully covered no matter where in Canada a cancer patient lived and what standard medical treatment they were receiving. Diagnosis and follow-up care were the responsibility of physicians so these too were covered.<sup>82</sup>

From the mid-1970s to the mid-1980s, a fundamental shift in thinking about breast cancer took place, redefining the disease as systemic rather than local (Lerner 2001).<sup>83</sup> A major consequence of this redefinition was that researchers and cancer treatment specialists began to take chemotherapy more seriously as a potentially effective treatment for breast cancer. Beginning in the late 1960s and throughout the 1970s and 1980s, clinical trial results gradually accrued providing evidence that two types of drug treatments, as defined by their mechanism of action (MOA), had benefits for breast cancer patients. The first type were *cytotoxic*, that is, their MOA was to kill cells as they were dividing; by 1990 ten or eleven of these were in common use for breast cancer (Love 1990:388-390; Harris et al 1993).<sup>84</sup> Because the treatments were extremely toxic, many cancer specialists were hesitant to adopt them without evidence of substantial effectiveness (Patterson 1987: 306-7). These drugs were almost always given by intravenous drip and carried out as a hospital procedure. The second type of treatment was *hormonal*, which worked by inhibiting or stabilizing cell growth (DeGregorio and Wiebe 1999:17, 30). Of six hormonal treatments in use for breast cancer in 1990, all were

taken orally on a daily basis (the most commonly used anti-hormonal treatment by far was tamoxifen, which was taken two times per day).<sup>85</sup> Because they were taken at home, hospitals did not have to pay for them under the Canada Health Act and payment for this treatment coverage varied depending on the patients province or territory of residence and/or whether they had coverage through an employer-sponsored or individual private plan (Anonymous 2009:9). Despite this potential for inequity in accessing breast cancer drugs like tamoxifen, they were available in generic form in Canada at a relatively low cost which (although still significant for some women) meant gaining access to them was not the source of intense controversy it was to become.

In the late 1980s, with anti-cancer medications gaining equivalent stature with surgery and radiation as the standard treatment for breast cancer, a set of interconnected circumstances brought drug treatments for breast cancer to the policy fore. First, pharmaceutical treatments for breast cancer began to be seen as potentially curative, especially if administered in early stages of the disease; second, treatment options began to diversify: two new breast cancer treatments, Taxol® (paclitaxel) and Herceptin® were in the development pipeline (Bazell 1998; Walsh and Goodman 2002) and a hyper-toxic, costly procedure known as high-dose chemotherapy with autologous stem cell rescue<sup>86</sup> was being used both experimentally and, particularly in the United States, outside of clinical trials (Lerner 2001). This procedure was attracting attention in Canada, where women who could afford it were travelling to the United States for treatment (House of Commons 1991:1,48). Third, a policy change in Canada delayed the use of generic versions of new drugs, removing a mechanism for keeping drug prices in Canada low; and fourth, the costs of new cancer drugs began to rise dramatically, worldwide

(Anonymous 2009). I discuss these treatment and policy changes in more detail below. The central point here is that, prior to 1990, the lack of a national drug coverage plan within Canada's health care system had a limited impact on breast cancer patients' access to medications. In the next section I discuss a variety of factors that came into play in the late 1980s and early 1990s and which helped to generate competing discourses on the question of drug access within the breast cancer arena.

### **4.3 PHARMACEUTICAL COMPANIES AND DRUG REGULATION IN CANADA**

#### **4.3.1 Canada in the World System of Drug Regulation**

The pharmaceutical industry emerged as a powerful global actor in the early part of the twentieth century. In an early analysis of the drug system and Canada's place in it, political scientist Ronald Lang characterized the pharmaceutical industry as an international actor that, from the beginning, has operated out of, and benefitted the economies of, a few wealthy countries, notably the United States and certain countries in Europe (Lang 1974). Within this global structure, Canada's role has been contradictory. Initially, despite a few indigenous companies, Canada did not develop a strong industry and the country's relatively small population has made it a minor market. Nonetheless, Canada has the potential to destabilize the pharmaceutical industry's well-honed discourses. Its proximity to the industry's American base and the subtle cultural differences between Canada and the U.S., as manifested in each country's system of government and health care, combine to make Canada an actor for the industry to watch and control (ibid).

### 4.3.2 Why Regulate Drugs?

Although technically a new actor in the last century, the pharmaceutical industry was recognized from the outset as belonging to a group of manufacturers traditionally set apart because its products, like food and drink, were simultaneously essential to and potentially threatening to health (Löwy 2000). Morals and the social order thus require these products to be available, safe, and affordable; at the same time, the pressures of business competition regularly spawn practices that mislead and endanger the public. Central discourses about “big pharma” thus embody an ongoing tension between the industry’s ethical obligations to the consumer and the business of making profits and contributing to economic growth (Cohen 2004).

### 4.3.3 The Public *versus* Private Regulatory Cycle

The practice of state intervention to ensure the safety of herbal and other substances used as medicines dates back to the ancients (Huguet-Termes 2008) while efforts to regulate food have been recorded as early as 13<sup>th</sup> century England (Letheby 1888). Pharmacy products, made by apothecaries from botanicals, minerals and animal substances, have been in use since antiquity. Recipes for these medicines were compiled in pharmacopoeia, special books dedicated to this purpose.<sup>87</sup> In the Renaissance, public health authorities in major political jurisdictions in Europe such as Florence and London authorized an official pharmacopoeia for their area. The City of London issued its first pharmacopoeia in 1618. The ostensible purpose of a pharmacopoeia was to protect the public health by ensuring that the apothecaries who prepared the medicines for physicians

did so correctly and safely although protecting the reputations of physicians may have been an additional purpose, or even the main one (Huguet-Termes 2008).

In England, a proclamation under the reign of King John of England in 1203 set standards to regulate the price and quality of bread. Henry III, King John's successor, passed a statute titled the Pillory and Tumbrel, the first law ever to protect the public from dishonest bakers, vintners, butchers and other trades-people who might fraudulently adulterate "a pure or genuine commodity for pecuniary profit" (Letheby 1888: 167).<sup>88</sup> Henry Letheby, a 19th century physician and public health crusader who wrote about England's adulteration laws for the *Encyclopedia Britannica*,<sup>89</sup> interprets the restrictions as an embodiment of the dual mandate of food producers, that of protecting the public health and while upholding commercial standards and so preserving the reputation of companies and guilds within a particular city. The strength and enforcement of such laws depends on the willingness of the state to intervene in commerce. The statute of the Pillory and Tumbrel was repealed during the reign of Queen Anne (1702-1714); competition became more cut-throat and the moral standards of commerce declined to the point where adulteration became an "art" practiced by unscrupulous merchants across the whole spectrum of culinary necessities, from chalk added to flour to increase its weight, to iron compounds used to colour meat sauces red (Letheby 1888). Similarly, Letheby wrote, the adulteration of drugs "at all times has been considered a serious offence" and punishable in London by both prison and fines since the time of Henry VIII (1491-1547); but although these "wholesome powers ... are still in force, and might be advantageously exercised, yet they have long since fallen into disuse" (Letheby 1888:175). It was only through the efforts of the Pharmaceutical Society of Great Britain, founded in 1841,

Letheby added, that practice of pharmacy became regulated and the adulteration of medicine prohibited, under the Adulteration of Food and Drink Act of 1860.

The integrity of pharmacopoeial drugs had been corrupted with the advent of the so-called patent medicines which emerged in Europe and the United States in the 17<sup>th</sup> and 18<sup>th</sup> centuries. These “drugs,” with their secret ingredients and claims to cure a grab-bag of diseases as varied as cancer, rheumatism and syphilis with a single potion, might contain herbs, such as peppermint, filler, or potentially poisonous or addictive ingredients, such as cocaine, arsenic and opium (Hilts 2003: 27, Soucy 1953). The claims of curative powers were pure fiction and relied on packaging and advertising. Despite the efforts of lawmakers, and some honest drug-makers and doctors, druggists became dependent on the easy profits of patent medicines which they sold alongside genuine medicines. Patent medicines became a “conspicuous and highly profitable market,” particularly in the United States in the 19<sup>th</sup> century (Leslie 1988: ix). During the American Revolution, medicines could not be imported from England so enterprising businessmen in the colonies obtained the bottles or had facsimiles made locally then filled them with a secret mixture of substances. Rather than patenting the ingredients in their products, manufacturers patented the shape of the bottle, the box or features of the label (Hilts 2003). Populist movements, including networks of women’s organizations began to press for regulation to ensure some baseline quality in food and drugs – “a women’s movement and a consumer movement combined” (Hilts 2003:32).

#### 4.3.4 Three Countries Create Regulatory Regimes

The mid-19th century saw a revival of food, drink and drug regulation in the United Kingdom; soon after, the U.S. and Canada (following Confederation, in 1867) enacted similar regulations of their own. The pharmaceutical industry as we know it today had not yet taken shape, but the regulatory systems put in place between 1850 and 1920 in all three countries set the standards for the drug regulatory system that was to come. This shift away from laissez-faire commerce was marked by a liberal borrowing among the three countries of regulatory initiatives. Public health reformers launched orchestrated and sustained campaigns to challenge the truth claims of dishonest merchants and to protect the public from health catastrophes. In England in 1820, Friedrich Accum, a highly regarded chemist published a book in which he exposed the extent of adulteration in culinary items from bread and pickles to coffee and alcoholic beverages.<sup>90</sup> Following on Accum's exposé, between 1850 and 1875 three London physicians led a campaign against adulteration of food and drugs with the goal of exposing the dangers of adulteration and promoting protective legislation. Thomas Wakley, an enterprising public health reformer and the founding editor of the medical journal the *Lancet*, commissioned two colleagues, Arthur Hill Hassell and Henry Letherby, to conduct extensive tests on samples of food, drink and medicines purchased throughout London. Wakley then published the results in the *Lancet* between 1851 and 1854.<sup>91</sup> Their campaign gained momentum in 1858 when a druggist's assistant in the small English town of Bradford accidentally sold arsenic for use in making peppermint lozenges, poisoning hundreds of people and killing twenty (Carter 1999).<sup>92</sup> The scandal aided the reform efforts of the three physicians and the Adulteration of Food Act of 1860

passed. Weaknesses in the original Act were strengthened in subsequent revisions -- the Adulteration of Food Acts of 1872 and 1899 and the Sale of Food and Drugs Act of 1875 and 1879. These amended laws made provisions for food inspectors and analysts and authorized penalties for convicted adulterators, including fines, publication of the offender's name, and prison terms with hard labour (Letherby 1888: 167; Anonymous 2011).

These events in England played out in the years immediately before and after Canadian Confederation, in 1867. In the colonies, the initial concern of lawmakers was to ensure that essential food and alcoholic beverages were available at stable prices (Gnirss 2008a). Following Confederation, a report of the Commissioner of Inland Revenue claimed that fully half of all foods sold in Canada contained contaminants such as floor sweepings and/or cheap filler substances (e.g., water added to milk and roasted wheat to coffee) while the practice of deliberately adulterating alcoholic beverages with substances like opium, strychnine and tobacco provoked calls to ban alcoholic drinks (Gnirss 2008a, Huguet-Termes 2008). The *Inland Revenue Act to Prevent the Adulteration of Food, Drink and Drugs* of 1875 avoided a ban but set fines and jail sentences for sellers of adulterated products.<sup>93</sup> The 1884 *Adulteration Act*, modeled after the U.K.'s Act of the same name, removed food and drugs from the Inland Revenue Act, set standards for strength, quality and purity, and made the sale of adulterated food and drugs a criminal act.

A similar shift to drug safety regulation was taking place in the United States in the same period and would have lasting repercussions in Canada and internationally. The U.S. Pure Food and Drug Act, passed in 1906, was landmark legislation capping two



decades of efforts by a group of prominent reformers in New York and Washington DC.<sup>94</sup> The American Act created the first regulatory agency in the United States, the Food and Drug Administration (FDA) (Hilts 2003: 53). The Pure Food and Drug Act sought to protect the consumer from both unsanitary manufacturing practices and toxic additives to foods and patent medicines. More broadly, the Act recognized that industry was inherently a more powerful player than the average citizen and therefore gave the government a mandate to protect the consumer against businesses that made unsafe products and fraudulent claims. Like the Adulteration Act in the UK, the American legislation embodied a belief in science as a tool that could be used in the public interest; for example, procedures for inspecting and approving essential products before marketing were implemented to improve the safety of foods and drugs. These regulatory efforts met strong opposition, just as they had in the UK. Food and drug manufacturers, worried that the legislation would curtail business, weakened the legislation, for example, by striking the requirement that companies disclose all ingredients (Hilts 2003)<sup>95</sup> and exempting therapeutic claims from the requirements regarding false and misleading statements (Carter 1999). The Act also failed to authorize a ban on unsafe drugs (Hilts 2003). An amendment passed in 1912 prohibited false or misleading therapeutic claims, but opponents again scored a victory by placing the onus on the government to prove fraudulent intent (Carter 1999).

Despite its weaknesses, the U.S. Pure Food and Drug Act set a new standard that influenced laws and regulatory structures in other countries, including Canada. In 1909, Canada passed the Proprietary or Patent Medicine Act, making it the first country to legislate against drugs administered without medical supervision; however, this act was

limited to “secret formula, non-pharmacopoeial packaged medicines”, i.e., patent medicines (Soucy 1953). In 1920, Canada replaced the Adulteration Act with the Food and Drugs Act,<sup>96</sup> legislation based closely on the U.S. model. The Act of 1920 set quality standards for foods and alcoholic drinks, gave the government the power to inspect products, and prohibited misleading advertising (Gnirss 2008).

#### 4.3.5 A Modern Pharmaceutical Industry Emerges

As this regulatory framework for food and drugs was being honed in the USA, Canada, the UK and elsewhere, the modern day industry was still in its infancy, evolving within parent companies that produced other chemically related products (Sevigny 1977, citing Levinson). The original intent for these companies was to expand their markets by diversifying their products from synthetic dyes, petrochemicals and agrichemicals; drug development, however, soon became a thriving industry in its own right (Harding 1987; Löwy 2000). To distinguish its products -- prescription medications -- from the patent medicine trade, the burgeoning industry highlighted the scientific basis for its discoveries and adopted the term “ethical drug manufacturers” (Lang 1974; Avorn 2011).<sup>97</sup>

The oldest pharmaceutical companies trace their origins back to the late 19<sup>th</sup> century, and include several Canadian entries, such as Charles E. Frosst & Co., founded in Montreal in 1899, and Frank W. Horner Ltd. also of Montreal.<sup>98</sup> The industry as we know it today really began with the mass production of anti-infective drugs or antibiotics in the mid-1930s (Harding 1987). It expanded rapidly during and after the Second World War, a period of new drug discovery (Lang 1974). Intensive experimentation to discover

cancer drugs began in the United States in the period immediately after the war, initially in secret and then publicly (Patterson 1987).

As mentioned, the structure of the pharmaceutical industry has from the beginning been global rather than national, with a small number of companies based in a few industrialized countries exercising global control over the market (Lang 1974). By 1921, Swiss companies had pioneered a model that remains largely intact today; Roche Products, CIBA Laboratories and Sandoz Products had all assembled large research teams based in Switzerland that specialized in drug development, with marketing experts for promotion distributed throughout foreign markets via branch operations. By the early 1940s, Germany and the United States had thriving industries based on the same model; leading firms headquartered in Germany included Bayer and Boehringer Ingelheim, while American entries included Lilly, Upjohn's, Pfizer, and Merck. Britain, France and the Netherlands subsequently gained entry to the elite club and Japan followed in the 1970s (Lang 1974; Sevigny 1977, citing Levinson). Other industrialized countries, Canada among them, were minor actors. These countries had a negative balance of trade in pharmaceuticals and they were almost completely dependent on the dominant companies for the research, development and manufacture of their drugs (Lang 21, 1974 Appendix C).

#### 4.3.6 Modern Food and Drug Laws in Canada

From a broad social perspective, principles of human rights require the pharmaceutical industry to be publicly accountable while still making a return on its investments (Dukes 2002).<sup>99</sup> Defined more formally and narrowly, pharmaceutical

companies are obliged to comply with the regulatory frameworks of national governments which foreground the public interest while supporting a secondary, competing responsibility, that of fostering economic growth (Cohen 2004). Contemporary regulatory standards governing the industry define the public interest requirements in terms of three interlocking standards: quality (drugs should both work and be safe), honesty (product claims should not be fraudulent or deceptive), and affordability (essential drugs are necessities, not luxury goods). Safety, efficacy, honest representation and affordability are all subject to social construction, however and their meanings are regularly contested. Differences arise not only from the competing demands of shareholders and the public but from contrasting cultural framings of social justice. American values, for example, conceptualize social justice in terms of individual freedom and personal choice -- including the freedom to take risks with novel medical interventions. Other cultures, by contrast, privilege equity and social solidarity over an array of expensive benefits (Das 1999, Cahill 2003). In Canada, our health care system was built on a communal vision which, at least in popular mythology, puts us in the social solidarity camp (Romanow 2002).

This section provides background to an argument I will develop over the remaining chapters: that the rising political strength of patients' organizations in Canada has not, as one might expect, heightened pressure on drug manufacturers to support the goals of a sustainable, universal system of access to medications based on need. Rather, patients' groups in Canada have become increasingly dependent on the pharmaceutical industry for funds, particularly to conduct advocacy; at the same time, a discourse with respect to drugs has emerged from the advocacy of patients' groups that dissipates the

tension between the industry's public duty and its pursuit of profits. In this construction of the public interest, the patient has a right to choose among medications for which standards of safety and efficacy are still in development; and the industry's drive for profits serves patients by ensuring a constant stream of novel products.

This framing of the public good constitutes a break from the immediate past. As seen in the historical overview that follows, for several decades the Canadian government tightened its regulatory controls with respect to efficacy, safety and truth claims in concert with other national governments, while showing leadership in with respect to drug prices. Beginning in the late 1950s, Canadian lawmakers resolved to hold prices in check so that pharmaceuticals could be made available to all who need them without displacing other potentially beneficial interventions. Structural factors that allowed the government to take these steps, in the face of strong industry opposition, included the existence of its publicly funded health care system, health and consumer advocacy groups with core funding from the government that saw their mandate as providing a countervailing force to industry, and the fact that multinational pharmaceutical companies were not central to the Canadian economy.

*“Elixir of Sulfanilamide” and Thalidomide: Focus on Safety and Efficacy.* A drug disaster in 1938 spurred the U.S. Congress to remedy the weaknesses of the Pure Food and Drug Act. Canada followed the U.S. lead, in part because manufacturers were thought to be using Canada as a testing ground for the American drug market (Carter 1999:219). A liquid form of sulfa drugs devised by a company based in Tennessee caused 107 reported deaths, mostly of children. In the 1930s, sulfa drugs were widely used in the US and Europe as an effective antibiotic treatment for diseases such as pneumonia and

meningitis. In 1937, Massengill, a company based in Bristol, Tennessee, produced a liquid form sulfa-based antibiotic using antifreeze as a solvent and raspberry extract for flavouring. The company conducted no clinical tests before marketing its product, Elixir of Sulfanilamide (Carter 1999:218, Hawthorne 2005:42).

Under the new Food Drug and Cosmetics Act of 1938 (FDCA), a manufacturer had to conduct safety tests and submit an application to the Food and Drug Administration demonstrating that the drug was safe when used according to instructions on the label before it could market a new drug. Furthermore, the government no longer had to prove fraudulent intent and it gained the right to make factory inspections and seizures. The FDCA also introduced the concept of a prescription drug; certain drugs were deemed too risky to be used without a doctor's supervision and could only be dispensed when the patient's physician prescribed the drug as treatment (Carter 1999:218-19). In 1954 a modernized Canadian Food and Drugs Act came into force (Gnirss 2008b). Once again, Canada's Food and Drugs Act put many of the same safeguards in place as the U.S. legislation -- including the requirement that safety data be submitted to the federal government prior to licensing.<sup>100</sup>

The thalidomide tragedy in 1961 prompted further tightening of drug safety regulations. The disaster dramatically illustrated that the industry's international structure meant mistakes could have far-reaching global consequences. A German company, Chemie Grünenthal, marketed thalidomide<sup>101</sup> as a sleeping pill and as a remedy for morning sickness during pregnancy. The company had tested thalidomide on animals but had not tested for birth defects; the drug caused severe abnormalities when taken in the first trimester of pregnancy (Regush 1993: 9-10; Avorn 2011). In countries that approved

the drug, including Germany, Canada,<sup>102</sup> the Netherlands, Australia and Japan, some 8,000 babies were born with absent or badly deformed limbs. An estimated 115 of the babies were born Canada.<sup>103</sup> The tragedy also illustrated the necessity of drug regulation to protect the public. A vigilant drug reviewer at the U.S. Food and Drug Administration, Frances Kelsey, managed to block approval in the United States although, as medical historian Barbara Clow points out, Frances Kelsey's stand did not entirely prevent the use of the drug in the United States; physicians widely regarded the "complaints of pregnancy" as a psychological disturbance and hundreds of American doctors eagerly entered their patients into clinical trials; some American physicians, imported private supplies while the drug was still under review, and individuals determined to try the drug managed to obtain it from physicians, friends, or while living or travelling abroad (Clow 2003: 49-50). In the U.S., the thalidomide tragedy empowered hearings led by Senator Kefauver in 1957 to 1967 to require evidence of efficacy and safety as a prerequisite to drug approval (Avorn 2011). Amendments to Canada's Food and Drugs Act in 1963 similarly made approval for marketing a drug conditional on "substantial evidence" from manufacturers that the drug was both safe and effective in recommended clinical use; other countries put similar requirements in place (Carter 1999:220).<sup>104</sup> The Canadian Food and Drugs Act provides the broad framework of Canadian Health Protection law for pharmaceuticals, with details provided in regulations published in the Canada Gazette (Carter 1999:225-6).<sup>105</sup> All western countries now include laws that consider the principle of verification of lack of toxicity and efficacy of drugs and all recognize the clinical trial as the way to test efficacy (Löwy 2000).

The 1963 revisions were the last substantial changes to the Canadian Food and Drugs Act until 1985 although a new round of efforts to “modernize” the Act has been ongoing since 1998.<sup>106</sup> The 1954 Act and its 1963 revisions set out a drug approval review system comprising four phases or steps in which the company produced evidence for the Department of Health and Welfare, the Food and Drugs Divisions to review.<sup>107</sup> (As in the U. S., reviewers must be satisfied with the evidence that the drug is both safe and therapeutically effective to treat the condition(s) for which it was tested (Carter 1999: 230-233).<sup>108</sup> The process involves:

- An initial, *preclinical phase* comprising bench and animal studies to provide preliminary evidence of safety and therapeutic benefit for a particular disease; if these studies are successful, the sponsor proposes human (“clinical”) trials on volunteer “subjects” or study participants.
- A *clinical phase* which the company can initiate upon approval of the proposal; clinical trials, follow a three-step plan: *Phase 1* tests for safety and appropriate dosages on a small number of healthy human volunteers; *Phase 2* tests for safety and efficacy on a small number of humans who suffer from the specific conditions for which the drug is intended; *Phase 3* -- a full-fledged clinical trial -- is carried out using a sufficient number of closely observed patients to obtain reliable results on the drug’s safety, efficacy and optimal dosages compared to a placebo arm or other treatments.
- A *New Drug Submission* (NDS) to the Food and Drugs Division, which the company may submit if satisfactory data are obtained after Phase 3; when government regulatory reviewers receive an NDS, they examine the extensive statistical data,



analysis, and pharmacological information yielded by the clinical research. Reviewers can ask for additional information, or reject an application if the data is insufficient. Regulatory approval signifies that the drug can be marketed.

#### 4.3.7 Post-Kefauver: Canada's Spotlight on Price

In Canada, price was at the heart of a 10-year struggle between state and the pharmaceutical industry that began in 1958. By the mid-1950s the price of drugs had become a policy concern worldwide and governments everywhere, including Canada, began to critically scrutinize the industry's business practices. Ronald Lang's in-depth analysis highlights Canada's role in this early struggle (Lang 1974).<sup>109</sup> Governments had begun to question not only the high price of drugs but the industry's underlying monopolistic structure (Lang, 1974). Surprisingly, perhaps, in view of the American industry's favoured place in the international power structure, a US Senate Subcommittee led the charge against the industry with a ten-year inquiry into its pricing and marketing policies. Headed by Democratic Senator Estes Kefauver, chair of the Antitrust and Monopoly subcommittee and a firm believer in price competition, the inquiry ran from January 1957 to October 1967 (Lang 1974; Avorn 2011). The subcommittee's preliminary research detailed industry practices based on an ingenious use of patents, compulsory licensing, trademarks, brand names and promotional techniques -- all of which ran counter to Senator Kefauver's liberal, free enterprise political convictions.

Kefauver introduced Senate bill S.1552 "to make vital prescription drugs available to the people at reasonable prices" (Lang, 1974: 16, citing B. Stephenson). The bill took aim at anti-competitive patent and marketing practices that contributed to

unnaturally high prices and to misleading physicians about drug effectiveness and safety. The pharmaceutical industry vowed to fight the American bill “to the death” through its national industry association pressure group, the Pharmaceutical Manufacturers’ Association (PMA) (ibid: p 16). The hearings had a limited impact on American legislation because the industry succeeded in gutting the section of the bill that it most strenuously opposed, that which governed patents and licensing procedures.<sup>110</sup> Nevertheless, the landmark investigation provided fifteen volumes of testimony which gave governments of other countries ample evidence of the methods the industry used to keep the cost of pharmaceuticals high (ibid: 16, 20).

Countries around the globe took notice of the Kefauver hearings and 17 of these, Canada included, undertook investigations of their own.<sup>111</sup> In the 1960s a series of reports known as the Green Book (1961), the Hall Commission Report (Canada 1964) and the Harley Report (Harley 1967),<sup>112</sup> found that drug prices in Canada were among the highest in the world and patent protection was identified as a major cost driver (Cohen 2004:7).<sup>113</sup> Newly elected Liberal Prime Minister Pierre Trudeau used the reports to argue for a licensing system that would overrule patent protection of pharmaceuticals allowing Canadian generic companies to manufacture and import drugs that were still under patent, a provision known as “compulsory licensing.” This provision allows a third party to manufacture a patented drug using the process of the patent-holder on the condition that the company pays a royalty to the patent-holder. The patent-holder is obliged to issue the license (hence the designation “compulsory”).<sup>114</sup> The bill which Senator Kefauver put forward would have introduced a modified compulsory licensing system in the US – a proposal which the American industry, represented by the

Pharmaceutical Manufacturers Association (PMA) strongly opposed and ultimately defeated.<sup>115</sup>

In Canada in the 1960s compulsory licensing was an existing feature of patent law and was intended to ensure competition so that drugs would be available at the lowest possible price. The provision was seldom used, however, because the import of drugs from companies outside Canada was not allowed and Canada's market is too small to support the manufacture of drugs, particularly lower-priced ones (Cohen, 2004, Lexchin 1997b). The new law allowed the Canadian companies to import a drug into Canada rather than solely manufacture it. They could make and sell generic versions of a patented drug for a minimal royalty fee, usually four per cent, which they paid back to the patent-holder (Carter 1999: 241). The hope was that this would increase price competition for pharmaceuticals, support a Canadian generic drug industry, and make drugs more affordable to Canadians (Cohen 2004, Carter 1999).

Ronald Lang's analysis of this decade-long struggle identifies how the main actors aligned themselves in the pricing debates (Lang 1974). The Canadian government's intensive work on pharmaceutical drug prices began in 1958 and culminated in legislation passed in 1969.<sup>116</sup> Not only were prices in Canada high by world standards, Canadian-owned firms held fewer than five per cent of the patents on drugs sold in Canada and had only one per cent of the world exports of drugs.<sup>117</sup> Seven or eight large international companies holding U.S. patents dominated the Canadian market and they viewed Canada as simply an extension of their domestic territory.

The Canadian branch companies of American firms all belonged to the Pharmaceutical Manufacturers Association of Canada (PMAC), a pressure group with 59

members from international companies which together represented 85 per cent of the total Canadian market. A subsidiary company was not likely to develop, manufacture and market a product in competition with its own parent company or to use compulsory licensing to compete with another brand name company.<sup>118</sup> The result was that the Canadian drug trade operated according to U.S. patent law, which gave patent holders a legal monopoly on the sale of their products for up to 17 years. Canadian subsidiary companies obtained patents in Canada under the terms of American patent law and charged as much or more for their drugs in Canada as they did in the United States.

The *Green Book* argued that the compulsory licensing system remained dormant in Canada because decision-making for PMAC members lay in a structure dominated by American firms. A second organization, the Association of Canadian Drug Manufacturers (ACDM), made up of about 15 Canadian-based generic manufacturers, had ten per cent of the market.<sup>119</sup> The two groups generally had diametrically opposing views; PMAC considered its members to be “innovators” and excluded ACDM members from its membership on the grounds that they were “copiers” (Lang 1974: 53).<sup>120</sup>

The Green Book and the Harley Report also singled out the pharmaceutical industry’s promotional practices as factors limiting competition and contributing to high prices. At least twenty-five per cent of net sales was spent to promote brand names and to undermine confidence in generic alternatives by implying that they were inferior. Promotional material to physicians was deemed to be “excessive and objectionable” (Lang 1974: 44). PMAC vehemently attacked the recommendation for compulsory licensing system as well as a second proposal that generic names be required to appear on labels and in advertisements in a type “at least as large as that used for the brand name”

(*Green Book*, p 497, cited in Lang 1974:33). Lang describes PMAC's lobbying efforts as so transparent and insensitive to the concerns of Canadians and their political representatives that they surpassed ineffectiveness and were counterproductive. An industry insider who had been hired by PMAC told Ronald Lang that the American industry's main concern was not the relatively small Canadian market, but rather, the strategic need to block "legislation that might prove to be precedent setting and possibly attractive to the legislators and consumers of other countries -- in particular the United States" (Michael Sheldon of PMAC, cited in Lang 1974:42).<sup>121</sup> Adding to PMAC's problems was the fact that the American parent companies, from which PMAC took its direction, were preoccupied until 1963 with their own fight with Kefauver and the US Congress (Lang 1974).

Lang argues that PMAC undermined its claim to be guided by ethical principles of "public service" by defending drug prices in Canada as in fact low – despite being the highest in the world – in view of the small number of hours Canadians had to work to pay for their drugs. In other words, the basis for pricing was not the intrinsic worth or cost of the drugs, but what the companies judged Canadians could afford. PMAC further alienated potential allies in government, among politicians, and in the media by misrepresenting its profit margin and the cost of quality control. In another tactic, the industry tried to use the thalidomide scandal to shift the discourse from drug costs to drug safety.<sup>122</sup> The bill, when it was tabled, surprised the industry which had expected the government to lower prices by eliminating a tax. Senior civil servants – who had been guiding the proceedings from behind the scenes from the beginning – had always intended a more comprehensive strategy. They were strongly committed to lowering

prices, to promoting a generic industry in Canada and to defeating an industry they viewed as “arrogant” (Lang 1973:136). Their multi-pronged “package” approach, which centred on attacking the patent system, was reflected in the recommendations of the Harley Committee and in Bill C-102, the legislation that was passed into law in 1969 by Pierre Trudeau’s newly-elected government.

The Act to Amend the Patent Act, the Trademark Act and the Food and Drugs Act as the new law was called did not immediately result in lower drug prices and a year after it was passed the new law was already being called a failure (Lang 1974). In 1984 Prime Minister Trudeau set up a Commission of Inquiry into the pharmaceutical industry, headed by Harry Eastman, which concluded that the new regime had supported the development of a robust Canadian generic drug industry and lowered drug prices, saving the public an estimated \$212 million in 1983. At the same time, the Eastman Report found no evidence that the multinational companies had suffered financially; they lost only 3.1 per cent of the Canadian market to generic companies and their profit levels in Canada remained above that of most other industrialized countries, except for the United States (Lexchin 1997b). The availability of cheaper drugs had also made possible provincial drug subsidy programs for seniors and welfare recipients (Lexchin 1997b). The Commission’s report, published in 1985, strongly recommended keeping the system of compulsory licensing although perhaps with some modifications to appease the industry. Notably, drug prices in Canada achieved levels that by 1986 were twenty per cent below those in the United States (Cohen 2004:7-8).

Pharmaceutical companies and their Canadian and US lobbying organizations, PMAC (since rebranded Canada’s Research-based Pharmaceutical Companies, or

Rx&D), and the PMA (now the Pharmaceutical Research and Manufacturers of America, or PhRMA) continued to strongly oppose the Canadian compulsory licensing law, litigating the licenses granted almost routinely;<sup>123</sup> Canadian courts upheld the practice, however, taking the position that containing drug prices serves a social purpose. Although the experiment in compulsory licensing antagonized the international pharmaceutical industry, it achieved both social and economic goals by giving Canadians access to essential drugs at reasonable cost and at the same time spawning a home-grown generic pharmaceutical industry. In 1987, a Canadian Federal Trial Court concluded that the Food and Drugs Act's primary purpose is to regulate public safety; economic and trade goals are secondary (Carter 1999:222).<sup>124</sup> The U.S. Food and Drug Administration's primary role has, similarly, been determined to be protecting consumers (Carter 1999:225).

#### 4.3.8 Failures of the Drug Approval System

The Health Protection Branch (HPB) was established under the Foods and Drug Act of 1952-1953 as the enforcement agency of the Act (Wassenaar 1980:454). In 2000, the agency was restructured and renamed the Health Products and Food Branch (HPFB) (Gray 2000). Under either name, the agency wields what one analyst calls a "most formidable" power, that of approving new drugs so they can enter the market in Canada (Nielson, cited in Carter, 1999:229, note 115). Safety, efficacy, the time taken to approve a drug ("lag times"), and the government's perceived relationship to industry are all topics of regular contestation by industry and a range of other actors including

physicians, journalists, and civil society groups. As outlined here, each elicits discourses from a relatively standard roster of interested parties.

The late Nicholas Regush,<sup>125</sup> one of the few Canadian journalists specializing in health protection issues, claimed that Canada's drug safety review system "sparkles" on paper, comparing well with other developed nations and "very favourably" with those of developing nations; however, he cautioned, "on a scale of ten, the highest score among industrial nations is about five. Being one of the best is not so terrific." (Regush 1993:11-12). Despite the apparently rigorous regulatory regime put in place after thalidomide, drug-related tragedies continued in the decades following the 1963 revisions, often the result of truth claims based on flimsy or absent evidence. Among the concerns Regush and others have raised are the industry's ability to circumvent regulations, its use of regulatory loopholes to make misleading claims that define the public's understanding of drugs, and its tendency to market to women.

Once a drug is approved for marketing, the company can begin promoting it. In Canada, as in most industrialized countries, the regulatory regimens governing pharmaceuticals introduced in the mid-20<sup>th</sup> century allowed manufacturers to promote drugs only to physicians, the designated "gatekeepers" of prescription medications. The rationale was that physicians' training and knowledge of a particular patient's case would allow him or her to decide whether a drug was appropriate to that patient's condition and safe enough on balance to warrant prescribing. Except for the U.S. and New Zealand, drug regulators outlawed advertising directly to the consumer on the grounds that drugs can cause serious harm and patients are vulnerable targets for misleading claims (Mintzes 2009). Nonetheless, advertising to physicians through their medical journals and the



process of “detailing,” in which sales representatives visit physicians in their offices to promote the use of a company’s new drug, involved a range of questionable tactics designed to maximize “scripts” or prescriptions, regardless of whether the drug in question was the most economical and appropriate, or whether it was an appropriate treatment at all (Greene 2004, Oldani 2004; Avorn 2011).

The injectable contraceptive Depo Provera is an example of a drug<sup>126</sup> for which promotional material overstated benefits and downplayed potential harms. The drug was typically promoted to physicians through drug advertising in medical journals or at lavish dinners paid for by the company (Regush 1987). Another promotional strategy that critics claimed resulted in drug overuse defined drugs to physicians as solutions to socially-based problems. In the 1960s and 1970s, drug use statistics from England, Canada, and the U.S. showed that psychotropic drugs, specifically tranquilizers, accounted for approximately 20 per cent of all drug use and advertising to physicians and specifically profiled emotionally distressed middle-aged women as the drugs’ main potential beneficiaries (Cooperstock and Lennard 1979). Medical sociologist Ruth Cooperstock, who spent much of her career working for the Addiction Research Foundation in Toronto, was among those who argued that the widespread use of these drugs depended on the social construction of physical diseases. Political changes, she suggested, are a more appropriate method than drugs for addressing problems such as anxiety from highly gendered role pressures (Anonymous 2006, Cooperstock and Lennard, 1979).

DES and the Dalkon Shield are two other instances of pharmaceutical products that suffered regulatory system failures. DES is a synthetic sex hormone developed in London, England in 1938. Beginning in 1940, the drug was given to pregnant women to

prevent miscarriage and for gynecological and menopause-related symptoms, without adequate testing for either safety or effectiveness. In the 1950s a double-blind trial showed that DES had no benefit for pregnant women, yet the drug continued to be prescribed to prevent miscarriages until 1971 when a published report showed that it was associated with a rare vaginal cancer in the daughters of women who had taken it while pregnant (Goodman et al 2011). The Dalkon Shield, a contraceptive device, was also aggressively marketed despite lack of evidence to back the company's claims. As a medical device the Dalkon Shield came under the same regulatory regime as drugs (in Canada, the Health Protection Branch of the then-Department of Health and Welfare; in the US, the FDA). The American pharmaceutical company A.H. Robins purchased the Dalkon Shield in 1970 from a smaller company that had developed the device. Robins sold an estimated four to five million devices before taking the Dalkon Shield off the market. The company was besieged by lawsuits claiming that the device caused miscarriages, sterility and infections -- some of which were fatal (Regush 1993; Hawkins, 1997).

That Depo Provera, DES, the Dalkon Shield and tranquilizers were all drugs marketed exclusively or primarily to women is no coincidence; from the beginning, the industry understood women to be its major market (Anonymous 2006). Because so many drug and medical device scandals have involved products specifically for women, or targeted largely to them, women's health activists mobilized to form advocacy organizations and counter-campaigns focused on particular pharmaceutical products, including the psychotropic (mood-altering) drugs, DES and the Dalkon Shield. They

joined forces with journalists and researchers to develop a critical analysis of the pharmaceutical industry in this era.

The length of time required to complete a drug review without compromising safety is a topic of ongoing contention. I examine the pre-1990 discourse about drug approval times in some detail because, as I will show in the next chapter, the issue is one to which patients' organizations have brought particular attention.

A drug review balances the need to ensure safety and effectiveness (the review's central purpose) so advocates for whom drug safety is a priority tend to be skeptical of rapid reviews. Pharmaceutical companies, by contrast, having brought a drug to its final regulatory hurdle are eager to move it to market as quickly as possible. Patients like to have timely access to promising new drugs and perceive needlessly slow reviews ("drug lag") as an impediment to such access. The term "drug lag," with its pejorative overtone, implies that bureaucratic processes within regulatory agencies slow the conduct of drug reviews, delaying access to important therapeutic advances and restricting the profits necessary for a healthy pharmaceutical industry (Hilts 2003<sup>127</sup>, Lexchin 2008).

In his history of the U.S. FDA, Philip J. Hilts argues that the issue of drug delay has come to the fore in the United States in more conservative times and that the term is meaningless because judgments about a drug's safety and efficacy must be made case-by-case. In some instances, taking the time to ensure that a drug is supported by better data than that initially provided will ultimately mean fewer patients are harmed and more will benefit from the drug (Hilts 2003: 376). Thus, to translate "rapid review" as meaning "more patients will benefit" misrepresents the truth and masks the importance of market forces in the drive to speed reviews. Few drugs are truly innovative. Most new drug

submissions are “me too” drugs,<sup>128</sup> virtual copies of “blockbuster” drugs that have been profitable for other companies. Furthermore, companies spend more money on marketing than drug development (Hilts 2003: 191). They have little interest in developing drugs for diseases that cost millions of lives annually in poor countries, but will invest heavily in drugs for medically trivial conditions like baldness. Advocates of case-by-case review times argue that reviewers should, and usually do, give priority to innovative drugs so that the review times of these drugs are much faster than average, while me-too drugs are given low priority because bringing them to market has little therapeutic benefit (Regush 1993).

Government agencies in different countries track their safety records and their review times against one another and try to improve. In the 1970s, Canada’s review times were considered ahead of the international standard, with a complete review of an “important, new” drug taking 16 months; the average review time for priority drugs in the United States in the same era was 23 months (Carter 1999: 235, n 165, citing GAO, 1980). Throughout the 1970s, however, the HPB’s workload increased by about ten per cent a year<sup>129</sup> with no increase in staff and review times slowed; by 1982 the head of the Bureau of Human Prescription Drugs was feeling pressured by drug companies to speed drug approvals (Regush 1993: 15-16). Between 1985 and 1987, four government reports were published expressing concern about a drug review backlog.<sup>130</sup>

#### 4.3.9 Post-Marketing Surveillance

Claims of a drug’s safety and effectiveness, on the part of the industry, prescribing physicians, insurers who pay for the drugs, the media, and ultimately the

public, are negotiated through a complex and largely unseen process. A “new drug,” as defined in the Canadian Food and Drugs Act, is one that has not been sold in Canada long enough and/or in sufficient quantity, to establish its safety and effectiveness (Carter 1999: 229). This definition recognizes that clinical trial results are necessary but not sufficient to establish a drug as safe and effective. Clinical trials are of limited duration, and typically involve only hundreds or a few thousand patients; clinical trial evidence therefore cannot detect safety problems that are relatively rare nor can it establish clinical risks and benefits over long term. This knowledge comes from real-life usage after the drug is approved. Thus, approval of the New Drug Submission allows the company to begin marketing the drug in Canada but the drug remains on probation for a period determined by the Health Protection Branch<sup>131</sup> which decides when the drug has been in use long enough and by enough people to determine that it is safe and effective. The length of time varies depending on the drug. According to lawyer Patricia Carter, writing in 1999, this was usually about five years. During this time, the drug remained classified as “new drug” and the manufacturer was required to report any adverse reactions occurring in Canada (Carter 1999: 233). In 1998, Health Canada introduced the NOC/c classification system which was revised in November 2002.

Post-marketing surveillance was another discursive battleground within pharmaceutical policy in Canada in the 1980s in which, by Nicholas Regush’s account, safety was sacrificed to a politically motivated drive for faster approvals. In 1982, two senior bureaucrats were pressing for a structured, effective post-marketing surveillance system to replace the passive, voluntary process that was in place. The latter depended on physicians and hospitals to fill out and file voluntary reports of adverse drug side-effects

when they occurred, a method widely recognized to be ineffective because only a small proportion of such events are ever reported. Dr. Edward Napke who headed the Ministry of National Health and Welfare's Drug Adverse Reaction Reporting Program,<sup>132</sup> had been trying to get a systematic post-marketing surveillance system in place since the thalidomide tragedy. He wanted to be able to collect, collate and evaluate information on pharmaceuticals in use in the population, then feed the data back to the medical community and the drug industry (Regush 1993: 17). In 1982, however, his total budget was only \$21,000. Dr. Ian Henderson, a colleague who headed the Bureau of Human Prescription Drugs in the Ministry of National Health and Welfare, had proposed that drug companies be required to monitor their drugs as a condition of sale. Indeed, the issue of post-marketing surveillance had been flagged as a key area of concern for drug safety in the United States and Europe, with a major US commission on the subject recommending that an independent, university-based centre be established for the purpose (e.g., Culliton and Waterfall, 1980; Banta et al 1982). Yet, says Regush, attention in Canada was focused on the politically-driven goal of speeding drug approvals (Regush 1993:17). Regush saw the government's lack of attention to a drug safety monitoring system as simply a sign of shifting priorities, away from safety, effectiveness and a concern about honest claims, to marketing and economic growth. The need for the former had been particularly brought to his attention in his coverage of the Môme breast implant.

#### 4.3.10 Internal Breakdown: Public Safety and the Môme

The marketing of a polyurethane-covered breast implant, the *Môme*, to both breast cancer patients and to healthy women, began to make news headlines in both Canada and

the United States in the late 1980s, and became a focus of concerns about the process of regulating medical devices and pharmaceuticals in Canada.<sup>133</sup> Although silicone breast implants had been on the market since 1963, they had been largely unregulated and were assumed to be safe. The FDA had classified the implants as potentially risky in 1982, noting that little safety and efficacy data was available; the same year Health Canada had introduced a new regulation requiring (for the first time) safety and efficacy data for any implants put in the human body for 30 days or more. Still, little information was available on the safety of the devices. Between 1985 and 1988, questions about breast implants were raised by a variety of people in Canada who had a platform, including research scientist Pierre Blais of the Health Protection Branch in Ottawa, University of Laval research chemist Robert Guidoin, and Linda Wilson, a BC woman who had had implants inserted after a doctor advised her to have her breasts removed as a precaution against cancer and who suffered severe side-effects (Regush 1993:73-105).<sup>134</sup> While the concerns about the safety of breast implants were not exclusive to the Môme,<sup>135</sup> this particular brand attracted attention because of an unusual foam covering that broke down in the body, releasing a chemical that was a potential carcinogen. The scandal led to the formation of a national women's health advocacy organization, *Je sais/I know* whose members began to speak publicly about their experiences. The predominant users of implants, about 80 per cent, were women who wanted to increase their breast size; the remaining twenty per cent were women who had had mastectomies as part of their cancer treatment (Wilson and Brown 1995). When women with breast cancer began to organize in the 1990s, the breast implant issue had already spawned a movement of its own which overlapped with, but was not integral to, breast cancer activism.

In his coverage of the Mème affair Nicholas Regush was particularly struck by the federal government's apparent wish to minimize the problems with the device rather than to take action. His investigation led him to write a book-length examination of Canada's Health Protection Branch, *Safety Last: the Failure of the Consumer Health Protection System in Canada*. He concluded the agency had undergone a gradual change over the previous decade, shifted its guiding principle from one of protecting the public's health to promoting industry and trade. The introduction summarizes his thesis:

The [Health Protection] branch had begun its decline during the late 1970s. Tough economic conditions led to government cutbacks. Programs that reviewed the safety of drugs and medical devices did not broaden according to plan. Staff shortages caused discontentment among overworked scientists and friction between them and their managers. By the early 1980s, government safety reviewers were under increasing pressure from their managers and industry representatives to speed up pre-market evaluations (Regush 1993:2-3).

Adding to the economic pressures, Regush claimed a cultural shift occurred when a Conservative government took power from the ruling Liberals in 1984, gradually eroding government regulation in the service of a "trust-industry philosophy" that "shredded a safety net that, at the best of times, has been delicate." (Regush 1993: 3) A strong believer in both the safety net and in the aggressive monitoring of industry, Regush concluded, after a 1990 meeting with Margaret Catley-Carleson, the Deputy Minister of the Department of Health and Welfare, that she was neither; in fact, she described his reforming style of reportage to be "obso" (i.e., "obsolete").<sup>136</sup> His account



of the meeting portrays a shift in government ideology from the top and a sharp contrast in views over the question of the government's role:

She ... detailed her vision of a new partnership between government and industry: Industry really wanted to do good because it was in industry's best interest to do so. Think partnership, not conflict. Crusaders who would keep industry in check were obso.

... I pondered whether she and I were from the same planet. Her suggestion that the drug industry does not require aggressive monitoring seemed evidence of an active fantasy life.

(Regush 1993: 3)

#### 4.3.11 Breast Cancer Drugs and Regulation in Canada

Drugs have long been recognized for their ability to simultaneously attract and repel. Anthropologist Emily Martin points out that the word "pharmakon," used in ancient Greece to mean both "remedy" and "poison," captures an inherent ambivalence towards medication (Martin 2006). Martin has specifically studied psychotropic drugs; however, the ambivalence she documents may be even more marked with cancer drugs, since the disease is one of the most dreaded in contemporary life while chemotherapy treatments are among the most toxic in the current pharmacopeia. Against the negative stereotypes of chemotherapy's effects on the patient as, "nausea, vomiting, fatigue and hair loss," chemotherapy may also conjure images of "powerful drugs patrolling the body, destroying wayward cancer cells" (Lerner 2001: 252, 253). Both faces of the drug are, to some degree, socially constructed. In her study of psychotropic drugs, Martin found that manufacturers used marketing firms to invest drugs with particular personalities, like a person's, which would capture the drug's positive and negative

characteristics in an appealing way to create a “core-brand idea” (Martin 2006: 275).

Thus, based on focus groups with potential users, an advertising agency might decide to promote a drug to be “[like] Hillary Clinton ... [she’s] strong and tough and knows what she wants to do, and yet [is] sensitive to social issues.” Such a drug would “work really well” but would also have “a feminine sort of feeling” (ibid: 275). The concept of drugs as actors with dual-faceted, socially constructed personalities is useful in understanding the contestations over the meanings of drugs used to treat breast cancer.

Because cancer is considered one of the more serious (i.e., potentially fatal) diseases, the margin of toxicity considered acceptable has exceeded that for diseases that are not life-threatening (e.g., arthritis); furthermore, the evidence required to demonstrate efficacy has been correspondingly less – to the point where one oncology specialist characterized approvals for new cancer drugs circa 1992 as “willy-nilly” (Williams 1992:233). This dynamic underpins what Delvecchio Good et al (1990) have called “the discourse on hope” in oncology treatments and anticipates a point that historian of science Ilana Löwy has made, that clinical trials for cancer have accepted “surrogate endpoints” for drug approvals rather than true endpoints that demonstrate actual benefit for the patient (Löwy 2000). Thus, cytotoxic chemotherapies are approved for patients with advanced disease if they show tumor shrinkage. In the case of tamoxifen, a reduced risk of a cancer in the opposite breast, rather than extended life, served as the surrogate endpoint. Williams’ framing of the exceptional standards by which treatments are judged makes explicit the expanded role for social actors in the process of their evaluation:

This difference in emphasis means that toxic drugs can be used for potentially fatal diseases that would never gain a license for less serious indications. However, these may also be used as a way of gaining a tacit acceptance of a new drug without demonstrating whether it is beneficial to the patients.

Traditionally new anticancer drugs have been submitted for licensing on the basis of demonstrating the rate of tumour shrinkage (percentage response rate). Such data have not demanded that it be shown that patients feel better or live longer for their treatment. The decision as to whether drugs be used has been left to the discretion of the individual clinician, market forces (including drug company promotion) and to a lesser extent clinical trials or “directives”... from governmental bodies or research organizations. (Williams 1992: 232).

The increased reliance on chemotherapy treatments reflected the gradual shift in medical thinking about breast cancer as evidence began to accumulate that breast cancer cells were disseminated systemically from the outset through the blood (Lerner 2001). In 1976, a prominent cancer research group in Milan headed by Gianni Bonadonna found that the combination cytotoxic chemotherapy regime known as CMF (cyclophosphamide, methotrexate and 5-fluorouracil, also called 5-FU)<sup>137</sup> significantly reduced the risk of recurrence in premenopausal women with stage 2 disease (i.e., cancer was detected in one or more underarm lymph nodes); subsequent follow-up showed improved overall survival (Bonadonna, Brusamolino, Valagussa, et al 1976). These findings generated a debate about whether such combination cytotoxic chemotherapy should be standard for all women with stage 2 disease, and whether the treatments should be made optional for women whose disease was still stage 1 and thus, presumably, even more curable. Barron Lerner summarizes the debate:

But there was a catch. At least 80 per cent of women treated with such surgery for clinical stage 1 disease survived without a recurrence for ten to twenty years, indicating they were probably cured [i.e., without chemotherapy].<sup>138</sup> Of the remaining 20 per cent who might benefit from chemotherapy, only a minority, perhaps one fifth, avoided death or a recurrence as a direct result of receiving chemotherapy. Thus the vast majority of women treated for adjuvant<sup>139</sup> chemotherapy for stage 1 breast cancer would experience no actual benefit from this therapy, only the side

effects, such as nausea, vomiting, fatigue and hair loss. These drugs also led to suppression of the bone marrow, making patients susceptible to infections, some of which could be life-threatening. Risk of future leukemias was another potential complication. (Lerner 2001:252)

In the language of personalities, cytotoxic chemotherapy is often referred to as “aggressive” – a quality not entirely pejorative when applied to a drug meant to “fight” a deadly disease.

The anti-estrogenic drug tamoxifen also emerged as a treatment for breast cancer in the mid-1970s and in 1977 the FDA approved its use specifically for those women whose breast tumors were classified as estrogen-receptor-positive, that is, dependant on estrogen to grow (DeGregorio and Wiebe 1999; Jordan 2003). Unlike cytotoxic chemotherapy, tamoxifen inhibits cell growth. Prior to 1990, tamoxifen was given only to women over 50 who had been shown to have estrogen-sensitive tumours, usually for three to five years. Whether the drug would actually extend or save lives was not known in 1990, although for a woman over 50 who had had cancer in one breast, tamoxifen had been shown to reduce the risk of a cancer developing in her second breast. Since tamoxifen is in pill or tablet form, usually to be taken twice a day, it was easier to administer than cytotoxic chemotherapy, which had to be infused by a trained nurse in a hospital. As a personality trait, this quality could be translated as “convenient.”

Enthusiasts of tamoxifen describe the drug as “nontoxic” (Jordan 2003); others described tamoxifen’s side-effects as “usually minimal” compared to those of cytotoxic chemotherapy (Love 1990: 324) or “for the most part, . . . well tolerated” (DeGregorio and Wiebe 1999:47). The most common side effects were hot flashes, nausea and vomiting for one or two months, vaginal spotting and weight gain. Some patients experienced more

severe effects, however, including depression, loss of appetite, headache, loss of vision, blood clots and, in one study, endometrial cancer. The American surgeon, Dr. Susan Love, in her first book on breast health and breast cancer aimed at lay women, published in 1990, advised, “tamoxifen should not be considered lightly” (Love 1990: 324).

With both these types of chemotherapy, then, the risks in 1990 for individual patients were uncertain, as were the benefits, and yet they had moved into standard practice, particularly in the United States, but also in Canada. The readiness to accept risky treatments despite minimal evidence of benefit fits a pattern that historians and anthropologists studying cancer have identified as particularly characteristic of American cancer specialists (i.e., physicians and researchers). They tend to infuse cancer treatments that involve high risks with the power to provide hope and American cancer patients reflect this same value orientation (Good et al 1990, Lerner 2001). American cancer patients thus accepted chemotherapy with much greater enthusiasm than patients in Canada, Great Britain or France (Löwy 1996). America’s for-profit medical system encourages this openness to costly untested treatments as does the economic and political power of the pharmaceutical industry in the US. Yet the availability of risky experimental treatments in the United States has the potential to exert pressure on the Canadian cancer care system, particularly if patients with advanced cancer -- who have little hope of long-term survival -- believe they are being denied a potential cure or a chance to have their life prolonged.

This contrast in US and Canadian approaches to treatment and the potential for a spillover effect was seen in the case of the experimental procedure known as high-dose chemotherapy with stem cell rescue (Lerner 2001). The procedure rose in popularity in

the United States in the late 1980s and was offered to women with advanced breast cancer. It required removal of stem cells from the woman's bone marrow, followed by the administration of cytotoxic chemotherapy at up to twenty times the standard strength, designed to kill all the cancer cells after which the woman's stem cells were then infused. The hope was that the chemotherapy would eliminate the cancer and the stem cells could restore her white blood cells – which the chemotherapy would also kill. Women demanded the procedure and hospitals provided it, although it had not been evaluated in clinical trials; indeed few American women were willing to enter clinical trials because they did not want to risk being denied the opportunity to have the treatment (Lerner 2001: 255). “High-dose chemo” with stem cell rescue was both expensive and risky; it required lengthy hospital stays and was driven partly by the opportunity for hospitals to profit and partly by the strong demand for a treatment for advanced breast cancer that was potentially curative (Lerner 2001:255). The practice continued for over a decade; in 1999, clinical trial data collected in four international trials were published which found that the procedure offered no survival advantage over standard-dose chemotherapy (Lerner 2001:255). Shortly thereafter, sensational revelations published in the *Lancet* exposed the only clinical trials demonstrating benefit, conducted by a team in South Africa led by Dr. Werner Bezwoda, to be fraudulent (Weiss et al 2000).<sup>140</sup> Bezwoda's actions illustrate the powerful incentive to researchers invested in the hope of discovering a cure. High-dose chemotherapy with stem cell transplant was discontinued in the US and everywhere else. In Canada, the procedure had not been given outside of clinical trials and some Canadian women travelled to the United States at their own expense to gain access to the procedure (Morrison 1991:48). The “hope factor” gained power with the advent of breast cancer

advocacy groups. As women in the groups themselves engaged in co-constructing the personalities of new breast cancer treatments, their voices raised the discourse of hope to a new level. The turn to pharmaceuticals as a holy grail clashed with the women's health advocacy that prevailed in Canada in the 1980s, however, as the following discussion suggests.

#### **4.4 THE RISE OF HEALTH-RELATED PRESSURE GROUPS IN CANADA**

Miriam Smith observes that, "the study of disability movements and health social movements in Canada is in its infancy" (Smith 2008:30). Groups with an interest in health are not new in Canada, however. In this section, I examine the precursors to contemporary patients' organizations, in particular groups that have focused on women's health, as they have evolved through periods leading up to the neo-liberal era when patient-focused breast cancer groups began to form.

Organizations that engage in advocacy to influence public policy are an important class of political actors, known by a variety of names including "pressure groups," "interest groups" or "civil society organizations."<sup>141</sup> Civil society is often viewed as a third major actor, along with government and the private sector; the divisions between the three sectors are fluid and the boundaries can shift and blur, however. From colonial times to the present, Canadians have formed organizations and these groups adapt their characteristics as economic and political structures shift (Pross 1992, Pross and Webb 2003). Pressure groups have long been viewed as a mixed blessing, Pross observes. On the positive side, they can perform unique, useful functions, such as communicating changing political concerns, a contribution that makes them vital actors in a democratic

state. On the negative side, two main problems are unequal resources and legitimacy. Influencing the Canadian policy system requires resources beyond the capacity of most public interest pressure groups; and the legitimacy of groups can be hard to judge (ibid 1992). Thus, two problems underlying my research – the resources and legitimacy of groups – are not new. The larger political framework in which the groups operate has changed, however.

From the mid-1960s to the mid 1980s, pressure groups became more numerous, active and publicity-conscious than they had been previously (Pross 1992:23). In addition, with the advent of neo-liberalism, traditional boundaries between civil society, government and the private sector began to blur (Smith, 2005). Smith (2005) argues that, in Canada, the meaning of civil society underwent radical change. She examines the period during which Canada made the transition from welfare state to neo-liberal state. In her assessment, this recent (and continuing) transition constitutes more than an evolutionary change. She asserts that this move constitutes a massive paradigm shift in the nature of global capitalism which calls for a reassessment of the roles of all actors, including collectivities or pressure groups.

Neoliberal globalization entails much more than free trade agreements, free markets, deregulation, or privatization. ... the patterns of group and social movement influence *vis-à-vis* the state have been fundamentally altered. The transition from one set of economic policies to another has entailed a shift in the paradigm of politics in Canada, one that has important consequences for democracy.... The means and methods of influence for groups and social movements have been altered in ways that have heightened the legitimacy of business groups while undermining certain social movements (Smith 2005: 13).

Like other analysts of Canadian politics (Jenson and Phillips 1996, Bashevkin 2002) Smith concludes that the globalized neoliberal regimes alter the very concept of



citizenship, bringing under attack once-legitimate forms of collective action intended to provide groups that are disadvantaged in the political system with more power. Strategies involving conflict and contestation have been delegitimized while methods that engage the individual consumer/ client/citizen are now privileged (Smith 2005:16).

#### 4.4.1 First and Second Wave Feminist Health Discourses

The breast cancer advocacy groups that emerged in Canada and the United States in the late 1980s or early 1990s adapted discourses, structures and tools of community activism that had deep roots in women's social and political lives (Kaufert 1998). These continuities can be seen by examining the two periods of feminist activism in North America that scholars identify as first and second wave feminism (third-wave feminist activism corresponds to the period in which breast cancer groups evolved). Both earlier stages included claims about women's bodies and health. Canada's first wave of feminism dates from the late nineteenth century to 1930 and was spearheaded by affluent political reformers whose main goals were suffrage and recognition in law as persons. They did not self-consciously fashion a "health movement;" nonetheless, their activism implied a demand for more control over their bodies and lives (Morrow 2007).<sup>142</sup> As Kaufert implies, the motivating factors, organizational shape, and discourse of today's breast cancer groups are recognizable in organizations like the Women's Institute<sup>143</sup> and the Victorian Order of Nurses,<sup>144</sup> both founded in 1897 with health-related missions. The founder of the Women's Institute turned to health activism after her infant son died from drinking contaminated milk; the Victorian Order of Nurses was a response by the then-Governor General's wife to desperate pleas from women in isolated communities across

Canada who were unable to gain timely access to medical care when they or their children were sick. At an annual meeting of the National Council of Women, members passed a resolution formally appealing to Lady Aberdeen for help in the form of visiting home-care nurses. The result was the Victorian Order of Nurses, a cross-Canada network of nurses who provided medical care to isolated, housebound women and their children. The Women's Institute set up libraries and organized talks to increase rural women's education and civic engagement, particularly on issues related to food and healthy eating. Local groups were linked through regional and national networks; members met in one another's homes and in churches and community halls, producing newsletters, and organizing campaigns to lobby legislative bodies.

Traces of these early organizations, formed in response to women's personal suffering and their desire for more knowledge and better health services, are recognizable in the breast cancer groups described in the last chapter. The vehicles they devised included local organizations linked regionally and nationally which held meetings and produced publications designed to increase their personal and collective knowledge and to influence health policy. The activism of this era was undertaken primarily by white Christian women who were middle-class or affluent and the goals were skewed towards their concerns (Morrow 2007). As Kaufert (1998) observes, the early breast cancer movement adapted the goals and strategies of earlier health activists and replicated this class-based limitation.

The second wave of feminism began in the 1960s and 1970s and spawned an organized movement in Canada more clearly dedicated to women's health issues, particularly issues related to women's reproductive rights. Three unifying themes were,

first, that women have the right to knowledge about their own bodies; second, that much of the information about women's bodies in the medical and societal canon was based on myth, not fact; and third, that lay women possessed valuable knowledge about themselves (Morrow 2007). This discourse emboldened women to research and produce their own health publications, sometimes in opposition to official knowledge claims. One of the most striking early Canadian examples was the *Birth Control Handbook*, produced by students at McGill University in 1968, when providing contraceptive information was still illegal in Canada.<sup>145</sup> The 1972 American book *Our Bodies Ourselves (OBOS)*, a ground-breaking publication produced by a lay collective of women in Boston, was influential among women in Canada. OBOS challenged societal and medical myths about women's health and encouraged women to become experts about their own bodies (Morrow 2007). A Toronto-based feminist health magazine, *Healthsharing: a Canadian Women's Health Quarterly*, launched in 1978, was conceived in the same tradition and continued to publish feminist articles on women's health issues for 15 years.

Activism to change laws and policies related to women's health was integral to second wave feminism's women's health movement and the formation of groups was part of this process. The fight for abortion rights illustrates the interaction between organizations and action and state support that supported the proliferation of women's health groups in the country during this period. In 1969, the Trudeau government passed the first law designed to make abortions legal in Canada under limited circumstances. To protest the restrictions surrounding the law, the following year a local group of Vancouver feminists, the Vancouver Women's Caucus, organized the Abortion Caravan, which had pro-choice activists travel from Vancouver to Ottawa, gathering supporters

along the way. Their demonstration in the House of Commons for the decriminalization of abortion shut down Parliament. This action spawned a national abortion rights organization, formed in 1974; subsequently, abortion rights groups formed provincially along with clinics that together fought to make safe legal abortions a woman's right (Tudiver 1994).<sup>146</sup>

By the 1980s, women's health activism in Canada was well-developed and had significant government support through federal and provincial programs designed to improve the status of women.<sup>147</sup> One result was a cross-Canada network of 100 women's centres supported by federal funding, sometimes augmented by provincial funding. Some, including rape crisis centres and women's shelters, were formed around specific health issues; others, like Women's Health Collective in Vancouver, had a broader women's health mandate. These centres led to a range of alternative approaches to care and housed self-help groups to address problems such as breast cancer, endometriosis, and mental health. While the second wave feminist organizations were again dominated by the concerns of women in the mainstream (white, middle-class, able-bodied, heterosexual), this period also saw the creation of autonomous health groups by women who identified as lesbian, disabled, as women of colour and/or as immigrant women (Morrow 2007).

#### 4.4.2 Group Politics and the Feminist Discourse on Drugs

Second-wave feminism introduced the important innovation of consciousness-raising groups, at which women met for focused discussion about the structural reasons for women's exploitation (Morrow 2007). A theme that emerged from groups in the

women's health movement was the medicalization of women's bodies, including the control that pharmaceutical companies exercised over women. The networks of women's centres not only provided health-related services to women, they became sites for feminist analysis on the social roots of women's health problems, moving feminist discourses to the community level (Morrow 2007). The critique of the pharmaceutical industry and the harms of pharmaceuticals directed at women drew from the series of pharmaceutical disasters involving women, including thalidomide, DES, Depo-Provera and the Dalkon Shield to point out the potentially devastating effects of drugs and devices related to reproduction (Regush 1987).

The 1970s and 1980s were thus a period in which Canadian women mobilized to protest the promotion of dangerous drugs to women and to push for better drug regulation. Women who had been harmed by drugs formed the grass-roots women's groups DES Action Canada and Dalkon Shield Action Canada. Another protest initiative was a play titled *Side-Effects*, about the harmful effects of pharmaceuticals prescribed to women, which toured Canada in 1985 (Tudiver 1994; Clement, 2006:3-6). The idea for the play was conceived and developed at a workshop hosted by the Ottawa-based development agency, Inter Pares. The agency collaborated with a theatre company and local women's groups to develop a play based on women's own stories, which toured English Canada and (in translation) Quebec. As the play toured, it drew support from existing women's health groups and spawned regional networking groups (Tudiver 1994).<sup>148</sup> At the heart of these protests was the claim that the health protection system was inadequate because it accepted uncritically the biomedical model of health while ignoring the social and political drivers of drug and medical device use. Significantly,

women's health advocacy organizations concerned about drugs received financial and moral support from government agencies, such as the Ministry of National Health and Welfare, provincial community and public health departments, and federal and provincial Status of Women offices and offices. Support from government agencies was not monolithic, however; they also encountered resistance.

Margaret, now a university professor whose work remains rooted in women's health and pharmaceuticals, describes her initiation into pharmaceutical activism as follows:

I started work in 1983 at the Vancouver Women's Health Collective [VWHC]. This was very soon after I'd graduated from university and ... soon after I started working there I went to a conference on women and pharmaceuticals where I met various people I still work with. .... And also, I went to a presentation that Harriet Simand [the co-founder of DES Action Canada] gave.<sup>149</sup> This was very soon after she had recovered from the surgery and such [that] she'd had from the cancer she had from the DES exposure. She was trying to find out how much was known about DES exposure in other parts of the country and also to stimulate others to be involved in awareness-raising. I had just started working at my job at the VWHC and I brought back a pile of brochures and started really trying to get women involved ... to try to find out about what had happened with DES.

I should go back a bit. The first responses [Harriet] had [when] she contacted Health Canada<sup>150</sup> and others to try to find out if there were others who had been exposed prenatally to DES and also had been harmed by it -- she wasn't able to get much information at all. And really, the main response she got was that [DES] wasn't really a problem in Canada -- that it was prescribed much more often in the US. Then she and her mother ended up -- they were quite frustrated by the lack of response and they wanted to get some funding to find out if there were others who were exposed to DES -- so they ended up going to the press. And they had a massive response! [They had] thousands of calls from women who thought that they might have been exposed during pregnancy. So I tried to find out a bit about what had happened in BC, and the answers I got was that, "Oh no, it wasn't a problem here, maybe it was a problem a bit in Montreal...".

So that was an awareness-raiser for me. [With] any press work that we ended up doing on it, we certainly got calls from women who had no idea -- who knew they had taken something during pregnancy and didn't know what it was, or they knew they had taken DES but they weren't aware of some of the extra gynecological exams and other things that they needed. It was a bit of an eye-opener... and I guess I was in a position, because I was working at a local women's health centre, I could do some local awareness-raising on the issues. I think, what made it possible to do it was having resources that at the time were publicly funded behind me. (Interview with *Margaret*, 2007)

As Margaret's story illustrates, groups that took an interest in pharmaceuticals became sites of lay knowledge about the effects of particular drugs, based on the stories women related about their own experiences. They gathered and disseminated information that was not forthcoming from governments or the pharmaceutical companies and they developed a counter-discourse to the official discourse on these drugs. Part of the feminist discourse on pharmaceuticals concerned the gendered nature of the pharmaceutical culture. One focus was drugs related to reproduction and birth control, another was the promotion, prescription and use of tranquilizers and anti-depressants to women (Tudiver 1994).

The critique developed in women's community organizations resonated strongly with the perspective of some members of the Canadian health policy and health research communities. Canadian health professionals publishing work critical of the pharmaceutical industry in the 1970s and 1980s included Ruth Cooperstock, a medical sociologist with the Ontario Addiction Research Foundation who developed a feminist analysis of the social meanings of anti-depressants (Cooperstock 1974, 1979), Joel Lexchin, a Toronto physician who published *The Real Pushers: A Critical Analysis of the Canadian Drug Industry* (Lexchin 1984), and Jim Harding, a sociologist based in Saskatchewan whose analysis of the over-prescription of anti-psychotic drugs depicted

the industry as “one of the most effective and yet understudied lobbies in existence” (Harding 1987: 552). The overlapping concerns of feminists critical of the industry with these professionals spawned informal and formal collaborations between the two sectors. An example was the book, *Adverse Effects: Women and the Pharmaceutical Industry* (McDonnell 1986), the product of an international, intersectoral coalition that had a strong Canadian component. Published by the International Organization of Consumers’ Unions,<sup>151</sup> the book’s contributing authors included four activists from the Canadian women’s health and international development movements,<sup>152</sup> and Jim Harding, then-director of the School of Human Justice at the University of Regina. Three interrelated themes the book developed were that women in rich and poor countries had a shared interest in having safe, effective, affordable drugs; that organizations bent on population control, the pharmaceutical industry, and governments were all potential threats to these goals;<sup>153</sup> and that networks of citizen’s groups -- local, national and international -- provided an important means of responding to abuses by industry, government and NGO actors (ibid). To this end, the International Organization of Consumers’ Unions, which published the book, had set up Health Action International (HAI) in 1981 as an international activist watchdog group that would specifically monitor the pharmaceutical industry on behalf of consumer’s interests.

Margaret R. had worked at the Vancouver Women’s Health Clinic for nine years when she began working with Health Action International (HAI). Her transition to the international stage illustrates the dense interconnections among Canadian groups and other national and international groups working on pharmaceutical issues in the 1980s.

I actually got involved in HAI through ... some [international] DES Action meetings, you know, because the drug was prescribed in many different



countries. So there were these groups that were founded in many different parts of the world by women who were exposed to the drug. And I met [two women] who had started the Dutch DES, at a meeting in the US. And then, for family reasons I was in France. ... And while I was there, I got in touch with the DES Action group, and they were involved in some assistance with other European groups, providing support in terms of materials and encouragement and out of their own experiences out of groups in France and Ireland and the UK .... [One of the women] told me about a job that was opening up at HAI and so I went and applied for it, not thinking that my chances were very high because I had been working just really at a local women's health organization and this was an international health organization. But I did end up getting the job and moving to Amsterdam with my family, then very young children. ...

HAI started in 1981 as an international advocacy network on pharmaceutical issues. It modeled itself on the international network on breast milk issues, on baby formula, but there had been successful work by a number of organizations to press for the WHO [World Health Organization] code on baby formula ... basically an international movement to confront the international situation of unethical marketing of breast milk substitutes.

... [G]roups that had been working in pharmaceuticals saw a lot of parallels with that [baby formula] situation in terms of unethical marketing practices -- particularly concerns about multi-national companies that were marketing medicines unethically in developing countries. Both in terms of which products were for sale, but also in terms of the lack of warnings about harmful effects and the promotion for uses for which there wasn't enough scientific evidence of effectiveness. So, the HAI network really formed, to begin with, to try to press for a similar kind of WHO code on the unethical marketing of pharmaceuticals. And then it has expanded to deal with a whole range of other issues. The second issue that was very much a priority was the lack of access to essential medicines in many countries, which is still a major problem [interview with Margaret, Nov 23, 2007].

The concerns of women's health activists about the pharmaceutical industry resonated not only with groups in the international development movement like Ottawa-based Inter Pares but with the consumer movement, represented in Canada primarily by

the Consumers' Association of Canada (CAC) and internationally by the International Organization of Consumers' Unions. Wendy Armstrong, a nurse and a long-time activist with the CAC in Alberta, saw many links between that organization and the concerns of women working in health and pharmaceuticals.

The CAC actually arose out of a lot of women's groups. ... What people seem to have forgotten is that, at the time the CAC was formed in 1947, arising out of the Wartime Prices and Trade Board, the CAC had a long history of involvement from day one in food safety and food pricing, which deals a lot with agriculture, and food and food processing. ... One of the main reasons it formed was to balance or provide a countervailing force to the power and influence of some very dominant companies in the marketplace and in bureaucratic decision-making [at a time when] labour rights didn't exist. ... And what people in the health area don't realize is that the pharmaceutical industry is just one branch of the chemical industry, okay? And that, really, the chemical industry is heavily embedded in agriculture. A whole number of consumer products -- pesticides, biotech application, fertilizers, pharmaceuticals -- it's all one and the same. (Interview with Wendy Armstrong, 2008)

#### 4.4.3 Glimpses of Funding from "Big Pharma"

Towards the end of the 1980s, the issue of pharmaceutical companies providing funding to grass roots groups began to surface within the groups. Women I interviewed who were involved in health activism related to pharmaceuticals at that time did not recall it as part of the dominant discourse before then. Indeed, for members of those groups which saw their mission as watchdogs monitoring pharmaceutical ethics, the very idea of taking funding from the industry would have been completely contrary to their culture, says *Francine*, an activist who worked with DES Action Canada in the 1980s:

I was involved with DES Action going back to 1983 or something when it first started so, a good ten years. I mean I'd had paid jobs, I'd been on boards, I'd been at the national level. I helped start the Toronto group. I ran

the Toronto group out of Women's College Hospital. I was very, very involved. I knew these people and this organization really well. We met in the U.S. several years in a row; we hosted an international meeting in Toronto. And the language that that group spoke around big pharma was *so* consistent. You never wavered from the place of betrayal and that they were the source of the problem, right? And so people wouldn't have *dreamed* of taking pharma money! It was just like, we would have laughed if, if it – I don't ever recall it coming up. If someone did [suggest it], they would probably have just been, you know, so squeezed out by embarrassment. Now, part of that was probably the era. (Interview with *Francine*, 2007)

In the mid- to late-1980s, however, the question of funding from pharmaceutical companies and other health industries began to surface as an issue that groups discussed in conjunction with the cuts in government funding that were beginning to take place around the same time, and the growing use of infertility drugs. *Margaret* recalls:

I think it was the late '80s. [W]hen I was involved with the [Vancouver] Women's Health Collective, which would have been from the early '80s to '89, there were also, we were I think aware then of some of the infertility groups for instance having funding by manufacturers of infertility products, and menopause groups and hormonal treatment. It certainly wasn't as widespread a concern but it had come up as a concern by the late '80s... It's hard to think of something specific on it, but I'm fairly sure that there were examples then that raised alarm bells of organizations that were providing information on medicines, or on [health-related] conditions as well, that had come from a sponsoring company.

The Women's Health Collective that I worked with, we had a lot of problems with funding. We had been one hundred per cent funded by the provincial government and then we moved, in a day, to zero funding. We ended up having to go without core funding and to depend on various short-term project funding and to depend on staffing through employment assistance programs. So really, things that were quite problematic in terms of the quality of service that we were providing to the public. They were programs that were quite short-term so you could not have long-term staff. You couldn't get people properly trained to the point so that they were at higher levels in terms of their understanding of the issues and being able to provide information to

the public. Or even to provide training to the volunteers, it was a real problem. And so there was, there were certainly discussions internally in our organization in terms of where to go for sources of funding. And we had decided at that point certainly not to go to the pharmaceutical industry, or to any other health product industry for funding. (Interview with *Margaret*, 2007)

Government cuts to funding of community groups were driven by the rise of neo-liberal policies and were beginning to send shock-waves through the women's health community. Activists became concerned, not only about their organizations' ability to train and retain staff, but about the loss of critical edge that could result if women's health groups turned to corporate funding. One article from the Canadian women's health movement that discusses this question directly includes a case study of a fertility group that women's health activist Anne Rochon Ford conducted in a report for the Royal Commission on Reproductive Technologies that was established in 1989.

I don't recall what kind of got me going down that path; it was probably my involvement with DES Action and the number of DES daughters who have fertility problems and were associating with infertility groups. I'd been watching them for a number of years as well, and ... I'd noticed that they were dealing with the pharma issue as well. They were being, you know, they had no money to operate. Infertility Awareness Association of Canada [IAAC] was the one I was particularly focussed on. And they started taking money from Serona, one of the manufacturers of, or the manufacturer of one of the bigger IVF [in-vitro fertilization] -associated drugs.

And we used to get their newsletter in the DES office. I used to read it regularly. I had been noticing that there was a change in the tone, in the level of critical perspective. They were also starting to look a little more slick. And so, when I was involved with the Royal Commission on Reproductive Technologies, I did a chapter for the report on the relationship. That was directly about the relationship, the impact. (Interview with Anne Rochon Ford, 2007)

Her report dates the IAAC's founding to 1985, when it was called the Infertility Self-Help Support Group (Rochon Ford 1993). The Canadian group was modeled on an American support group for infertile individuals called RESOLVE Inc. and operated out of the offices of Planned Parenthood Ottawa until 1990. IAAC produced a regular newsletter for its members, which was partially funded by Serono Canada, a company that distributed key drugs used in Canada for infertility treatments. An early issue, in 1985, included four pages of treatments taken from a pamphlet produced by Serono. Rochon Ford examined the content and tone of articles in the newsletter over six-and-a-half years. She notes that IAAC, as a support group, subscribed to the self-help philosophy that "couples should be presented with as much accurate information as possible and supported in whatever choices they decide are best for them" (ibid: 84). Articles provided readers with "the full range of viewpoints, from major indignation about the harms caused by the technologies to unqualified support of them," (Rochon Ford 1993: 84). The newsletter provided women and couples experiencing infertility with tools for coping with their "pain and despair," but also responded with "signs of hope, usually in the form of medically assisted reproductive techniques" (Rochon Ford 1993: 85).

The advent of the Royal Commission on Reproductive Technologies forced the organization to take a clear position of support or condemnation; in its 1990 presentation to the Commission, IAAC chose to support "the safe and responsible use of NRTs" (ibid: 84). In all, Rochon Ford concluded, the newsletter was more positive about the technologies than neutral or critical. She concluded that Serono's sponsorship had

numbed the group's critical edge, although she could not determine the extent of the influence (ibid: 85).

The pharmaceutical industry's practice of spending lavishly to encourage physicians to prescribe drugs and medical devices was well known to feminist health activists involved in pharmaceutical issues. For one thing, critical journalists were writing about these strategies (Regush 1987: 226-236); and, as health activists began to attend medical conferences, they witnessed these promotional tactics firsthand. *Dierdre*, a Canadian woman who became active in women's health in the mid-1980s, formed her own skeptical views about the pharmaceutical culture through this route. In 1984, at 50, she was undergoing a difficult menopause and started a newsletter for women to counter the medical community's characterization of menopause as a disease. *Your Monthly Friend*, the first newsletter to provide a woman's perspective on the experience of menopause, took off internationally. This success allowed *Dierdre* to finance the publication entirely through subscriber's fees; she took no advertising, no government funding or corporate funding, and certainly no funding from the pharmaceutical industry.

I think I just saw so much of the bad side of the pharma companies going to the menopause – the International Menopause Congress meetings and the North American Association of Menopause meetings, you know -- where there was obviously *so* much money floating around that it turned me off. ... As far as I knew they weren't giving money directly to groups then, but they were interested in what I was doing. And they were certainly interested in co-opting me if I could be co-opted.

... I should go back to the first menopause conference I went to, one in Epcot, Florida, in '84 or '85 – '85 I think it was -- it was the International Menopause Congress. That was when I'd just started the newsletter and I thought I could go down there and find all sorts of experts on menopause, women who were my age, you know (I was about 50 at the time), and instead what I found was all these gynecologists, and the GPs [general practitioners]

too, who would sign in the morning and then go off to the Epcot Centre, or to Disneyland or whatever it is,<sup>154</sup> for the day, and then come back in the evening. And they didn't listen to any of the conference! And it just struck me as being such a *cheat*. I think that was a terrible eye-opener for me (Interview with *Dierdre*, 2007).

As with the women who participated in *Learn from Health Tragedy*, *Dierdre's* health activism was a formative experience that shaped her knowledge of the pharmaceutical industry's involvement in the world of medicine. She became part of a community of women who were critical of established medicine and of the pharmaceutical industry's promotional strategies to physicians.

*Dierdre*: [I was skeptical] of the kinds of claims that they would make. They had *no* proof that hormones were going to make life just a paradise for menopausal women. Their advertising was unrealistic, the kind of expectations that women had as a result of the advertising were unrealistic, I think if they hadn't been quite so avaricious I could have lived with them. But there were some -- and there still are some -- companies that comport themselves in a more or less honest way.

On the other hand [the gynecologists] behaved so badly that the women who were on the sort of edges of this, we started connecting immediately over this and we began having a meeting and forming a sort of loose organization of women...

Sharon: "Women on the edges" in what sense?

*Dierdre*: Women on the edges – they weren't gynecologists, although some of them were -- who just were appalled at what was going on, at what the men were saying. A gynecologist got up and said there was no point in writing a book about menopause, women weren't interested in books, they liked little leaflets and things they could read quickly and ... you know and you have to 'love them up' because they're going through such a hard time, the dears, and we have to get them into the office and get them on hormones, and that sort of thing. And we were all sort of rolling our eyes! (Interview with *Dierdre*, 2007).

#### 4.4.4 AIDS Patients' Activism—Setting A Precedent

In the 1980s as well, both in Canada and in the U.S., HIV/AIDS activism within the gay community was redefining health activism to include radical political action by patients (Epstein 1996; Silversides 2004). This movement enlarged the critique of both the pharmaceutical industry and of drug regulatory agencies, while adding a new dimension to health activism: collective pressure on researchers to target their research to particular diseases, and to exert pressure on drug regulators to provide access to novel treatments still in the pipeline.<sup>155</sup> The first wave of the AIDS activist movement, which began in the U.S. in the early 1980s, combined demands for drugs with a strong critique of the pharmaceutical industry (Epstein 1996). Michelle Brille Edwards, who was a Canadian drug reviewer in the Canadian federal government from 1989 to 1996, when she resigned, recalls the AIDS activists' strategies, both in Canada and the United States, as unprecedented:

In late 1989, I had just come back to Health Canada from a period of training at Sick Kids in Toronto, where I became a pediatrician and a clinical pharmacologist. .... I was put into a senior position, but not responsible for AIDS. And then there was a crisis period where the minister was being burned in effigy for lack of access to AIDS drugs and lack of research in Canada. There were demonstrations on Parliament Hill. There were headlines regularly, weekly criticizing the department for what it was not doing. And finally, there was a very embarrassing CBC-TV program that showed that we at Health Canada would block access to a drug that was made in Toronto but it was shipped off to – I think it was the Bahamas – and then imported back in so it could be legally accessed. [laugh] The insanity of that - - I mean, the drug actually wasn't important. It was rather a fraudulent drug. But it did make the point that this is how crazy this regulatory process is, and here are these dying patients who see this craziness. And it's, you know, they're inflamed, and rightly so. And so that aired, I think after the 10 o'clock news in the evening. And the next morning at 8:30, AIDS was assigned to me. [laugh]



As a drug regulator responsible for HIV/AIDS drugs, Dr. Brille Edwards saw the activism and the government's response to activist groups from the inside.

[F]rom my perspective...the activist approach to AIDS was a dramatic change in the social fabric. And all of the sort of advocacy, patient advocacy groups that have come since really took their model from AIDS. I can't tell you how many times people would say, "Where are these AIDS activists getting all this attention? Because, you know, more people die of breast cancer." And you think, "Well, yeah. But they're not on the streets with placards that say the Minister of Health is killing them, right?"

...And, I think that in the early days the activists were true activists. They were, largely at odds with the industry. The AIDS activists saw the industry as – I would not say enemies, but certainly as treacherous entities. You know, they saw the dilemmas. They unmasked the close rapport, the too-close rapport between the companies that wanted a product on the market and the experts and researchers who, "collaborated" with them. And they, they unmasked the hollowness of much of medical research. So on those two points it was the AIDS activists who did their homework and tracked down the \$200, \$300, \$400 thousand "honorariums" that were flowing from the companies involved in AIDS research to the expert staff at NIH [the National Institutes for Health in the US] who were getting paid public salaries, but who were taking this private money through the back door. ...

So it had a way of turning the tide. It changed the balance of power in the AIDS research game such that those paid in the public interest were reminded that if they failed to serve the public interest, they would, they could be damaged. And that really was dramatic. ... It produced dramatic change. After that, the AIDS activists had a much, much larger say in things. And as a result, it created the model where patients had a much, much larger say.

Unfortunately, industry adapts to every new scenario, right? ... It may take them, you know, a day, or a week, or a month, or a year, or a decade – but they will adapt. And they will capture control over that new model.

[Interview with Michelle Brille Edwards, 2008]

Toronto-based health journalist Ann Silversides wrote extensively about Canada's AIDS activist community, from its early years until 2000.<sup>156</sup> Like Brille Edwards, she observed a depoliticization in the stance of many in the AIDS activist movement towards

the pharmaceutical industry and government, which she dates to the early 1990s. Her book *AIDS Activist: Michael Lynch and the Politics of Community* (Silversides 2004) based on Toronto-based AIDS activist and writer Michael Lynch who died in 1991, documents the early years of the movement in Canada. Like the American movement, Canada's in the 1980s was characterized by dramatic, symbolic public actions, critical of government and drug companies. At the 5<sup>th</sup> International AIDS conference in Montreal in 1989, for example, activists took the stage in advance of Prime Minister Brian Mulroney's opening remarks to chastise him for not speaking about HIV/AIDS in the five years previous when he had led the government; throughout the conference, they succeeded in "shifting the conference away from being solely an industry platform to ensuring the needs and concerns of people living with HIV/AIDS were acknowledged" (Silversides 2004: 198).

Reflecting on the relationship between AIDS activism and the pharmaceutical industry, Silversides told me in an interview in 2008:

It was fortuitous when I was writing about Michael Lynch that he died in '91. I remember thinking very clearly, 'I'm so glad I ended this book in 1991 because if I had to deal with the politics of pharma it would be so god-damn complicated.' You know, because [the movement] wasn't penetrated really very much at all by '91, and then the scene just changed. ... That's my view of it. And I remember people told me that I should write a follow-up, and I thought, 'Oh god, it's so much more complicated.' ... I mean, my book ended in '91 and at that point, there wasn't a whole lot of pharma conflict-of-interest that I ran across, these kinds of issues, which I was pretty attuned to. And then it all started up. (Interview with Ann Silversides, 2008) <sup>157</sup>

Early activists in the Canadian HIV/AIDS movement found that some of their conflicts with other actors in the system overlapped women's movement activists and representatives of the two movements met to share political analysis and strategies. Areas

of common ground included the constraints imposed by accepting government funding, strategies for confronting the state, and the ways in which the medical establishment and pharmaceutical industry medicalized gender-related behaviours (Silversides 2004: 80, 132-133). The HIV/AIDS movement developed dramatic tactics that had no counterpart in the Canadian women's health movement, however. Lori Wasserman, who analysed the Canadian women's health movement in the 1970s and 1980s, concluded that, although women's health activists felt rage at their treatment in the medical system, they had been socialized to be treated dismissively and so acted quietly, forming support groups and engaging in public education, rather than demanding better treatment "with the same kind of gusto" as the (largely male) activists in the early HIV/AIDS movement (Robin Barnett, quoted in Wasserman 1997: 56).

#### 4.4.5 An Absent Actor in the Women's Health Movement

More central to Wasserman's thesis was the absence of discourse about breast cancer issues in the Canadian women's health movement of the second wave. She found that, while the active women's health community of this period had an awareness of breast cancer, the movement's leaders were preoccupied with reproductive health issues. This was less because breast cancer lacked the conditions for politicization than because a combination of factors, including the enormous legal, medical and religious control that existed over reproductive rights, concentrated feminists' energies on these issues. Most of the movement's leaders were young, healthy women, so that reproductive issues were personally central to them and structured most of their contact with the medical profession (Wasserman 1997: 68).<sup>158</sup> Many of the feminist struggles over medicine and

reproduction never seemed to end, or they resurfaced in a new form with the advent of reproductive technologies.<sup>159</sup> A related factor, as activist Anne Rochon Ford told Wasserman, was that second wave women's health activists tended, in general, to neglect health problems that kill women (smoking and lung cancer among women, for example, received less attention than they merited).<sup>160</sup> By the late 1980s, women's health centres were beginning to lose their funding which further limited the ability of activists to examine issues that had not previously been central (Wasserman 1997).

The silence about breast cancer in the Canadian women's health movement that Wasserman documents has striking similarities to Maren Klawiter's analysis, ten years later, of the same phenomenon in the San Francisco area (Klawiter 2007: 166-167). Klawiter contrasts the development of the AIDS movement in San Francisco to the absence of a similar movement for breast cancer until 1986, when a group called the Women's Cancer Resource Center was established. The women's health movement in the U.S. had not ignored breast cancer, notes Klawiter, but neither had it launched a movement around women's cancer or breast cancer. "Instead of breast cancer, the women's health movement focused its attention on the politics of reproduction – sexuality, birth control, abortion, pregnancy, childbirth, breast-feeding, unnecessary hysterectomies, forced sterilizations, and the safety of pharmaceutical technologies (for example, the birth control pill, the DES controversy, hormone therapy) – and on violence against women" (ibid: 167). As in Canada, the result was invisibility and a lack of politicization. "Despite the network of feminist rape crisis centers, shelters and Planned Parenthood offices across the US, "ordinary flesh-and-blood women with breast cancer

were still invisible to each other and invisible, as embodied speaking subjects, to the public.” (ibid: 167)

#### **4.5 ROSE KUSHNER’S “NATURAL ALLIANCE” WITH TAMOXIFEN’S MAKER**

The question of pharmaceutical company funding had begun to cause minor ripples at the community level in Canada prior to 1990, although it was not part of the public discourse. And breast cancer was likewise not widely discussed as a political issue, and had not been taken up by women’s health activists either in Canada or the United States. A few individual women with breast cancer had, however, framed the disease politically, one of the most prominent being American breast cancer activist, Rose Kushner, who died in 1990.<sup>161</sup> While researching this dissertation I discovered to my astonishment that Kushner had developed a financial arrangement with a pharmaceutical company – a well-kept secret of which I was unaware until 2007. I close this chapter with an account of this partnership, described by medical historian Barron H. Lerner, which has a curious intersection with my own experience as a patient.

In 1975, the year after her own diagnosis, American journalist Rose Kushner wrote an investigative book about breast cancer and set up a counseling centre for women out of her own home (Lerner 2007). Kushner’s individual activism is sometimes cited as a precursor to the breast cancer movement of the 1990s (Batt 1994, Knopf-Newman 2004, Lerner 2001). Although U.S. based, Kushner travelled widely and was known in Canada and beyond. She actively sought to compare cancer treatment practices in the U.S. with those abroad and in the process met cancer specialists the world over; in addition, she established a reputation as a lay expert among women with breast cancer,

through her book and counseling service. Her stance towards medical practice, particularly the then-routine use of mastectomy in the United States, was that of a well-educated, critical consumer: she confidently “discussed and evaluated the medical literature. Too many physicians, she argued, had the science all wrong,” writes Lerner (ibid: 227). In the 1980s, the decade before an organized breast cancer movement took shape, thousands of women turned to Kushner for “the truth” about breast cancer treatments.

I was one such woman. Shortly after my own diagnosis, in 1988, I found a battered copy of Kushner’s book at the McGill University library which I later described in my own book as “a godsend” (Batt, 1994: 7):

Kushner tells her own story with disarming wit, and I feel like I’m listening to a big sister who’s been there. Her investigation reads like a detective novel – mystery: breast cancer. Her questions are so much like my own, I stop feeling foolish for being confused (Batt, 1994: 8).

Kushner became thoroughly familiar with the medical literature on breast cancer. She questioned the surgical practices in the United States at the time of her treatment, which she judged to lag well behind both the science and the standard of practice in countries outside the U.S. She was critical of a push from some medical oncologists, in the late 1970s, to extend the use of chemotherapy from women with stage 3 and 4 diagnoses, where the cancer had clearly metastasized, to women diagnosed with stage 2 cancers – those cases where the cancer had spread to the underarm lymph nodes but which showed no evidence of distant metastasis.

When Gianni Bonadonna’s research team in Italy published clinical trial data in 1976 to show that the combination chemotherapy regime known as CMF

(cyclophosphamide, methotrexate and 5-FU) significantly reduced the risk of recurrence in these women, Kushner was not impressed. She argued (as did many oncologists), that the researchers' follow-up time of 14 months was too short a time to conclude that the benefits of such a toxic treatment were worth the risks to women whose cancers might never prove lethal. Based on her own investigation of medical practices in other Western countries, Kushner concluded that oncologists in the United States were particularly prone to adopt aggressive treatment modalities on the basis of preliminary evidence. When her own cancer recurred in 1981 she decided to take the anti-estrogen pill tamoxifen, produced in the United States by Stuart Pharmaceuticals and marketed under the brand name Nolvadex. Like adjuvant chemotherapy using CMF, tamoxifen was still experimental but its adherents in the medical community promoted it as having fewer side-effects than combination chemotherapy. Kushner wrote scathingly of the "toxic regimes" given to post-menopausal women and accused the physicians who used them of being insensitive to their patients' quality of life (Lerner 2007).

In his assessment of Kushner's perspective in the debate over the relative risks and benefits of tamoxifen versus CMF for post-menopausal women, Lerner concludes that financial support from the makers of tamoxifen helped shape her advocacy:

As her opposition to chemotherapy continued, her confidence in tamoxifen as an alternative treatment grew. At some point, she purchased stock in Imperial Chemical Industries (ICI), the British company that manufactured Nolvadex, and regularly mentioned the medication in her frequent articles and lectures on breast cancer. When her book, *Alternatives: New Developments in the War on Breast Cancer*, was published in 1984, a natural alliance was formed: ICI and its American affiliate, Stuart Pharmaceuticals, were eager to help publicize the book, which was not only an excellent treatise on the disease but also spoke very favorably about their product. Kushner received travel funding from the two companies, enabling her to appear at meetings and to sell her book. Stuart

Pharmaceuticals also bought 10,000 copies of *Alternatives*, distributing them to physicians as gifts (Lerner 2007:238).

That wasn't all: ICI donated money to Kushner's advisory centre and contracted her to write the text for a patient-information leaflet about Nolvadex®, in which she claimed the therapy had "no side-effects" (ibid: 239). Kushner was 59 when she died, in 1990, of cancer-related causes.

I read Lerner's account with astonishment. Kushner's skeptical views of chemotherapy assumed an importance for me that still resonate when I recall my own treatment decisions. I was diagnosed with breast cancer in October 1988. Six months earlier, the results of three large clinical trials studying the efficacy of giving chemotherapy to women with a stage 1 diagnosis had been announced, with great fanfare. The studies found that, after three to four years, the cancers of women who received chemotherapy were less likely to recur than those of women given a placebo, although evidence that they actually lived longer was lacking.<sup>162</sup> Vincent deVita, then the director of the U.S. National Cancer Institute (NCI), judged the finding so significant that he took the unusual step of sending an Alert to major media and to 13,000 cancer specialists and cancer institutions. The Alert, which I read about in *Ms. Magazine* three months before my diagnosis, stated that *every* woman with early stage breast cancer should consider chemotherapy or hormone therapy.

Since only 20-30 per cent of women with Stage 1 breast cancer suffer a recurrence, 70 to 80 per cent of patients would be subject to the effects of chemotherapy, with no benefit in their outcome. As breast surgeon Susan Love wrote a few years later, "many cancer specialists thought the pronouncement was premature" (Love with Lindsey 1990: 256), particularly since the results had not yet been published in peer reviewed



scientific journals. Indeed, the issuing pre-publication Alerts is a practice of cancer agencies that has provoked in-depth critical analysis (Omura 1992).<sup>163</sup> When the results finally appeared the following February, in the *New England Journal of Medicine*, an enthusiastic editorial by Vincent DeVita (1989) appeared with a cautionary one by another prominent American oncologist, William McGuire (1989). DeVita heralded the result of the studies as “the capstone of 32 years of clinical trials of treatment for breast cancer” (527-529); McGuire weighed the limited number of women who would benefit against the costs, both financial and in toxic side-effects, and concluded “that the considerable cost outweighs the benefits of treating all node-negative patients, especially in the absence of a proved survival benefit” (McGuire 1989:526).

After my own diagnosis, I read and reread the article in *Ms*. My oncologist recommended that I enter a U.S.-Canada clinical trial that would compare three dosage levels of CAF, a chemotherapy regime that replaces the methotrexate in CMF with Adriamycin® (doxorubicin hydrochloride) -- a more toxic drug in the same family. Kushner, my trusted “big sister,” had sounded a clear warning against the rising acceptance of toxic chemotherapies like CMF and CAF. Following my recovery from surgery in December 1988, I needed to make a decision quickly. Although my cancer was classified as Stage 2, not Stage 1 (because cancer was found in one of my underarm lymph nodes), Rose Kushner’s account of chemotherapy’s history suggested to me that the controversy over the Alert simply reprised the similar debate that ensued following the publication the 1976 results by Bonadonna’s team. Although ultimately I decided to follow my oncologist’s advice, for years after I was haunted by the fear that my decision

was foolish, and that I had exposed myself needlessly to an overkill treatment that might, at any time, bring on a treatment-induced leukemia or damage to my heart.

Lerner concludes that Kushner's interactions with the manufacturer of a drug which she was taking, and which she so enthusiastically endorsed, put her in a conflict of interest that provides a cautionary tale "about individuals who function simultaneously as patients and spokespeople" (ibid: 240). He argues, however, that the mid-1980s were a period of transition in ethical standards within medicine from an earlier time, when "largesse from industry was tolerated, even lauded"; for this reason, he argues, even though she apparently never publicly disclosed her relationship with ICI and Stuart Pharmaceuticals, we should not judge Kushner by "our modern ethical standard" (ibid: 239).

At least one similar author-drug company arrangement, again from the United States, predates Kushner's and is now regarded as a deliberate, successful exercise to construct knowledge about pharmaceutical drugs that runs counter to the facts. The 1966 book *Feminine Forever* by New York physician Robert A. Wilson promoted estrogen as a youth potion for post-menopausal women and was marketed as a popular women's health "Bible." In the 1970s, two New York writers discovered that three leading hormone manufacturers had given Wilson over a million dollars in funding to tour and promote his book (Seaman and Seaman 1977).

Is Lerner right when he suggests that the standard of the 1970s and 1980s was more tolerant of conflicts of interest than our "modern ethical standard"? I'm not sure I agree with his analysis on this point. His account of Kushner's financial arrangement with ICI and Stuart Pharmaceuticals stands, however, as a fascinating harbinger of what

was to come, even though our understanding of her views may always be clouded. By contrast, the movement of the past two decades can be examined up close and this is the purpose of the chapter that follows.

#### **4.6 SUMMARY**

In this chapter I pulled back from Chapter 3's close-range examination of the pharma funding issue viewed from inside three contemporary Canadian breast cancer organizations. Using Singleton and Michael's (1993) metaphor of an Actor-Network narrative composed by a film director on an elaborate, movable scaffold, I swung my camera 180 degrees to capture three areas of discursive struggle that predate the beginnings of the breast cancer movement. The narratives of Chapter 4 depict an historical view of Canada's system of government-funded single-payer healthcare, the regulation of pharmaceutical companies, and the place in Canada's democratic system of civil society groups concerned with health. By creating a narrative tableau featuring three overlapping discursive landscapes my intent is to make visible the continuities, as well as the breaks, among the networks depicted in Chapter 5 and those that came before.

## CHAPTER 5      THREE PERIODS IN A MOVEMENT

### 5.1 INTRODUCTION

In Chapter 3 I used biographies of three breast cancer groups to underscore the tension within the breast cancer movement over the issue of funding from the pharmaceutical industry. These groups were selected as points along a continuum from an explicit “No Pharma Money” policy to one which received all of its funding from the industry. In Chapter 4, I pulled back to depict the historical backdrop against which these and other patient-centered breast cancer groups evolved. I focused on three areas of Canadian policy which are relevant to the evolution of these groups: health care, pharmaceutical policy, and the role and funding of civil society organizations in the area of health. In this chapter I adopt a middle-range perspective, a moving panorama in which I examine how breast cancer groups and alliances with the pharmaceutical industry developed in Canada over the past two decades, and the contribution of these alliances to the construction of knowledge about breast cancer drugs and biologics. The main purpose of this analysis is to determine whether pharma funding changed the groups over time in a way that could be considered “cooptation” or “assimilation.”

In Chapter 2 I introduced *periodization* as a methodology for tracking actors through distinct phases of their evolution. In my analysis of how pharma funding became the norm within Canadian breast cancer groups I identify three periods in this normalization process and use periodization to understand the factors underlying the significant shifts and breaks that created them. I follow the shifting relationships among three main actors -- breast cancer groups, breast cancer drugs, and the pharmaceutical

industry -- and document the evolution of their networks as they evolve over the span of a generation, from the emergence of the first groups in 1989 to the present (2011).

To focus on the aspect of these relationships that I want to highlight – their effect on how drugs are understood as socially embedded technologies -- I use the concept in Actor-Network Theory known as *translation* -- the progressive development of new social relationships to re-order scientific knowledge (Callon 1986). I looked for evidence of the four steps that Callon says that actors use to effect a translation: *problematization*, *interessement*, *enrolment*, and *mobilization* (described in Chapter 2, page 68). The translation, if successful, realigns the area of scientific knowledge in question to fit the perspective of the primary actors.

The three periods described in this chapter are defined by two major ruptures. In the first period, which spans 1989 to 1996, breast cancer patients' groups form, proliferate and create a new actor-network that includes powerful government actors and which makes the groups an *obligatory passage point* in the cancer policy system. As seen in Figures 5.1 and 5.2, an initial problematization process takes place at two critical events: a year-long Study of Breast Cancer undertaken by a Parliamentary Subcommittee, and a National Forum on Breast Cancer, initiated by Health Canada as a follow-up to the Subcommittee's Study. In this first period, several of the groups initiate actions to shape scientific knowledge of drugs and to influence drug policy. Some interventions are aimed at gaining access to new cancer treatments (specifically, to Taxol® and to high-dose chemotherapy) while others call attention to risks and potential harms (concerning the use of tamoxifen as a preventative).

During the first period (the Grassroots Period, 1989-1996), the pharmaceutical industry makes preliminary overtures to the groups and they in turn conduct internal discussions about the wisdom of forming alliances with the industry; actual alliances, however, are rare early in the period and remain so until the end of the period in 1996, when a rupture transforms the configuration into two competing networks, one allied with the pharmaceutical industry and the other rejecting such alliances. This rupture takes place at a third key event, a conference called *Together to an End*, which is sponsored largely by the pharmaceutical industry. At this meeting, some participants articulate new discourses in which access to new drugs is identified as the key to improved breast cancer survival, government bureaucracies are identified as an impediment to gaining this access, and the patient-group community is defined as comprising two components, one which is best suited for advocacy, the other for providing services.

In Period 2, between 1997 and 2001, groups opposed to funding from the pharmaceutical industry bring the issue out into the open, making their case at a public event and in a published document. Groups in this camp adopt formal policies in which they define funding from the industry as a conflict of interest and a source to be avoided. The industry, meanwhile, develops formal strategies for “partnering” with groups; these strategies are tied to drug promotion and are also spelled out in publications and at meetings. The question of funding from the pharmaceutical industry provokes vigorous and overt contestation within and among organizations. Companies seek approvals for several costly new cancer drugs and drug combinations, including an anti-anemia drug (Eprex®) used to combat chemo-induced fatigue, and a chemotherapy cocktail including Taxol®; several organizations make these drug treatments the subject of advocacy. A

central point of discursive difference among groups is whether industry funding will influence their advocacy positions, either encouraging the promotion of a company's drug or silence over the drug's risks and/or cost.

Another rupture creates the third period, from 2002 to 2011, in which “pharma partnerships” are normative and codified, with written agreements and rules of engagement which have relatively broad acceptance within the community. In the face of sustained opposition, the pharma-funded groups and companies both recognize the potential dangers of alliances. One response is to adopt another actor into the network, the public relations firm, which plays an intermediary role as matchmaker and trouble-shooter. Some breast cancer advocates form a new pharma-funded advocacy organization that cuts across all cancers, sharpens the ethical argument in favour of partnerships, articulates rules for disclosure, and puts the onus on critics to demonstrate interference by pharma sponsors in group activities. Rapid access to new cancer treatments becomes the agreed-upon area of common ground for these alliances. Complex, sophisticated advocacy campaigns, funded by the industry and orchestrated by public relations companies argue for access to new treatment drugs as a right. Herceptin® and a new class of costly drugs called “aromatase inhibitors” are the main focus of group advocacy in this period. Although two drugs, hormone therapy for post-menopausal women and Eprex®, are shown to have harmful effects in relation to breast cancer, these revelations do not translate into cautionary tales within the movement. A discourse of resistance to the practice of pharma funding continues, but the actors who advance this position have limited access to funds. Former avenues for government funding and partnerships are

almost entirely shut off, diminishing the power of these groups within the cancer policy community.

Thus, by the end of 2011, the original scattering of small, grass roots organizations has become a well-structured network of groups and coalitions. The most powerful groups are funded by the pharmaceutical industry and enjoy a position of influence in the construction of knowledge about breast cancer treatment drugs. I argue that the term “cooptation” can fairly be applied to this process of change although resistance and ambivalence remain within the breast cancer movement (now better described as “movements”). I conclude the chapter with an analysis of the underlying factors and shifting social relationships that enabled this transformation to take place over a period of two decades. The role of federal government policies in creating conditions for this capture is particularly important to recognize. I supplement the chapter with a Breast Cancer Pharmacopoeia which summarizes three of the drug treatments discussed in the chapter and the ways in which the social events of the narrative contributed to their identities.

## **5.2 1989 TO 1996: THE GRASSROOTS PERIOD**

### **5.2.1 New Sites of Knowledge and Action**

**Burlington, Ontario, 1989.** Pat Kelly was in her late 30s and had two young daughters when she was diagnosed with breast cancer. She was desperate to discuss her breast cancer experience with others in the same situation when a mutual friend introduced her to Barb Sullivan, a nurse who had also had breast cancer. The two women placed an ad in the local paper inviting other breast cancer patients to meet at the Y.



Thirty-five women showed up to their first meeting. “And it was amazing,” Pat recalled when I interviewed her in 2007. “We just sat in a circle and women started telling their stories.” The women decided to meet at the Y twice a month and a delegation of three approached the Cancer Society -- which held monthly support group meetings at the local hospital -- to ask that younger women, in particular, be told about their meetings. Two women who ran the Cancer Society support group met them but expressed concern about whether they intended to compare treatments. “Well, of course we will,” the women replied. “But you’re not qualified to give treatment advice!” was the response.<sup>164</sup> The three patients countered that the point of exchanging experiences was not to advise one another but to share knowledge. They in turn questioned the expertise of Cancer Society’s group leaders when they learned that they had not themselves had cancer, did not seem to grasp the value of peer support, and were running a support group that appeared to have no active members. The new group continued to meet and became the Burlington Breast Cancer Support Services. Within two years, they had their own donated meeting space in a shopping mall.

**St. Catharine’s Ontario, 1991.** Paula McPherson, a young lawyer from St. Catharine’s, had just had her first child and was practicing law in Toronto when she was diagnosed with breast cancer. Throughout her pregnancy, she had felt knowledgeable, in control and confident about making decisions, thanks to the countless resources available to her. As a cancer patient, by contrast, she felt “cut adrift ... Every bit of information I had to work hard to get” (McPherson 1992d:19). She set about researching the disease and was shocked to learn that over 12,000 women and men were being diagnosed every year in Canada,<sup>165</sup> and that 5,000 Canadian women a year were dying of breast cancer.

She was equally shocked to discover that the causes of breast cancer were unknown. The focus of research had to shift to cause and prevention, she concluded. In early 1991 she set up a non-profit charitable organization to promote understanding of the connections between the environment and breast cancer, built on the public interest research model developed in the early 1970 by consumer activist Ralph Nader.<sup>166</sup> She called the group the Breast Cancer Research and Education Fund and its slogan was “FIGHT BACK! STOP IT BEFORE IT STARTS.” To address a second concern, the neglect of the psycho-social stress of uncertainty after a cancer diagnosis, Ms. McPherson founded a self-help group, similar to the one in Burlington, in which women could share experiences and resources about living with breast cancer in a positive, informal atmosphere. In just two-and-a-half months she had 22 recruits.

**Montreal, Quebec, 1989.** S.B.<sup>167</sup> was a journalist working in Montreal as an editor on a consumer protection magazine published by the Quebec government when she was diagnosed with breast cancer. In 1989, while still undergoing chemotherapy treatment in Montreal, she was struck by the contrast between the passivity and invisibility of cancer patients and the high profile of AIDS activists at an international conference in the city. She wrote an angry op-ed article for the local newspaper about the culture of optimism in the breast cancer world which masked the punishing treatments and the failure of research to advance understanding of what caused the disease. She exhorted cancer patients to organize, as AIDS patients had done (Batt, 1989). Among the responses she received was a note from a breast cancer patient named Carolyn, which ended, “You sound like an activist. Call me if you ever decide to start a group.” Two years later, she and Carolyn and two other Montreal women with breast cancer began

meeting every month and in April 1991 held their first public meeting, launching the group Breast Cancer Action Montreal. Eighteen years later, Carolyn reflected, “I have a sense that we all came together from our dissatisfaction with various aspects of the status quo. In those early meetings, we were all alarmed by the rising breast cancer rates and were concerned that so much effort was directed to drug trials and so little to understanding the cause of the dramatic increase in rates. We quickly determined that prevention should be our primary focus” (Interview with Carolyn, 2009).

**Montreal and Vancouver, 1991.** Marcella Tardif was 45 in January 1990 when she was diagnosed with breast cancer. Over the next six months she had numerous biopsies and lumpectomies until finally a doctor recommended that she have a mastectomy. The idea of a mastectomy terrified her – she wanted to look feminine. The doctor reassured her that a breast implant would allow her to have the mastectomy with no change to her appearance. In June she had a single operation to remove her breast and insert an implant. Alarming secretions, swelling and pain began almost immediately and continued for months. Her surgeon said the implant was not the source of her problems but when she finally obtained a second opinion from a general surgeon, he advised her to have the implant removed immediately. She did so and the symptoms subsided.<sup>168</sup> Outraged by the plastic surgeon’s denials, she told her story on a television show and the next day, “the phones were ringing off the walls because women were phoning in to tell me, ‘I had this happen to me!’” (House of Commons 1991: 9:34) She formed a breast implant support and advocacy network with two women from British Columbia who heard her story, Linda Wilson and Joy Langan. They named the group *Je sais/I know* because when they told one another their experiences they found themselves nodding and

saying, “I know, *Je sais*.” The group’s founders were determined to call physicians to account and to pressure the government to stop the implantation of unsafe products in women’s bodies. By February 1992 *Je sais*/I know had over 800 members across Canada and Marcella Tardif had an office in east-end Montreal where the phones rang constantly with calls from women whose doctors had dismissed their symptoms as unrelated to their implants (House of Commons 1991; Picard, January 17, 1992].

Between 1989 and 1991 small pockets of women in Canada began launching new meeting places, under their own control, where they could discuss their experiences of living with breast cancer, collectively formulate questions they felt were important, and take action to have these questions answered. As the foregoing examples illustrate, their activities were simple and familiar: they met at one another’s homes or at local community centres to exchange personal experiences, they researched the disease at their local library, bookstore or medical school, they discussed what they had read, and they told their stories to the media.

### 5.2.2 First Translation: Parliamentarians Study Breast Cancer

The groups thus became sites of knowledge construction about breast cancer in which participants used tried and true methods of community activism to develop “lay scientific knowledge” (Bucchi & Neresini, 2008; Callon, 1999; Wynne, 1996). In the four narratives above, each group provided a forum for formulating questions and redefining the breast cancer problem from its members’ own perspective, based on their embodied experience of the disease, its treatments and the system in which treatments and care were provided (i.e., they *problematized* the disease). Having claimed expertise, whether it

was about how to cope with their day-to-day lives during and after cancer treatments, how to redirect research to cause and prevention, or how to keep unsafe implants off the market and demand honesty from physicians, they began a *translation* process aimed at re-orderings scientific knowledge.

If they were to move these claims forward, they had to make their groups *obligatory passage points* -- sites that others would have to consult in the process of knowledge-making. Their opportunity came in the fall of 1991, when a Parliamentary sub-committee on the Status of Women<sup>169</sup> began a study of breast cancer and breast implants. The national hearings initiated a chain of events that put breast cancer on the federal government's policy agenda and offered the groups an opportunity to define themselves as obligatory passage points. Representatives from each of the four groups appeared before the all-woman sub-committee, chaired by Barbara Greene from the (then) ruling Progressive Conservative Party of Canada. The sub-committee was itself seeking to re-order knowledge about breast cancer. According to NDP member Dawn Black, each woman on the sub-committee had a deeply personal interest in the proceedings:<sup>170</sup>

One of the reasons I pushed for this study with this committee is that two of my personal friends were diagnosed with breast cancer, one of whom was in her mid-thirties, and the other was just 40. Having known older women, as we all would in our own circles of friends ... we all know women who have been affected by breast cancer. (11:28).

The sub-committee called on a range of policy actors as witnesses but chose to give women from the then-nascent breast cancer activist community a prominent role.<sup>171</sup> In doing so, the members of Parliament and their researcher became co-constructors of the Canadian breast cancer movement. The emerging breast cancer movement in the

United States was also a critical force, providing the organizations in Canada with models and contacts. The pharmaceutical industry, by contrast, had little or no influence in shaping these early groups.

In all, the sub-committee members brought 48 individuals from the breast cancer arena to testify before it over a period of eight months (Table 3).<sup>172</sup> Medical researchers comprised by far the largest category, numbering 29 in all.<sup>173</sup> The next largest category, however, is made up of eleven witnesses who identified themselves as patients and/or representatives of grass-roots patients' organizations. Although speaking from a variety of perspectives and organizations, the activists collectively made the case that existing knowledge-making structures were inadequate. The testimony of each emphasized the gulf between what patients' needed to know and what researchers, physicians, and the professionalized charitable organizations serving patients were providing.

While the established charities<sup>174</sup> claimed to be serving the needs of cancer patients with information booklets, hospital visitations, and fundraising programs for patient services and research, members of the emerging grass roots groups contested the adequacy of these projects. Indeed the activists claimed the established agency sometimes withheld information in a way that circumscribed patients' knowledge of the disease and misrepresented the inadequacies and failures of treatments. As for health professionals, two activists stated that, in their region, male oncologists were paternalistic, that they didn't adequately explain the procedures they were proposing, and that they dismissed women's concerns about breast lumps with "glib assurances" which sometimes had fatal results (Kelly and Morrison 1991a:35). Furthermore, the agencies, physicians and researchers focused on mainstream medical treatments rather than on prevention, or on

providing necessary emotional support. The activists depicted the assumed experts as treating patients and their families as passive and dependent rather than as resourceful collaborators in the shaping and using of knowledge. Thus, they continued the processes of translation they had begun in private meetings in a very public venue, problematizing their plight in a way that redefined the established actors as failed providers of knowledge important to patients, an act of *interessement*. They then positioned their own organizations as the solution to these unmet needs (see Figure 6).

The testimony of lay witnesses met with a mixed reaction from professionals who appeared before the sub-committee. One attending Member of Parliament who was not on the Sub-Committee launched a strong defense of the Canadian Cancer Society and the medical profession (Bertrand 1991:34), and two oncologists emphatically contested the paternalism label (Hryniuk and Levine 1991). The core members of the sub-committee, however, continued to encourage the activists and suggested an avenue of possible financial support from a government program. Their receptiveness indicated successful *enrollment* on the part of the activists; indeed, they encouraged the women's stated interest in advocacy to the extent that the subcommittee could be termed a *co-constructor* of a breast cancer movement in Canada. The concept of co-construction as used in actor-network theory derives from the understanding that, in a heterogeneous knowledge-construction network, more than one actor group may engage in *translation* and sometimes the strategies of several actor-groups will reinforce or complement one another. Thus, activists in different localities learned of each other's existence and views, and the committee members actively encouraged (and ultimately recommended) that financial support be given to assist the development and interaction of local groups. In

April 1991, in a show of support for the sub-committee, a group of four women who had attended the hearings on a regular basis initiated a project to promote national awareness of the hearings, which they felt were receiving too little notice (a *mobilisation*) (Jones 1992: 24).

Collectively, the activists' testimony built the case that patients should be consulted on matters which had to that point been the exclusive domain of professionals, a move which positioned patients' groups as *obligatory passage points* for deciding what information patients needed, what research should be pursued, and how patients were treated within the healthcare system. The sub-committee's report, *Breast Cancer: Unanswered Questions*, which appeared in June 1992, underlined its commitment to this goal (Greene 1992).

The pharmaceutical industry was yet another actor represented at the Parliamentary hearings and the testimony of its representatives provides a record of how the industry sought to *problematize* the breast cancer question in yet a different way. Two members from the Pharmaceutical Manufacturers' Association of Canada (PMAC),<sup>175</sup> the industry lobby organization, appeared before the sub-committee in March 1992 and submitted a written brief on Canada's drug approval process, comprising the only direct contribution to the sub-committee hearings by the industry. The two industry witnesses were Gordon Postlewaite, PMAC's Director of University and Scientific Affairs, and Leonora Marks, the Director of Publications. Their brief, *Response to the Review of the Canadian Drug Approval System*, praised the drug approval process for its "enviable standard of safety" (Postlewaite and Marks 1992: 17A:2) but called for a "renewed mission statement that would include a goal to make safe modern therapeutic advances



available at the earliest possible time” (ibid: 17A:2). Two previous witnesses, both physician/researchers, had criticized the industry for spending too little money on research and too much on advertising, criticisms which members of the sub-committee used to frame a series of pointed questions. As a result, Mr. Postlewaite and Ms. Marks assumed a rather defensive stance, defending themselves against accusations that their association’s “consumer information campaign,” was actually, “an advertising campaign” (Marks 1992(17):13)The ads were a public service, the industry representatives argued. They were designed to inform consumers about their members’ medications -- information the public wanted but which Canadian physicians and pharmacists were failing to provide. They elaborated that, in the past few years, PMAC had sponsored consumer information seminars and appointed advisory panels with the specific goal of designing programs for consumers – particularly seniors and women – to fill gaps in information about medications. The industry representatives thus presented their organization as actively expanding its efforts to construct the public’s knowledge about drugs, and doing so as a public service. When a member of the sub-committee argued that a consumer registry of complaints about drugs and devices was needed because consumers had “nowhere to turn” when they encountered problems with these products, the two PMAC representatives problematized the issue of product complaints as a matter of consumers wanting to be more involved in decision-making, a desire which their outreach efforts were designed to address.

In September 1992 the subcommittee summarized its findings in a report titled *Breast Cancer: Unanswered Questions*, which highlighted, as the subtitle suggests, the many troubling gaps in knowledge about breast cancer. The most striking feature of the

sub-committee's recommendations is the attention given, at every turn, to including the "experience and expertise" (Greene 1992: xv) of breast cancer activists and survivors, and of support, advocacy and consumer group members, in all manner of decision-making bodies, from breast cancer curriculum review committees to cancer research agencies. They further proposed that Health and Welfare Canada would assist with developing the necessary infrastructure of lay expertise for all of this consultation. This endorsement came with a caveat: the movement would not be "disruptive". This assurance appeared in a section of the Sub-Committee's report headed "Advocacy and Activism" which began: "There is often a tendency to equate activism and advocacy with large scale 'disruptive' behavior. The Sub-Committee received an overwhelming message from the breast cancer survivors and activists who appeared before us that this is not their intention." (Greene 1992:41)

Since none of the survivors who appeared before the committee either advocated or disavowed disruptive behavior, this appears to be the sub-committee's way of preemptively circumscribing the type of activism its members were prepared to endorse (*enrollment*) and perhaps to counter in advance anticipated opposition. Thus, the preamble goes on to specify:

...their goal is to raise the profile of breast cancer as a major national health issue, to support appropriate research on breast cancer, to encourage an increase in research funding, particularly with respect to research into the cause of breast cancer, to ensure that women and their families have access to up-to-date information on the disease, and to offer emotional support to women who are living and dying with the disease.

Greene 1992:41

The sub-committee's enthusiasm for a movement of patients' organizations -- albeit one that would eschew disruptive tactics and focus on carrying forward the Sub-

Committee's own service-oriented vision of advocacy -- contrast with the near-absence of reference to the Canadian Cancer Society in the recommendations, save for one oblique reference (Greene 1992: 17). A further contrast came when Benoît Bouchard, the Minister of National Health and Welfare of the day, responded to the sub-committee's report and recommendations, as it was obliged to do. The response (Bouchard 1992) proposed no support for patients as activists or policy actors but rather, stated that the Canadian Cancer Society, with its nation-wide network of volunteers, was "uniquely placed" to support such groups (Bouchard 1992: 29). And instead of a conference directed by breast cancer survivors, the report of the ruling party responded that representatives of breast cancer groups would be "encouraged to participate" in a consensus workshop (ibid: 29).<sup>176</sup> Once again, a powerful actor had used *interessement* and *enrollment* to reconfigure the network, this time moving the activists back to the margins.

### 5.2.3 Mobilization: The National Forum on Breast Cancer

Despite this apparent rebuff, the relationship between decision-makers within the federal government and the grass roots movement shifted once again. In early 1993, plans moved ahead for the national consensus conference, to be called the National Forum on Breast Cancer, with Health Canada<sup>177</sup> providing the funding and organizational leadership. S.B. and *Eve*, another activist who had testified at the Parliamentary hearings, were invited to jointly chair one of four groups<sup>178</sup> which would be integrally involved in planning the Forum. The role of this group, formally titled the "Support, Advocacy and Networking Subcommittee" or SAN, was to ensure that women with breast cancer from

across the country participated at the Forum with their families and allies, and that their perspectives were included in the planning process included at every point (*mobilization*). This goal was largely accomplished. Of the approximately 600 invited participants at the Forum, one quarter comprised “lay” participants, selected by the SAN sub-committee. The majority were women with breast cancer, the rest were friends, family members and women’s health activists. The sub-committee was structured to establish the proposed network of survivor groups as a policy voice on a par with the professional actors in these domains. The event received ongoing national television and press coverage, invariably including the voices of women. The *Globe and Mail* ran an article about the Forum in its front section and hailed the conference as a “watershed event,” citing the involvement of women as key to the meeting’s success (Mickleburgh 1993). Fifteen years later, activists and health professionals alike whom I interviewed told me they still had vivid memories of the event.

Two public health physicians from Health Canada led in planning the event and the vision of the Forum, including the emphasis on consumer participation, was consistent with the ideals of the professionally-driven community health movement of the 1960s and 1970s. For this subculture of health professionals, writes Canadian sociologist Deena White, engaging consumers in health policy was part of a strategy to push back against the excessive use of technologies in health:

[The community health movement’s mandate was] the coordination of health systems in the public interest. This meant, amongst other objectives, establishing countervailing forces against the constant pressure towards rising costs that were considered inherent in the professional ambitions of the medical establishment that controlled the domain at the time. In this context, the community health approach was seen to hold promise for a more rational health-care system that valued the expressed interests of patients and potential

service users above competing professional interests such as high-technology work environments or intensive therapies (White 2000: 468).

This framing assumes that patients are not drawn to high-technology interventions, a questionable assumption in the case of cancer patients (Kaufert 1998, Lerner 2001). The approach is, however, consistent with a decision to exclude the pharmaceutical industry from the decision-making bodies within the Forum planning structure.

At the National Forum on Breast Cancer, the industry again emerged as an outsider to the cancer policy world. In contrast to the Health Canada organizers' pointed inclusion of women in all aspects of the 1993 meeting, the pharmaceutical industry was neither part of the planning process, nor did it contribute funding to support the meeting. The president of PMAC at the time, former Liberal Cabinet Minister Judith Erola, attended the meeting as a delegate, however. In a 2009 interview, she recalled the Forum as a positive event: "I felt the first Forum was particularly exciting. I thought, Wow! For the first time we're getting somewhere! It brought out the best in people."

When I asked her about the industry's absence as an official partner, she laughed and replied, "Well, no one invited us – we were careful not to go in where it would be an intrusion. I could only encourage the companies." The Women's Advisory Panel that PMAC representatives referred to in their testimony to the Parliamentary committee was in fact a project Ms. Erola had personally initiated. As a Minister in Parliament in the Liberal government of Pierre Trudeau she held the Cabinet portfolio for the Status of Women; she was also the Minister of Consumer and Corporate Affairs.<sup>179</sup> She lost her seat in the Conservative sweep of 1984 and became President of PMAC in 1987, a post she held until 1998. In our interview she told me that when she went into the

pharmaceutical industry, she believed in the protection of Intellectual Property but she also believed that, if the industry was going to flourish in Canada, it “had an obligation to participate in the whole issue of the Canadian health care system and they had to be good corporate citizens.”

Within PMAC, she explained, she created the Women’s Advisory Panel in part as a mechanism to institute broad reforms to support women within the industry.<sup>180</sup> The Women’s Advisory Panel also looked for ways pharmaceutical companies could promote women’s health issues in Canadian society, such as industry-funded research chairs in women’s health at universities and funding for women’s health organizations in the community. Reflecting on her reasons for wanting the industry to fund groups in the community, she said:

I encouraged those companies – they were obliged to spend ten per cent of their sales on research – but I said, “It’s not enough to do the research.” The industry also had to understand what it could do to support various groups in the country that were desperately in need of money. ... [As President of PMAC] I could only encourage the companies. Slowly, I encouraged the companies to fund these groups.

-- Interview with the Hon. Judith Erola, 2009

As I discuss in the next section, groups soon began to receive overtures from the pharmaceutical industry; however, at the 1991-1992 hearings of the Parliamentary sub-committee, activists scarcely mentioned the pharmaceutical industry, although they did talk about pharmaceuticals and breast implants. I found no evidence that any of the organizations formed prior to the hearings had received funding from the industry. In their testimony to the sub-committee, in newspaper accounts of these start-up projects, and in interviews I conducted, members of the early groups cited shoestring budgets using volunteer labour, small membership fees, community good will, occasional modest

legacy donations when members died, and small project grants from foundations, or their provincial or municipal governments. The earliest overture from the industry that I uncovered in an interview was in 1993, after the hearings but before the Forum (discussed below).

*Groups Proliferate, Grow and Diversify.* Together the Parliamentary hearings and the National Forum on Breast Cancer comprised a *translation* that moved breast cancer to the centre of the national policy agenda; the two events also catalyzed the formation of new breast cancer groups which began to develop on a provincial/regional basis (Table 4). Ontario was an early focus of growth. The province lacked a breast cancer group with an advocacy mandate and in late 1992, *Eve*, one of the activists who had testified at the hearings, founded *A Voice for Patients* in Toronto. Following up in 1993 on the recommendations in *Unanswered Questions*, *Eve* collaborated with *Francine*, a long-time women's health activist, and applied to the Ontario office of Health Canada for funding to start a network of breast cancer support groups throughout the province. They received a grant of \$200,000 over two years to assist women who wanted to start self-help groups in their local communities. By the time the Forum took place, in November 1993, the *Support Groups throughout Ontario* Project was well underway, with 15 local self-help groups of various sizes. The Forum, which had funded transportation and accommodation for a quota of women with breast cancer from each region of the country, energized women from other regions to return home and start their own survivor-directed groups. As a follow-up to the Parliamentary hearings and the Forum, Health Canada set up a special national funding initiative to address problems that had been identified. The Canadian Breast Cancer Initiative provided \$25 million over five years to support breast

cancer research, education and support projects of various kinds, including a national infrastructure of local and regional grass roots groups with a national coordinating organization (*The Hub*). The latter was to serve as central information centre and to be “the voice of breast cancer survivors in Canada” (see Figure 7).

As a follow-up to the *Support Groups throughout Ontario* Project, *Eve* and *Francine* conceived of another project, an organization which would have the ambitious goal of providing support and treatment information by telephone for women with breast cancer throughout Ontario, with an emphasis on materials tailored to underserved subgroups, including cultural communities, rural women, lesbians and the disabled. They envisioned a centre run by women that would operate out of an attractive walk-in space in downtown Toronto, with a lending library, and a 1-800 number. They approached the Ontario government and met with success: “We got a grant of \$25,000 just to write the proposal!” *Eve* exclaimed in an interview, in 2007, adding, “Those were the old days.” Next, they received a start-up grant of \$200,000 for their resource centre, which held its launch in June 1995 under the name *Helping Hand*.

The proliferating local organizations had varied mandates and, as the examples of *Down-home Peer Support and Education* and *Critical Advocacy to Prevent Cancer* in Chapter 3 illustrate, their cultures of action evolved over time. Most included some mix of support, advocacy, and providing information about breast cancer – with various definitions as to what these terms meant.<sup>181</sup>



#### 5.2.4 Groups Debate “Big Pharma’s” Overtures

In the interval between the Parliamentary hearings and the National Forum on Breast Cancer, the worlds of the breast cancer groups and the pharmaceutical industry began to intersect. The groups grew in number, size, and visibility. Although government funding was sometimes available for start-up and for particular projects, this money was neither long-term nor sufficient for the growing demands on the groups to provide services. Breast cancer groups began to receive offers of funding from drug companies and their boards began to discuss the question of whether such funds should be off-limits. In some cases, these internal discussions revealed deep divisions (see Table 5, Discourses over Pharma Funding) as well as overlapping ambiguities. The arguments of those opposed to pharmaceutical company funding drew in large part from the 1980s feminist critique of the pharmaceutical industry and deployed a coherent discourse to support this position. By contrast, the initial arguments of those defending industry funding remained superficial (e.g., “Why not?” and “Other groups do it”) and lacked an ethical edge.

The earliest instance of a Canadian breast cancer group encountering the issue of pharmaceutical company funding I have been able to document was an overture to a member of the Toronto advocacy group *A Voice for Patients*. In the Spring of 1993, the group held a public panel discussion about the controversial U.S.-Canada clinical trial known as the Breast Cancer Prevention Trial that assessed tamoxifen as a preventive (Bush and Helzlsouer, 1993; Fisher, Costantino, Wickerham, et al. 1998, Goel 1998, Smigel 1992). *Virginia*, who was a member of the board of *A Voice for Patients*, was approached by a representative from one of the pharmaceutical companies.

[The panel on tamoxifen as a preventative] was one of the few big things we did. ... I was approached by a pharma rep at that event. I remember her giving me a card and saying, "We would like to help you." And I slowly -- at the beginning I was really kind of innocent about this, not because I expected to take the money but because I couldn't really see why they'd be interested in us. It was kind of like, "Ooooh!!! That's interesting!!!" You know, that Pollyanna kind of thing; and then it dawning on me, "Oh, there's another agenda here."

There wasn't really an event that we were at where I wasn't offered something like that kind of card ... where we would have a table in a community, and these pharmaceutical cockroaches would come up and, you know, shove their cards in our face. And we talked about it [in the group], because there were some members who would say, "If we're struggling so badly, why *can't* we take this money?" And it really became an ethical thing. (Interview with *Virginia*, 2008)

*Vera*, another of *A Voice for Patients'* founding members concurred and explained that the discussions took place at a time when the group was undergoing rapid growth, which created pressures to find more funds:

We began to feel we needed a professionally-led support group. People were so sick, we were having trouble keeping people in the group -- they were scared off by the really sick women. We felt we needed a skilled facilitator. We eventually did hire one, and it helped. We needed to get ahead, to work harder. [The discussion about pharma money] was at the moment when we needed money for things like that. (Interview with *Vera*, 2008)

*A Voice for Patients* wanted to become an advocacy force and the context in which members discussed pharmaceutical company funding included this ambition. Members of *A Voice for Patients* were "very, very keen" on making breast cancer prevention a priority, said *Vera*, particularly the potential causal relationship between environmental contaminants and breast cancer. Lack of resources held them back; however, the members were almost unanimous in their opposition to taking funds from

the industry. *Virginia* recalls, “We went to the discussion table over it. We really struggled with it.” Ultimately, the arguments members made for refusing the funding from the pharmaceutical industry prevailed:

We wanted to be unbiased and there’s no such thing as a free lunch. And why, if we’re trying to be the voice of the community, why should we taint this voice with money from a private interest? I mean, we were quite happy taking government money, but you know, that didn’t seem as compromising for us; if we could get our hands on government money that was fine. ... But amongst it, rightly or wrongly was the notion that, these people are in this industry to make money out of cancer. And although many of us had taken the drugs that they were selling, and therefore may or may not be alive if we hadn’t, we didn’t think that had a place in what we were trying to do as a survivor organization. And that was the voice that continued. (Interview with *Virginia*, 2007)

*Vera* recalls that *Eve* was the group’s outlier on the issue:

We were very skeptical of working with the pharmas, we were very opposed to it, except for *Eve*. She was much more keen on [us taking pharma money] because we needed money. She felt -- and she was right on this point -- that if we were going to be an organization that made a difference, we were going to have to push harder.

I was very aware of that issue [conflicts of interest arising from funding from pharmaceutical companies] and very suspicious. ... We had several discussions – long discussions. There was a lot of concern about it because we thought we might need to say things the companies didn’t like. We thought, “Holey moley, this could be very problematic!” ... It was the advocacy we were worried about, that we would look tainted if we took it, and of course if we took it we would have to be open. (Interview with *Vera*, 2008)

In the end, all of the board’s members opposed the industry as a source of funding, except for *Eve*, who left *A Voice for Patients* about this time to work on starting *Helping Hand*. The group chose to survive on a shoestring, without paid staff. *Virginia*, explained, “Our credo was, ‘Don’t spend it if you don’t have it.’ The only time we got

money was when someone died. ... And because we didn't have a very big investment in spending money, we didn't owe anything to anybody.”

*Autoethnographic Interlude:* In the months leading up to the National Forum on Breast Cancer in November 1993, the issue of pharmaceutical company funding surfaced among the members of the patients' subcommittee. During the summer, the subcommittee had decided to mount a number of projects including “Faces and Stories,” a photo exhibit portraying a woman in each of the provinces and territories that had died of breast cancer. Like many of the Canadian initiatives, this project reprised a strategy that had succeeded in the United States. *Breast Cancer's National Voice*, a nation-wide coalition of American groups, had used a photo exhibit of American women with breast cancer as a focal point at their first national rally the previous spring. Since the Forum budget did not include funds for such a project, the question arose how the cost (approximately \$5,000) would be covered. Health Canada was prepared to provide half of the budget,<sup>182</sup> but said the patients' sub-committee would have to find matching funds; with the conference only a few months away, *Eve* proposed that the Sub-committee approach a pharmaceutical company. S.B. vehemently opposed the idea. To the latter's astonishment, given the discussion and general agreement within *Critical Advocacy to Prevent Cancer*<sup>183</sup>, described in Chapter 3, most other members of the sub-committee had no objections to asking a drug company for funds. As chair of the sub-committee, however, S.B. was responsible for the budget, and stood her ground.<sup>184</sup> When I interviewed *Eve*, in 2007, we tried to reconstruct the sequence of events:

*Eve:* We needed money to do the photo exhibit, and Bristol-Myers Squibb had funded the U.S. photo exhibit, that's what it was.

*S.B.:* Had they?

*Eve*: I had been down to see how *Breast Cancer's National Voice* was doing its meetings in Washington – and ...I had seen this photo exhibit down there, and then we got things rolling up here. And I thought, “Let’s find out if Bristol-Myers Squibb can do something for us.”...

But it never really went anywhere because you said “No, we’re not taking any pharmaceutical funding.” I thought, “Why the hell not?” The U.S. [activists] did it, and they’re certainly not in bed with -- I would never imagine them to be sort of an Astroturf group.<sup>185</sup> And *Sherri* [the president of the *Breast Cancer's National Voice*] is a pretty independent thinker. (Interview with *Eve*, 2007)

S.B. opposed industry funding because she felt this would undermine the independence of the groups at a critical moment, when patients’ organizations were trying to establish their credibility as a new voice in the system. Her prior experience as an activist in the feminist and consumer rights movements no doubt informed her perspective. The fact that the industry had been excluded from a sponsorship role in the conference as a whole would only make industry support of the one structure that was intended to give voice to patients and their supporters more jarring. S.B. was also conscious that Bristol-Myers Squibb, the company suggested as a funder, was deeply implicated in the breast implant scandal, which had still not been settled. (She was not aware, however, that the same company was in the process of applying to have the new ovarian cancer drug, Taxol®, approved as a breast cancer treatment.) As the conference date approached, the Health Canada organizers pressured *Eve* and S.B. to resolve their differences and move on. Following a series of phone calls that failed to resolve the dispute, *Eve* and S.B. were flown to Toronto for a meeting with two members of the Health Canada team. Following a discussion in which each presented her case, funding from the pharmaceutical industry was ruled out. *Eve* then approached a women’s clothing

designer who agreed to donate the money needed. A second mention of pharmaceutical company funding in the Forum context appears in a 15-page draft working paper on networking produced by a subset of Patients' Subcommittee members in August 1993. The paper, which outlined a strategy for developing a national "survivor-directed, independent" network of breast cancer groups, includes a list of possible funding sources, including drug manufacturers.<sup>186</sup>

*End of Autoethnographic Interlude.*

*Eve* recalled the post-Forum period as a critical turning point for overtures from drug companies at the local group she had co-founded, *Peer Support and More*: "It was about then that the pharmaceutical companies started recognizing us, because of the Montreal Forum [i.e., the National Forum on Breast Cancer]. There was such a high profile; we [at *Peer Support and More*] started getting calls from the pharma companies."

As with *A Voice for Patients*, these overtures came at the same time that groups were under pressures to expand. Despite the flurry of government grants that became available as breast cancer gained political capital, the explosion of organizations and the demands on them raised questions about funding and long-term sustainability. *Eve* was Project Director of the *Support Groups throughout Ontario* Project where, she recalls, the members' high expectations generated demands that were going to be hard to meet when the government funding ran out.

Women would complain, "you're not organizing us into meetings often enough." They really loved it when we would go on retreats, like a church retreat down at Niagara Falls or something. But everything was constantly on a start-up basis. .... We were getting this pressure, "when this ends, we want a clearinghouse. We want to be able to stay connected and have these training sessions [in how to run support groups]." You know, you have

\$200,000 dollars for two years. The expectations were so high that it was just sort of crippling. (Interview with *Eve*, 2007)

The *Helping Hand* board meetings became a site of intense debates about pharmaceutical company funding.<sup>187</sup> The new board was a mix of breast cancer survivors (fifty per cent, as mandated by the group's charter),<sup>188</sup> women's health activists, high profile women from the entertainment and media worlds, and women with connections to business. As they headed towards a splashy launch at the Royal York Hotel in Toronto, tensions ran high. Co-founder *Eve*, who had been hired as *Helping Hand's* executive director once the group received grant money, recalls:

When we were doing publicity for the launch we were sending out faxes by hand. And that's when the pharmaceutical companies started coming in and saying, "Oh, this is a fabulous event, do you have sponsorship?" ... And this one guy approached us and he said, "You know, this is a really important event and we'd like to help sponsor it." And [his company] gave us – twenty? – maybe five thousand dollars. Not twenty, maybe five.... And it was about the same time actually that Taxol® was just coming out. (Interview with *Eve*, 2007)

The group's minutes from September 1995 corroborate that *Helping Hand* received \$5,000 for its launch. *Eve's* mention of Taxol® is significant because the donor was the French pharmaceutical company Rhone Poulenc (now Sanofi-Aventis),<sup>189</sup> which had developed Taxotere®, a competitor to Bristol-Myers Squibb's Taxol®.

Throughout the fall 2006, *Francine* recalls, the issue of corporate funding was "the hot button with *Helping Hand*." *Francine* described herself as being part of a subgroup on the inaugural board who had strong opinions against funding from the pharmaceutical industry.<sup>190</sup>

*Francine*: As the board got set up, it took a long time to find space. We had temporary space for a while and then finally we got secure space on Queen

Street. But in the meantime, some of the more high-powered women on the board and their connections were talking up sources of money with people they knew in industry and the banking world as well. The CIBC [Canadian Imperial Bank of Commerce] was a big backer of *Helping Hand* in the early days. And Home Depot also gave a lot of money and in-kind service. But one of the board members felt very strongly that we should pay attention to an overture that had been made by Procter & Gamble. Somebody [from the company] approached her and asked her to go take it to the board. And that was sort of the beginning of the demise. (Interview with *Francine*, 2007)

Procter & Gamble had offered to train workers for the organization's 1-800 line and the company became a "case in point" at the board meetings for discussions about the ethics of industry funding. A few years earlier, an American journalist had written an exposé critical of the company's business and environmental practices,<sup>191</sup> prompting some Canadian environmental groups to organize a boycott of Procter & Gamble's products because of environmental offences involving the company's chlorinated by-products. An initial discussion at *Helping Hand* was framed generally, as "the ethical practices of large companies with whom we may choose to do business."

In November 1995, *Francine* called another meeting<sup>192</sup> to discuss ethical issues related to fundraising in more depth. Board members were encouraged to read the book about Procter & Gamble in preparation and *Francine* presented a critique of the pharmaceutical industry's history of harms to women to the board, drawing from her work in women's health movement. *Francine* provided examples of women's health groups in Canada and the U.S. that did not take any money from drug companies and other groups that had policies that were open to pharmaceutical company funding, emphasizing that the "Refusers"<sup>193</sup> felt it would compromise them in being able to speak critically about the industry. Following the discussion, the board agreed they would "view each case individually paying particular attention to pharmaceutical companies."



Discussions at successive board meetings became increasingly heated, *Francine* recalled, with the tenor of the discussions about pharmaceutical industry funding following a pattern:

*Francine*: The nature of it was always this one person in particular coming forward and presenting [the issue] like this was a no-brainer, “Why would we *not* take their money?” [She would make] exactly the kinds of statements that get raised over and over and over again, like “All money is dirty money, why can’t we just put it to clean use?” or “Pharma is no different from banks or any other big corporations, why do we make a distinction?” It’s all those kind of classic lines you hear around pharma funding of health-related consumer groups. And it just escalated and escalated. (Interview with *Francine*, 2007)

Eventually, feeling more and more isolated, *Francine* resigned, largely over the issue of pharmaceutical-company funding.

*Francine*: ... You know [with the various stresses of getting the organization up and running] it wouldn’t have taken much for us to kind of fall apart and for some of us to just walk out, which is what ended up happening. I walked out of a meeting and basically never came back. ... The pharma funding issue was the point in the sand that I wasn’t prepared to go past. I disagreed with too many people on the board. And, and at that point, if I recall correctly, it was a majority who was then [saying], “Let’s go for it.” (Interview with *Francine*, 2007)

This was not the end of the internal debates, however. *Helping Hand*’s official launch in June 1995 was, according to several accounts, premature because the organization was not yet ready to provide the telephone support and information services which were its *raison d’être*. In 1996, when the group set up its phone lines and newly-hired staff members began training the women with breast cancer who were to be the phone volunteers, the staff doing this work became passionate voices against pharmaceutical company funding, according to *Virginia*, who accepted one of the paid

positions training and overseeing volunteers.<sup>194</sup> She remained with the organization for ten years where she saw the struggle at *Helping Hand* from a staff perspective and over an extended time span.

Once the phone service became active, *Virginia* recalls, the organization did adopt a formal policy to refuse pharmaceutical company funding. The executive director at that time agreed with this position, which, despite the contrary views of some members of the board, was eventually put in writing:

*Virginia*: I don't know if there was anything written down at *Helping Hand* before I started around pharma funding, but I do know that within two years of me working at [the organization] we had a written policy of not taking pharmaceutical funding. And I remember the board/staff weekend meeting where the wording of that policy was thrashed out.

And it was not necessarily something that everyone agreed on, but the majority certainly agreed at that time -- the staff being the most vociferous around *not* taking this money. And not doing forward planning that would put us in debt, so that we would have to consider it [pharmaceutical industry funding] in the future. It was a very, *very* important part of who we were at *Helping Hand* at the time. (Interview with *Virginia*, 2008)

Board members, who were responsible for keeping the organization afloat financially and who, in many cases, had been sought out because of their contacts and fundraising abilities, could be more pragmatic. The staff's commitment to the group's independence from the industry was visceral, according to *Virginia*, and was rooted in the fact that they were responsible for maintaining the quality of information given to the public over the phones:

*Virginia*: I was hired to be a peer counselor, which meant that I had contact with women every day, who phoned asking for information and peer support in their breast cancer journey. And a large portion of the conversation was discussion around treatment. Our mandate was *not* to tell them what to do.

And we were very strict about that, Sharon, really strict! And we were good at being strict. But what we were there to do was to answer their questions *honestly*....

I can't stress strongly enough how *unbiased* our delivery of support needed to be; because, as you know, these women were vulnerable, they -- a great many of them want somebody to tell them what to do. And sometimes they'd rather have another survivor tell them what to do than a physician. ...So that's what made our position even more important to be clean on -- because we *shouldn't* be telling them what to do. And we shouldn't even be *implying* that we know, or be even tainted by anything that would even suggest that that we had associations with anything. Because I saw -- and this is very purist of me -- I saw organizations like *Helping Hand* as being the *only* safe place for survivors to go to get support that was agenda-less, that didn't have a back-speak to it. (Interview with *Virginia*, 2008)

*Virginia's* work as a *Helping Hand* staff member brought her into contact with the wider community, including industry representatives. The policy, she recalls, provided a shield from their frequent overtures.

In the beginning, because it was public at *Helping Hand* that we didn't take money, and we *were* public, we said, "We don't." And as a spokesperson at *Helping Hand*, I said it often, that we don't take pharma funding. And when I was at events then, promoting *Helping Hand*, on community tables, it was, sometimes you'd be at something like a hospital show, or the College of Physicians and Surgeons, or something like that, and a large proportion of the exhibitors at those things are pharmaceutical companies. And there would *always* be cards left on my table when I wasn't there. Or people would approach me, Astra Zeneca, *all* of them, *all* of those big names. And say, "You know, we'd love to help you out." And I'd just say, because I felt comfortable saying it, "Thank you, but no thank you. We don't take pharma funding." And some of them would say, "Why? Why wouldn't you take pharma funding? Why?! It's a win-win situation!"

It was like going to the disco in the '70s and the irritating guy coming up and asking you to dance, "Why *don't* you want to dance?" You know it was the same kind of thing, "Well, because I don't choose to. These are the reasons, read my lips." But some of them were very persistent, they would say, "Well, we're in negotiations with [the group in] Burlington" or "We're in ..." you

know, to make it seem like there was something wrong with you because you were looking a gift horse in the mouth. (Interview with *Virginia*, 2008)

### 5.2.5 Breast Cancer Treatments and Group Advocacy

Within the new organizations, these conflicts over pharmaceutical company funding arose from broad political and ideological differences, the members different roles (e.g., fundraising *versus* actually providing information) and from differing understandings of how such funding might affect the group's practices and/or the public's view of the organizations. At the same time, some organizations gradually incorporated drug-related advocacy into their repertoires. Since patients' organizations represent the end-users of the drugs, their advocacy for or against a particular treatment had the potential to dramatically shape the social construction of these technologies.

In discussing the repertoire of drugs and biologics used to treat breast cancer, I adopt Emily Martin's (2006) concept of the *pharmakon*, the Greek term meaning both remedy and poison (see Chapter 4, p 188) which she weds to the idea that drugs have social lives – from their conception throughout their life cycle (Figure 2) the way in which this dual personality is expressed is affected by their interactions with humans. In the 1980s and early 1990s the staples of the breast cancer pharmacopoeia were the cytotoxic chemotherapy cocktails such as CMF and CAF (see List of Abbreviations Used) which work by killing rapidly dividing cells, and the estrogen-blocking drug tamoxifen. The cytotoxic drugs were known for their toxicity and only benefited a small minority of women who took them; the benefits of tamoxifen were still being assessed and, although this drug was widely considered “easier to tolerate” than cytotoxic drugs, it also had a range of side-effects from mild to severe and, in rare cases, life-threatening. By

the late 1980s, however, a number of drugs with novel mechanisms of action were at various stages in the drug treatment pipeline. The introduction of these new treatments at the same time that advocacy groups were forming opened the door to a new co-construction: the groups were a potentially powerful force in defining the pharmacopoeia, and the new drugs became actors in the construction of the movement. In this section I examine how four of these innovations helped shape the discourse about pharmaceutical industry relationships in the early movement. The first two innovations were novel and (at the time) unusually expensive treatments that had been introduced for breast cancer treatment in the United States (Greene 1992): first, high dose chemotherapy with bone marrow transplant, a treatment procedure that used high doses of conventional cytotoxic drugs but which also required two costly drugs to boost red and white blood cells and second, Taxol®. Both were the subject of lobbies to have drugs added to provincial formularies. Third, a San Francisco-based biotechnology company, Genentech, had developed the antibody treatment, Herceptin®, and had begun to engage activist organizations to assist with the design of and recruitment for clinical trials. At the same time an American breast cancer group led a recruitment effort to force the company to put in place an expanded access program<sup>195</sup> (Bazell, 1998). Fourth, a large US-Canada clinical trial was undertaken to test the now-standard hormonal treatment tamoxifen as a preventative drug for women deemed to be at high risk of breast cancer. Two Canadian breast cancer groups joined with American health advocacy groups to oppose the trial on the grounds that tamoxifen was too toxic a drug to be given to healthy women. These were not the only areas of scientific innovation in breast cancer in this period but all four

were instrumental in developing the discourse between breast cancer activists and the pharmaceutical industry.<sup>196</sup>

As explained in the last chapter, high-dose chemotherapy with bone marrow transplant was a procedure that administered chemotherapy at two to twenty times the standard dose of cytotoxic chemotherapy drugs, in the hope of eliminating every cancer cell in the body and thus curing the cancer (Lerner 2001). The procedure was risky; five to fifteen per cent of patients died while undergoing treatment depending on such factors as the experience of the treatment team; this compared to a one per-cent treatment-related mortality with conventional chemotherapy treatment (Eddy 1992). Because the treatment destroyed the patient's white blood cells, which are integral to the immune system, a second step was to infuse stem cells that had previously been removed from the patient's bone marrow which would reconstitute the white blood cells. The procedure used two expensive biologic drugs sold under the trade names Neupogen® (filgrastim) and Epogen® (epotin alfa), to boost white and red blood cells, respectively. At the time, Neupogen® (granulocyte colony stimulating factor) was considered experimental and was not licensed in Canada. Epogen® was licensed and indicated for AIDS, but not breast cancer.

Taxol® is an extract from the bark of the Pacific yew tree which a U.S. National Cancer Research program discovered in 1964 to have anti-cancer properties. The discovery languished for decades because the compound was naturally-occurring and could not be patented. Promising Phase 2 clinical trial results were first reported in 1989. In order to move Taxol® to market, the U.S. government gave the American pharmaceutical company Bristol-Meyers Squibb exclusive rights to provide Taxol® from

Pacific yew trees under a 1991 agreement. The company developed a semi-synthetic method of production which made it patentable and in 1994 taxol became Taxol® (Walsh and Goodman 1999, 2002). The U.S. FDA approved Taxol® to treat metastatic ovarian cancer in 1992 and in April 1994 the drug was approved in the U.S. as a second-line treatment for metastatic breast cancer (i.e., to be used if a standard chemotherapy treatment fails) (Anonymous 1994). Canada approved Taxol® for breast cancer in 2000.

Researchers at the San Francisco-based biotech company Genentech had been working since the late 1980s on developing a novel biologic, Herceptin®, as a treatment for breast and ovarian cancers. By 1994 the researchers were designing Phase III human trials (Bazell 1998:117). Like Taxol®, Herceptin® had a different, genetically-based mechanism of action than the cell-kill and hormonal treatments.<sup>197</sup> In the early 1990s the drug was still some years from reaching the market but was creating excitement in the cancer research community, as well as in the lively community of breast cancer activists in the San Francisco area (Bazell 1998). Adding to the drug's potential importance, preliminary research indicated that the subset of women with breast cancer most likely to benefit from the treatment were those with "aggressive" tumours for which existing cytotoxic treatments were usually not effective.

Another area of breast cancer treatment research in this period was the administering the anti-cancer drug tamoxifen to women judged to be at high risk of developing breast cancer in the hope of preventing the disease (Jones and Powles 1992; Love 1992). In 1991, Canadian and American researchers launched a Canada-US clinical trial to study the preventative potential of the treatment drug tamoxifen. A well-established feminist women's health organization in the United States, "*Women*

*Advocates for Women's Health*,” developed a critique of the clinical trial, arguing that the drug had too many serious side-effects to be administered to well women (Fugh Berman 1991; Fugh-Berman and Epstein, 1992). Other women's health organisations, including the Canadian group *Critical Advocacy to Prevent Cancer*, joined with *Women Advocates for Women's Health* to protest the trial (Woodell 2004, Fosket, 2004; Ley, 2009), which some members of the research community questioned as well (Bush and Helzlsouer 1993; DeGregorio, Maenpaa and Wiebe 1995).

These diverse areas of activity suggested to some that breast cancer treatment was undergoing a revolution. At the same time, anti-cancer drugs were beginning to attract attention as an area of dramatically rising costs, the benefits of which were largely unproven (Evans and Walker 1997; Will, Berthelot, Le Petit 2000). Of particular interest to my analysis is the connection between the companies that actively wooed breast cancer groups and the involvement of these same companies in developing drugs used in some aspect of breast cancer treatment.

*Neupogen®*, *Epogen®* and *High-dose Chemotherapy* Sylvia Morrison, one of the patients who testified at the Parliamentary hearings, pleaded for a more rapid uptake in Canada of the novel, but highly toxic and unproven high dose chemotherapy regimen available in the United States. Despite a vigilant practice of self-exam and frequent mammograms prompted by her family history of breast cancer, Ms. Morrison had been diagnosed just eight months earlier with a rapidly growing tumour that had already metastasized. In view of her desperate situation, her oncologist in Hamilton had recommended the experimental treatment that was being used in the United States at the time but was unavailable for breast cancer in Canada. She had the procedure performed at



a hospital in New York, where two drugs sold under the trade names Neupogen® and Epogen®<sup>198</sup> were used to boost white and red blood cells, respectively.

Showing an impressive grasp of the workings of Canada's drug regulatory system, Ms. Morrison argued that patients like her should have easier access to experimental drugs. The costs of her treatment and related expenses "bankrupted us" she stated, emphasizing that her family was financially "in better shape than the majority of Canadians" (Morrison, 1991a:48). Specialists at her local Canadian centre told her that the treatment was not offered in Canada because it had not been proven to have better five-year survival rates than standard treatments. She countered that of course such proof was a logical impossibility, because "the drug has not even been available for five years" (Morrison 1991:46). Yet, the statistics available "...indicate that it is very promising. Do we have to wait five years before we give our women the opportunity to take advantage of research and experimental procedures going on elsewhere?" (Morrison 1991:47).

The argument that it would be unfair to deprive women in Canada of treatments available elsewhere (which usually meant in the United States) was gradually incorporated into the discourse in favour of relaxing Canada's drug approval regulations and the criteria for formulary listings, and specific lobbies for both Eprex® and Neupogen® were part of this process. Patients' organizations in Canada did eventually lobby to have both these drugs added to formularies for breast cancer patients. Advocacy to have Neupogen® approved was led not by a breast cancer group but by an organization formed by parents of children with congenital neutropenia, a so-called "orphan disease."<sup>199</sup> *Gloria*, the co-founder of this group, told me the organization began in 1989 when her two young sons were diagnosed with neutropenia, a rare genetic blood

disease.<sup>200</sup> Three other families in the same mid- Canadian sized city had children with the same condition, all of whom were being treated by the same specialists. The physicians thought it would be helpful to the families to meet and support one another and so asked *Gloria* if she would be willing to start a local support group. She agreed and in 1989 the four families founded the “*Genetic Orphan Disease Group*,” the only organization of its kind in the world at the time.<sup>201</sup> The group encouraged families to enroll their children in clinical trials to test the drug.

For the drug [to gain] approval, to show how effective it was, obviously it makes sense to use someone that’s born with a disease where it was a life-saving drug, where it gave them data that showed how effective it was. And there’s reams and reams and reams of articles about that and about all the clinical trials and everything else. That’s where, first of all, there were five Canadians [with neutropenia] that were in the American trials. (Interview with *Gloria*, 2008)

Most of the clinical trial participants, however, were cancer patients who had neutropenia induced by chemotherapy.

And then, once that information was presented to the FDA, then they were able to approve it for cancer patients [in February 1991]. .... We then had to go to bat to have it approved for congenital neutropenia patients, because it wasn’t going to be approved for that, because we’re an orphan disease. And because of ...our influence, it was, and thankfully we went down that path. So it was approved in Canada, and then a year later in the United States for congenital neutropenia. (Interview with *Gloria*, 2008)

*Gloria*’s two sons are healthy adults today and she is a passionate advocate for the drug, which she believes saved their lives (the disease resolved when they were in early adolescence). Once the drug was approved, however, the provinces were reluctant to put it on their funding formularies for cancer patients beyond very narrow uses, because of the extraordinary expense. *Gloria* explained:

And it was very specific as far as the cancer population, as far as the indications at first. That is, I think it's still growing [in 2008] as far as its use. But at first it was very, very, very specific in the pediatric community, and then in the breast cancer community. Like, it's still ongoing [i.e., the struggle to broaden the indications]. (Interview with *Gloria*, 2008)

When I spoke to *Gloria* the organization she started had a firm policy not to accept funding from pharmaceutical companies, but this was not the case when the group was formed. At the beginning, she said, the families were “neophytes in volunteerism”; they simply agreed there was “a tremendous need for information.” Their first project was to establish an information library but they also wanted to encourage research into the condition. They became a registered charity so they could raise funds and issue tax receipts to donors.

In 1989 we raised \$700 selling calendars. In 1990, we had a fashion show and a baseball tournament. ... And then we thought, “Oh, we need a newsletter,” and “Oh, we need a toll-free number,” and “Oh, we need a web site” – and it just keeps on going, right? [laugh] ...

Early on I approached some drug companies for money to publish a newsletter – no, it was a booklet. I think we received \$1,000 each from Amgen,<sup>202</sup> Sandos, and Schering. They were hands-off -- the money was for the printing. Then we approached Amgen for money to publish a booklet and we credited them on the back. (Interview with *Gloria*, 2008)

When the booklet appeared, one of the physicians advising the group suggested that, to maintain its credibility, the group should not accept any further funding from the pharmaceutical industry: “[He] picked up on the fact that, because we were using the drug company logos, we were perceived as being in the pocket of pharma. We made an executive decision in '91 or '92 to raise all the money ourselves.”

The *Genetic Orphan Disease Group* has since grown to have an international membership, but stands firm on its policy not to take funding from any drug company.

For *Gloria*, the incident was a learning experience:

At that point I didn't know there were any issues. I thought that as long as [the companies] were hands-off, it was ok. I wasn't aware of the problem of perception. Now ... someone from the staff of a drug company might donate something to a golf tourney, but it will be less than \$100. We are one hundred per cent voluntary -- we have never had any paid staff. (Interview with *Gloria*, 2008)

Unlike *Francine*, who had a long history of working in health advocacy, many women who became active in the breast cancer movement and other disease-advocacy groups were engaging in health activism for the first time. The experiences that *Gloria* and *Virginia* (p 280) describe, in which each woman realized “there's another agenda” that could constrain the group's ability to speak on some issues, and that the effect on public perception could damage their credibility with the public and with other actors, illustrate that patients' groups became sites for learning not only about diseases and related policies, but also about the pharmaceutical industry as an interested party with its own complex culture. As *Gloria* put it, they were “neophytes” to the health policy world; to be effective they had to acquire knowledge about the other actors in that world and to develop strategies for interacting with them.

*Tamoxifen for Prevention: The Breast Cancer Prevention Trial*. At the time of the Parliamentary hearings, Canadian and American researchers had just launched the Breast Cancer Prevention Trial, a cross-border clinical trial to study whether tamoxifen, the standard hormonal treatment drug for breast cancer, could be effective as a cancer preventive if given to women deemed to be at high risk of breast cancer. This study

elicited both criticisms and support from witnesses at the hearings. Pat Kelly recommended that chemo-prevention agents in high-risk women be made a research funding priority (House of Commons, 1991:1:41). By contrast, S.B. cited the critique of the trial by the Washington, D.C. organization, *Women Advocates for Women's Health* in, which argued that the study subjected healthy women to an unacceptable amount of risk, including a risk of endometrial cancer, potentially fatal blood clots, and cataracts. Committee members later visited the National Women's Health Network on a trip to Washington to hear their critique firsthand (House of Commons, 1992:15:A). Several researchers also commented on the trial, some in positive terms, others expressing ambivalence (House of Commons: 1992:16:27; 1992 Ibid: 16:34).

In 1993, the groups *Critical Advocacy to Prevent Cancer* and *A Voice for Patients* both engaged in advocacy to challenge this trial on ethical and medical grounds. The critique of these groups was in contrast to the arguments of the drug company and of oncologists who supported the trial (Early Breast Cancer Trialists Collaborative Group, 1998; Love 1992; Jones and Powles 1992). The arguments also contrasted with those that patients advanced to affect policies concerning Neupogen® (discussed above) and Taxol® (discussed below) which were aimed at providing faster and easier access to the drugs in question. Women's health critics of the tamoxifen prevention trial argued that public health interventions, because they were administered to large populations of healthy people (most of whom would never become sick from the disease in question) demanded a higher level of safety than treatment interventions (Fugh Berman 1991). Evidence from clinical trials showed that tamoxifen had a number of serious risks, including cataracts, potentially fatal endometrial cancer and pulmonary embolisms, as

well as commonly experienced symptoms such as hot flushes, nausea and vomiting, that affected the woman's quality of life (Fugh-Berman and Epstein 1992; Woolterton 2002). Thus, healthy women should be protected from the potential risks of the drug which, although arguably less toxic than cytotoxic chemotherapies, did not meet the standard of having the "vanishingly small" risks required of an intervention intended for a healthy population and, indeed, constituted "disease substitution" not "disease prevention" (Fugh-Berman, 1991). This discourse claimed that research on how to prevent breast cancer fell into the category of public health initiatives and should be confined to health-promoting interventions, such as dietary improvements, exercise, and reducing exposures to carcinogenic substances.

The groups opposing the Breast Cancer Prevention Trial also took note of the enormous cost of providing tamoxifen to tens of thousands of women who, according to the researchers who designed the trial, were defined as "at high risk" if they had a 1.66 risk of breast cancer over five years (Fisher, Constantino, Wickerham 1998). Disease prevention strategies, they argued, should be low cost, as well as low risk (Fugh-Berman 1991). At the time the trial was initiated, in 1991, tamoxifen was the world's best-selling anti-cancer drug and Astra-Zeneca's brand, Nolvadex, was still under patent in the United States where the annual cost for a standard dose of 20 mg per day was U.S. \$750 a year (Love, 1992: 354). If taken for five years (the recommended time-period for women with breast cancer) the cost to a healthy American woman would be a not-insignificant U.S. \$3,750.<sup>203</sup> If the FDA were to approve Nolvadex as a drug to prevent cancer, this new indication would open up a vast new market for the drug – in the U.S. alone, 29 million women would meet the eligibility requirements (Pearson 1998).

*Taxol® and the Ontario Access Lobby.* In 1991-2, at the time of the Parliamentary hearings, the drug Taxol was being used experimentally in Canada to treat ovarian cancer and was creating a buzz as an exciting new cancer treatment. Members of the Parliamentary committee asked Dr. Joe Pater, The Director of Clinical Trials from the National Cancer Institute of Canada, whether publicity about new treatments could result in the public being misinformed. He replied:

What we are dealing with most right now is the drug Taxol®; you have probably heard about it, uterus and ovarian cancer, etc. We're doing a randomized trial in ovarian cancer, not breast cancer ... The exaggeration as to the potential benefit of this drug makes it very difficult to explain to patients that it's not going to cure their cancer. It might cause it to go into regression ... (Pater, 1992 8:10).

By the time *Helping Hand* opened its phone lines in mid-1995, the U.S. FDA had approved Taxol® as a second-line treatment for advanced breast cancer, and it had been in use for ovarian cancer for three years. In Canada, the drug was only approved for ovarian cancer. *Eve* recalls a number of events that brought Taxol® to her attention.

Articles were coming out about the fact that this was considered the gold standard now [for treating ovarian cancer] and that women were actually being cured of ovarian cancer, which was phenomenal. Except the Ontario, government wouldn't pay for it. And [the head of the ovarian cancer society] was telling me about this, and I said, "Well, you know, this is the kind of thing that motivates people in the United States to sue. There's got to be some way [to gain access], and [it's] probably political." So that you started to see things happening.

... And it was often being indicated then [off-label] for breast cancer. And I think around that time the ASCO meeting<sup>204</sup> had come out and they said, "We're no longer going to treat with CAF or CMF, it's going to be CAF or CMF plus Taxol®." And so there was some controversy in Canada because we didn't have any guidelines or standards, [it] hadn't been approved. But there was all this press coverage around it. And then we [at her local breast cancer group] started getting asked, "What's your position?"

And that's when I heard about this woman, she was a professor at York [University]. ... And she had done some kind of a press conference, and it turned out that she had been paying for it herself for about two years. It was the only way she could get the drug. And she had very advanced breast cancer. And she was continuing to be quite functional. She was teaching and, I mean, it was sort of one of those Lazarus sort of stories. (Interview with *Eve*, 2007)

The Toronto advocacy group *A Voice for Patients* did much of the work to organize the press conference and other aspects of the campaign to have the Ontario government cover the cost of Taxol® for the treatment of advanced breast cancer in 1994. The effort is still invoked today as an example of successful drug access advocacy. To advocates of rapid drug approvals the government reluctance to approve drugs like Taxol® is evidence of heartless bureaucrats and a financially driven system (Blatchford, 2011). *Virginia*, who was on the board of *A Voice for Patients* in 1994, recalls that group's perspective at the time was one of equity for patients suffering advanced cancer:

*Virginia*: We had a board member, a *lovely* woman, who had liver mets [metastasis] and she was on Taxol®. ... She had young children. It was really giving her a lease, not on -- there wasn't a belief that she was going to survive -- but there was certainly a quality of life that she was experiencing which we as survivors and non-survivors were incredibly impressed by; because in a sense, from my understanding, Taxol® kind of broke some barriers for women living with metastatic disease. It was easier to tolerate. I mean it wasn't a cakewalk, but ... generally speaking, for most women, Taxol® and then Taxotere®, are easier to tolerate. It was certainly easier to tolerate than Adriamycin®.

And this woman who was on our board had a friend who was also on Taxol® and she was a lecturer at York and she was able to go back to work. So these women were coming back and they were saying, "Man, this is incredible!" So this was like, "Whoa! This is amazing! Not only are these women living longer, they are actually able to live their lives!" So we then became *really* pissed off that only a certain number of women were able to get access to this drug because it was only being funded through certain [research] protocols.



And so ... we went to the provincial Parliament. And we had a question raised in the House, and it was, "Please, can this be looked at, blah blah blah." And eventually, the Taxol® bar was lifted. I'm not saying it was because of what we did. ... I was there when the question was raised and it was given pretty short shrift. But we did do a press conference.

*S.B.*: Yeah, you got a lot of press coverage as I recall.

*Virginia*: Yeah, yeah, we did. ....

- Interview with *Virginia*, 2008

According to *Eve*, a representative from Bristol-Myers Squibb did have a role in the campaign. A woman from Taxol's® manufacturer, Bristol-Myers Squibb, approached *Eve* and said she was working with the professor from York who thought Taxol® should be covered for breast cancer. At the time, *Eve* was in the process of writing an updated version of a handbook about breast cancer for patients she had co-authored with an oncologist who worked at her local cancer treatment centre. *Eve* recalls the woman from Bristol-Meyers Squibb saying to her, "You've been with the group *Peer Support and More*, you're now with *Support Groups throughout Ontario* Network, you're writing these books – you should know about this [case]." *Virginia*, however, doesn't recall meeting the woman from Bristol Myers Squibb: "So whether or not there was any backdoor engineering from pharma, I don't know. I really can't say that there was, it certainly didn't feel like it at the time, but I was much more innocent then. It was the very beginnings, in terms of our community as well."

To supplement these contradictory memory fragments, it is useful to examine parallel developments in the American breast cancer movement about the same time. American anthropologist Mary K. Anglin began an ethnographic study of the U.S. breast cancer movement in 1992; based on her research, she describes a series of meetings

between representatives from the breast cancer group *Norcal*<sup>205</sup> and Bristol-Myers Squibb (makers of Taxol®), Burroughs Wellcome (makers of Navelbene), and Genentech (makers of Herceptin®). The meetings, including a lavish dinner, became formative sites of knowledge for that group's understanding the ethics of pharma funding. The first of these meetings took place when Taxol® "was about to be released" (Anglin 2009:5)<sup>206</sup> and when the Clinton administration was attempting to undertake health care reform (i.e., 1993-4). The representative from Bristol-Myers Squibb (Taxol®'s manufacturer) told the group that drugs like Taxol® "would not be available in 'a Canadian model of health care'" (ibid:5). The activists concluded that, in buying them dinner, the company had "bought our silence" or at least the company's right to have first say in a discussion. Determined that activists should set the agenda of such meetings, they resolved to accept "no more meals". Subsequent meetings with Burroughs Wellcome and Genentech compounded the group's disillusionment about the possibility of breast cancer groups negotiating as equal partners with "big pharma."

*Eve* was not following treatment advances closely enough to have an opinion on Taxol® (which at the time was still used primarily for ovarian cancer) so she asked the oncologist with whom she was co-authoring the book what he intended to write about the drug in the updated version. He didn't want to mention it because the drug was not available in Canada and he had no experience using it with patients.

He said, "Don't raise expectations. It's not out there." And I said, "Well wait a minute. If they're using it in the U.S...." You know, this is the time of the whole Krever Inquiry [into the contamination of Canada's blood system] where ... the U.S. Red Cross had been screening for HIV/AIDS for almost a year before Canada started screening. And the Krever Inquiry statement was, "You can't ignore standard of care in another country." So I thought, "How can we say that we're going to apply this [principle] in screening for blood,

but we're not going to apply that to clinical practice?" So that really got me, I think it was a true disparity.

Andre Picard<sup>207</sup> and [McGill University bioethicist] Margaret Somerville were writing about the whole Krever Inquiry about then. So it looked to me like there were some quite powerful thinkers, some very reasoned people, who were coming up with what's turned out to be principles... basically saying that we, ethically, we can't afford to take the stand that we will ignore what happens in the United States, or France, or elsewhere because we can't afford it ... which was the basis for the Krever Inquiry. We didn't think we could afford to screen [blood for HIV/AIDS]. Well, it turned out we couldn't afford not to.<sup>208</sup>

And I think at the same time probably [the American groups] *Breast Cancer's National Voice* and *Here for You* and probably others in the United States -- those other breast cancer groups were looking at, and coming out with statements about, Taxol®. Because this represented a dramatic shift in the way we had been treating breast cancer previously. So this was a whole new gold standard for treatment. (Interview with *Eve*, 2007)

*Eve's* argument invoking the Krever inquiry<sup>209</sup> to establish an ethical principle bears unpacking. This is a new *problematization* of the issue of drug access, with a rhetorical *enrollment* of Justice Horace Krever, a prominent Canadian health journalist (Picard), a prominent medical ethicist (Somerville), and breast cancer groups in the United States. The argument is an early version of the discourse which later formed the basis for drug treatment lobbies by patients' organizations.

Reading Justice Krever's recommendations I would not interpret anything he says to imply that Canada is obliged to adopt a standard of care implemented in other countries; on the contrary, the recommendations explicitly state that Canada should make its own regulatory decisions about blood products.<sup>210</sup> In Recommendation 44, Justice Krever references the move to international harmonization and welcomes the potential benefits of such international collaborations as standardized formats for submitting

information, information-sharing with respect to product reviews, and inspections based on good manufacturing practices. He then adds this caveat:

The Bureau of Biologics and Radiopharmaceuticals must, however, retain the authority to make the licensing decisions for Canada. It must also retain the authority and the ability to conduct its own inspections and lot-by-lot reviews of biological drugs, particularly blood products. (Krever 1997: 1071)

Krever's report, in fact, stresses the need for regulatory safety above all.

Recommendation 2e states: "The goal of the blood supply system must be to supply safe therapies to persons who need them. The principle of safety must transcend other principles and policies" (ibid: 1048). In his emphasis on safety, Justice Krever places the blood supply service firmly within the purview of the public health system – an area of medicine concerned with disease prevention and the maintenance of good health rather than disease treatment. Public health has different historical and philosophical roots than the medical treatment of disease and the principles of one do not readily transpose to the other. Thus, the Krever Report states (Recommendation 2e):

The safety of the blood supply is an aspect of public health, and, therefore, the blood supply system must be governed by the public health philosophy, which rejects the view that complete knowledge of a potential health hazard is a prerequisite for action.

The balancing of the risks and benefits of taking action should be dependent not only on the likelihood of the risk materializing but also on the severity of the effect if the risk does materialize, on the number of persons who could be affected, and on the ease of implementing protective or preventive measures. The more severe the potential effect, the lower the threshold should be for taking action. (Krever 1996: 1049)

In other words, although a blood transfusion is itself a medical procedure, maintaining a secure blood supply is comparable to maintaining a safe water supply; it is not analogous to deciding on whether or not to adopt a new drug into practice. The logic

of *Eve's* analogy, which compares the urgency of adopting new practices to improve safety in the blood system, even when all the scientific facts are not known, can't simply be transposed to the adoption of new medications. An analysis that conflates public health ethics with treatment ethics blurs an important boundary; indeed, many of those who opposed using tamoxifen as a preventive drug made this same distinction. Using a drug to prevent cancer involves intervening with large numbers of healthy people who might never become sick and is thus a public health measure analogous to a vaccination. For this reason, as Fugh-Berman argued (1991), the standard of safety needs to be higher than it would be if the same drug is used as a treatment. A woman given tamoxifen to treat cancer is known to be at risk of dying of the cancer and this risk is weighed against the risks of the treatment itself, which allows a greater tolerance for harm.<sup>211</sup>

#### 5.2.6 Second Translation: *Together to an End*

During the lead-up to the launch, *Eve* left *Helping Hand* following a disagreement with the board. She began to work as a consultant on a variety of breast cancer projects, including a breast cancer conference titled *Together to an End*, held in Orillia, Ontario in November 1996. The latter meeting, which was billed in the conference report as “the first venue of its kind since the 1993 Health Canada sponsored National Forum on Breast Cancer,” included many of the same individuals and organizations who had attended the meeting in Montreal, as well as new groups that had sprung up since, although the meeting was much smaller than the Forum, with about 100 participants (Kelly, Condy and Harder, 1997).<sup>212</sup> Sponsorship, too, was markedly different. Health Canada, which had been the main organizer and funder of the National Forum,<sup>213</sup> made only a minor

contribution, supporting delegates from vulnerable populations. Funding came primarily from the pharmaceutical industry, including (most prominently) Bristol-Myers Squibb, Zeneca Pharma, Eli Lilly and Company, Rhone-Poulenc Rorer of Canada,<sup>214</sup> and (given lesser billing) Amgen Canada, Biomira Inc, Glaxo Wellcome Inc, Pharmacia & Upjohn Inc, and the Pharmaceutical Manufacturers' Association of Canada.

*Together to an End* marked a shift in the discourse between Canadian breast cancer groups and the pharmaceutical industry. In my periodization analysis, it was the transitional moment between Periods One and Two. Rather than presenting a pre-set program, the conference used Open Space Technology a conference approach in which participants at a meeting set the agenda by posting topics they want to discuss and seeing who shows up (Owen 1995). The Final Report of the conference lists 25 issues that arose from this process and summarizes the discussion at each. Of particular interest to my analysis were four sessions that introduced counter-discourses to the prevailing discourses on advocacy, pharma funding of groups and breast cancer drug treatments. In Actor-Network terms, the four sessions *re-problematized* three major issues confronting breast cancer groups. In each case, the new discourse reconfigured the actor-network and set the stage for subsequent acts of *interessement*, *enrolment* and *recruitment*.

Two sessions which discussed the formation of a national advocacy organization (the stated, central purpose of the conference)<sup>215</sup> challenged the ability of *The Hub*, the government-funded group that had emerged from the National Forum on Breast Cancer as “the voice for breast cancer patients,” to be an effective advocacy organization. Arguing from the premise that the breast cancer community needed an organization that would devote one hundred per cent of its efforts to advocacy, two claims were made to

discredit *The Hub*'s legitimacy in this regard. First, with a mandate that included communication, support and information, the organization clearly had other demands on its resources; and second, as a registered charitable organization, the group could only, by law, devote 10 per cent of its activity to advocacy (Kelly, Condy and Harder, 1997: 54-57).<sup>216</sup> Summary notes in the published conference report acknowledged that the discussion in both these sessions had involved contestation among participants (members of *The Hub* attended the sessions and defended the group's legitimacy and its ability to advocate for the community). At the second of the two sessions, the summary report noted a concern expressed that an obvious tension reflected philosophical divisions within the community so that people felt they were "walking on eggshells." "Speaking with one voice" became difficult, if not impossible. According to one reported comment, the division was seen as especially problematic for advocacy, because "AS SOON AS THE VOICE IS DIVIDED, GOVERNMENTS, DECISION-MAKING ORGANIZATIONS "GET AWAY WITH MURDER." (capitals in original) (ibid:56).

One faction at this session thus *re-problematized* the question of advocacy, arguing that the breast cancer community needed an advocacy organization separate from *The Hub* (to which *The Hub* could belong). This group would *not* be structured as a charitable organization and it would *not* undertake the service work of education and support which was part of *The Hub*'s mandate. The reasoning was based on the claim that groups with government-funding could have their advocacy mission compromised – they could be silenced -- because "[a] breast cancer advocacy group will need to challenge government" (ibid: 57). Implicitly, this discourse separated the community into two sectors: the service-oriented groups, which could apply for government funds and solicit

charitable donations, and an advocacy coalition which -- like the Advocacy Conference itself -- might be more appropriately funded by the pharmaceutical industry. The logic of the discourse criticizing *The Hub* laid the groundwork for a group that emerged a few years later that was funded entirely by the pharmaceutical industry (“*All-Cancer Advocacy*,”). Furthermore, governments, rather than industry, were framed as the central problem underlying cancer policy and thus key targets for advocacy. From this logic it followed that the main conflict of interest for breast cancer groups lay in funding from government, not funding from industry.

At these two sessions, then, a process of *interessement* has taken place in which the alliance between patient groups and government public health and regulatory agencies is replaced with a patient group/pharma alliance. *The Hub* and its members are cut off from legitimate advocacy and the government public health and regulatory agencies are targets of patient group advocacy rather than an ally of the groups (Figure 9).

A third session of interest at the conference, titled “Guidelines for corporate/industry working w/breast cancer groups” recommended the formation of a patient-driven consumer information service that was staffed by credible, independent experts (the B.C. Therapeutics Initiative, the Cochrane Collaboration, and Ralph Nader were examples given). The session notes make four additional points concerning the relationships between the pharmaceutical industry and consumer-driven health groups:

- That industry wants good relationships with such groups;
- That current guidelines for collaboration are implicit and are being operationalized, but are not systemic;
- That health groups want “timely access to the most appropriate treatments/care”; and



- That “health groups can work with industry to create appropriate information/ educational materials.”

It was decided that PMAC would convene a meeting to determine the future of guidelines and that the (yet to be created) National Coalition would “develop a position statement on working with industry” (Kelly, P., C. Condy and S. Harder, 1997:66). Thus, a model for assembling and disseminating knowledge about breast cancer therapeutics was proposed which would involve independent experts, consumer-driven groups, and industry -- each playing interrelated roles which were yet to be defined. This process of role definition (*enrollment*) would, according to the notes of the conference session, take place at a meeting to be convened by the Pharmaceutical Manufacturers’ Association of Canada (i.e., PMAC, the industry lobby organization).

This proposal embodies several incongruities: technology assessment bodies like the Therapeutics Initiative at the University of British Columbia<sup>217</sup> and the organizations under Ralph Nader’s umbrella are science-driven, not consumer-driven; furthermore, they define their independence in terms of strict separation from the industries whose products and services they are set up to evaluate as well as from government (Public Citizen website, 2011; Therapeutics Initiative website, 2011). The proposal is thus an inverse construction of the models it purports to emulate. (Imagine a meeting convened and funded by the Automobile Manufacturers’ Association giving rise to *Unsafe at Any Speed*, Ralph Nader’s iconic book savaging the American automobile industry for ignoring known scientific principles in order to save costs in building their cars.<sup>218</sup>)

The third step in the *translation* took place in a session that *re-problematized* the issue of breast cancer survival. An oncologist, William Hryniuk (one of the cancer researchers who had testified at the Parliamentary hearings), convened a session titled,

“How can we reduce breast cancer mortality in the next ten years?” at which he presented evidence to demonstrate that Canada lagged behind California in its breast cancer mortality rates. As outlined in the conference summary of this session, he argued that the reason for this was that patients in California received more aggressive adjuvant chemotherapy, including high-dose chemotherapy with stem cell rescue. Furthermore, he stated, mortality rates among provinces in Canada were striking, with British Columbia showing the best rates of survival. These disparities, he said, were likely the result of inter-provincial differences in the uptake of new treatments. The summary goes on to suggest that “the superior performance of a commercialized approach providing health as a commodity” in the United States over Canada’s “government-run, universal health care system” might reflect a paradoxical difference in the rights of patients. In the U.S., patients “are protected by intervention by the courts and legislatures”; in Canada, the insurer is the Health Ministry and “cannot be sued, and is the direct agent of the legislature (a conflict of interest).” The provincial cancer agencies are caught between two masters, the patients they are supposed to serve and the provincial Health Ministry that directly finances them. “In the end, the patient is left with no forum for redress of her complaints” (ibid: 69-70).

The logic of this *problematization* upends a number of assumptions in the discourse of feminist health advocates, consumer protection advocates, and public health professionals: it framed under-treatment and lack of access to new drugs as the necessary focus of consumer advocacy problem, not overtreatment and toxic side-effect of drugs; it framed consumer rights in terms of access to “life-saving treatments” rather than to safe, affordable medications; it framed private health delivery as more able to deliver access to

new drugs -- and therefore more just --than a single-payer system; and it reframed the actors in need of a vigilant watchdog group as the regulatory agencies that limit corporate power (not the pharmaceutical industry, or government agencies that bend to corporate interests). Government agencies that denied patients' access to new drugs became the logical target of lawsuits to protect consumer's rights.

To improve the mortality statistics of breast cancer patients in Canada, the session recommended creation of "a national volunteer coalition to continuously lobby the Provincial and Federal governments for improvements in outcomes ...; such a coalition could be vigilant to ensure that the needed life saving treatments would be continuously available in the future..." (ibid:70). As in the two sessions on advocacy, a process of *interessement* takes place in which the alliance between patient groups and government public health and regulatory agencies, feminist health groups and consumer rights groups are replaced with a patient group/pharma alliance (see Figure 9). Government public health and regulatory agencies are reinforced as targets of group advocacy rather than an ally of the groups and the advocacy role of *the Hub* and its members is delegitimized.

In the years that follow, these interlocking themes resurface in the discourse of actors who argue in favour of industry funding as a source of revenue for patient groups: the need to separate the patient group community into *service groups* (largely funded by governments and tax-supported donations) and *advocacy groups* (possibly pharma - funded); the need for patients' groups to speak with one voice that targets government regulators (not pharma); and the need to provide patients with faster, easier access to new therapies in order to improve survival.

### 5.2.7 Intersections: Activist Groups and Other Worlds

The early-to mid 1990s were a period of rapid change in the three social worlds outlined in Chapter 4 (single-payer health care, pharmaceutical policy and civil society advocacy organizations): Canada's single-payer health care system came under increasing strain as the federal government struggled to bring its deficit under control while coping with rising medical costs; Canada abandoned compulsory licensing and curtailed the generic drug industry in return for an industry promise of more research and development spending by the brand-name pharmaceutical companies, and took steps to reduce drug review times. The new anti-cancer agents that began to emerge from the pipelines of pharmaceutical and biotech companies carried with them price tags previously unseen; and governments at all levels continued to cut funding to civil society groups, particularly those engaged in advocacy. Each of these shifts had implications for the growing community of breast cancer organizations.

*NAFTA and the End of Compulsory Licensing in Canada.* Despite the 1987 legislation to delay compulsory licensing by seven years, the American pharmaceutical industry remained concerned that compulsory licensing would set a precedent -- indeed, the Canadian experiment had attracted attention in Europe (Torremans 1996). Furthermore, by 1992 Canada had become one of the US industry's largest markets for pharmaceuticals, with imports of U.S. \$845 million (Carter 1999). Apart from direct pressure from industry, the U.S. government was eager to increase protection for the exports of the growing American biotechnology industry (McMahon, 1996-97). Negotiations for the North American Free Trade Agreement (NAFTA) were under way, broadening the FTA to include Mexico. The Canadian government, still under the

Mulroney Conservatives, anticipated that the terms of NAFTA would force it to abandon compulsory licensing and in 1993 acted in advance;<sup>219</sup> The government passed Bill C-91, bringing into law the Patent Act Amendment Act, which eliminated compulsory licensing for pharmaceutical products altogether and extended patent protection of brand name drugs to at least 20 years. The bill also retroactively voided all compulsory licenses obtained after Dec 20, 1991 (Cohen, 2003-4).

In a further move to appease the industry, in 1993 Canada added a new regulation to the Patented Medicines (Notice of Compliance or NOC) Regulations under the Patent Act, which prohibited Health Canada from approving a generic drug until after the courts had ruled on any claim of alleged patent infringement (Cohen:2003-4).<sup>220</sup> In return for these concessions, the industry promised to invest at least \$400 million or ten per cent of its Canadian sales in research and development by the end of 1996 (Cohen, 2003-4).<sup>221</sup> To maintain some control over prices, Bill C-91 also increased the power of the Patent Medicines Prices Review Board, giving it the authority to order reductions in prices deemed excessive, to impose penalties to recoup excess revenues, and even to take away the company's market exclusivity (Smith, 2000; Carter, 1999:246).<sup>222</sup>

*Canada's Health Care System and the Free-market Discourse.* The free trade agreements opened the door for private American management firms to take over public health care services in Canada, including hospitals, although the Canada Health Act's requirement for public administration provided a disincentive for such purchases (Fuller 1993, cited in Armstrong et al 1994). Health policy analysts Pat and Hugh Armstrong, along with other health policy analysts who are strong advocates of a publicly funded system, contend that the agreements themselves were a less important influence on the

health care system than the shift in the public discourse about health care that was part of the FTA-NAFTA era (Armstrong et al, 1994). Advocates of the free-market principles that the agreements encoded replaced a discourse of shared responsibility and public interest with a discourse that reframed health care as a business rather than a public service. Thus, the Conservative government of the period claimed that the national debt and the fragile economy were the result of Canadians living beyond their means, including alleged misuse of the health care system. The solution offered was a transfer of responsibilities from the public sector to the “efficiencies” of the private sphere and greater individual effort on the part of citizens. The valorization of small government, privatized services and competitive, market-driven economies echoed the rhetoric of international treaties as well as the World Bank and the International Monetary Fund (Armstrong et al, 1994).

When the Liberals regained power federally in 1993, they maintained the neoliberal agenda the Conservatives had put in place. Continuing Armstrong et al.’s 1994 analysis: because the public remained committed to the healthcare system, the government used the stealth tactic of cutting back transfer payments to undermine the services; meanwhile, news stories about hospital deficits and opinion pieces in the mainstream, largely conservative media reinforced the assumption that managers of health care institutions should adopt a business model, even though the single-payer system has repeatedly been shown to be more economical than a privatized system. As hospitals struggled to cope with cuts to their budgets, patients were sent home sooner to be cared for by unpaid family members, casual employees were used to supplement fulltime, unionized staff in nursing, cleaning and food services, and traditional ideals of

volunteerism were invoked to shift the burden of support, care and fundraising onto community organizations, businesses, families and individuals. The tactic of blaming the public for “misusing” the system drew attention from the real inefficiencies of the hospital-based, curative approach to health; yet the flaws in the free-market argument also encouraged resistance from many actors within the system (Armstrong et al, 1994:31-51).

Examining the breast cancer movement against the backdrop of this analysis, two cultures of action with respect to treatment advocacy emerge – one promotes disease prevention based on public health principles<sup>223</sup> and resists the privatization of the health system; a second subset of groups promotes free-market values, women as volunteer caregivers, and a curative model of health, via a privatized system and more spending on drugs to “cure” breast cancer.

*Reinventing Drug Regulation in the Service of Lean and Nimble Governance.*

Within the federal government, one example of the embrace of the free-market ideology was the Regulatory Efficiency Act. The Liberal government introduced Bill C-62 in 1994 to “modernize” and “streamline” the bureaucracy under the rationale of controlling the federal budget (Carter 1999:249-50).<sup>224</sup> The proposed legislation proved controversial and died on the order paper. The debate it provoked illustrates the discursive divide over this shift within competing social worlds. One of the lawyers who worked on drafting the bill described its purpose as simply procedural, “designed to improve the way in which Canada regulates risk” (Weiler, 1995). The proposed law would allow a corporation or industry group to circumvent strict compliance with regulations by applying to the regulator for an exemption that substituted a “compliance plan.” The latter would have to

meet the intention of the regulations, while speeding approval or reducing investment uncertainty. The regulating agency would review the plan and could accept it in place of existing regulations, perhaps charging a cost recovery fee.

Critics were scathing in their ridicule. The Executive Director of the environmental group Pollution Probe called the proposed law “bafflegab,” claiming the word “efficiency” was used as a cover for “special treatment for the few who enjoy access to the corridors of power” and to conceal “Ottawa’s loss of will to protect ordinary Canadians” (Pannell 1995). In an article headlined “A repugnant assault on the rule of law” *Globe and Mail* columnist Michael Valpy said the bill “would permit the federal government to exempt businesses and individuals from regulations... [and] would allow them to obtain the privilege of not being bound by the law that applies to everyone else ...” (Valpy, 1995).

*Expert Advisory Committees and Cost Recovery at the Therapeutic Products Directorate.* Despite Bill C-62’s failure to pass, changes to the drug regulatory system adopted aspects of the bill. In 1992, as a strategy for speeding drug approvals, Canada introduced the use of Expert Advisory Committees (i.e., contract reviewers) to conduct the first review of New Drug Submissions (Carter 1999).<sup>225</sup> Critics argued that outside reviewers had only one or two days of training and were poorly supervised, or they were consultants who both conducted tests and prepared submissions for industry and thus had conflicts of interest (Regush, 1993). In 1995, the Therapeutic Products Directorate adopted another controversial program, cost recovery, following a trend within federal government departments to charge user fees for its services. Costs to the pharmaceutical industry were expected to reach \$40 million per year (McMahon 1996); this raised fears



that pharmaceutical companies could pressure the government to reciprocate with faster approval times which could in turn compromise safety -- a charge that the HPB “vehemently denied” (Carter 1999).<sup>226</sup>

An additional policy shift of note during this period concerned the status and definition of advocacy by civil society groups. As mentioned, under Canada’s welfare state community-based groups had been eligible for government grants as a means of ensuring that minority voices on policy issued were heard – a policy that contributed to the growth of women’s health and consumer rights organizations through the 1970s and 1980s (Elson, 2009). Many groups in the non-profit civil society sector also depend for fundraising on their eligibility for charitable status, a designation from Revenue Canada that gives an organization the right to issue tax receipts for donations. As far back as 1978 the federal government began to rein in the political activities of registered charities, even to the point of forbidding groups to write letters to the editor; and since then, Revenue Canada has continued to tighten restrictions on advocacy so that “any act intended to influence government policy directly or indirectly (by affecting public opinion) is considered political” (Elson 2009: 59). In the early 1990s, (then) Liberal MP John Bryden<sup>227</sup> argued in a 1996 report, *Canada’s Charities: a Need for Reform*, that Canada’s registered charities included “many narrowly-aimed lobbying organizations [that] have obtained charitable status simply by stating as their avowed purpose that they are informing the public.” Among his recommendations was that “Revenue Canada should revoke the charitable status of those organizations that obviously exist primarily to lobby the government or the public” (Bryden 1996). In early 1996, Revenue Canada

made administrative changes to the reporting requirements for groups with charitable status, including stricter monitoring for compliance (Bryden 1996).

Claims that groups designated “charitable” and “non-profit” should be more accountable to the public were not without merit.<sup>228</sup> Many civil society groups, however, felt the call for greater scrutiny allowed governments to shut down legitimate criticism, including criticism of the policy shift to privatization; at the same time, governments were transferring the responsibility for providing services from paid employees to organizations that relied largely on volunteers.<sup>229</sup> The result, in the words of one recent analysis, is “a tethered advocacy regime which acts as a de facto muzzle on legal dissent and social justice issues” (Elson, 2009: 60) at the same time that the advocacy or “expressive” function of non-profit groups is cut off from the “service” function in a way that marginalizes smaller organizations with social justice mandates and favours the priorities of larger organizations:

The service-expressive divide within the voluntary sector has serious implications for the voluntary sector as a whole. ... The consequence of this trend is that, in the absence of a voluntary sector that clearly defines itself as an integration of both instrumental and expressive activities, governments continue to define the legitimacy of the voluntary sector in terms of its capacity to deliver services. (Elson, 2009: 60-61)

The redefinition of advocacy affected breast cancer groups in several ways. Part of the neoliberal project is to downsize government and one way to accomplish this was to have voluntary organizations take on the services that governments had previously provided so the newly-formed breast cancer organizations were thus viewed by government as potential cheap service providers. “Consultation” via committee participation became simply another unpaid service while groups providing a voice for underrepresented groups, or acting as a counterweight to powerful industry interests were

seen as “special interests” and expected to raise their own funds from supporters and private sources.<sup>230</sup> In this policy environment, a discourse that redefined *The Hub*’s role as service provision was consistent with neo-liberal government objectives; similarly, the formation of new cancer advocacy groups funded by the pharmaceutical industry was in harmony with policy goals that delinked advocacy from the public interest and aligned the voices of cancer patients with market principles.

### **5.3 1997-2001: THE CONTESTATION PERIOD**

#### **5.3.1 Introduction**

In the second period (1997-2001) breast cancer groups and industry actors staked out two opposing positions on the question of pharma funding and contestation between them. Debates that, in the previous period, took place informally and within the confines of conferences and board meetings are formalized and moved into public fora as prescriptive documents. These competing *problematizations* take shape against a backdrop of continued activity in the reshaping of government health care and pharmaceutical policies, and the redefinition of civil society advocacy. I begin with an overview of these macro-level changes. I then discuss the actions taken by health groups opposed to pharmaceutical company funding, in particular a public panel discussion and the publication of several documents arguing the potential pitfalls of breast cancer and other health related groups turning to the pharmaceutical industry. Next, I discuss a series of documents produced by the pharmaceutical industry, which also began to produce its own prescriptive materials, explaining the benefits of forming partnerships with patients’

groups and providing the corporate world of pharma with success stories, ethical guidelines and roadmaps to “best practices” (Table 6).

I illustrate these prescriptive statements with examples from actual practice, by discussing a series of contestations within breast cancer groups, each featuring a particular company alliance and breast cancer treatment. These examples show how the debate over pharma funding of groups became entwined with longstanding debates about drug policies and the ethics of drug promotion (Mintzes 1998, Gilbert 1999, Johnson 2000, Mills 2000) as patients’ organizations actively engaged in debates over pharmaceutical treatments, including approval times, benefits, side-effects and costs. As new, more expensive treatments entered the market, treating breast cancer became a serious cost issue for provincial governments, in part because of unprecedented costs of new drugs (Sibbald 1999) but also because the number of patients was so large (Will et al 2000). Patients’ groups were most often advocates for more rapid and expanded access (Anonymous 2000a, Anonymous 2000b), but sometimes took a critical stance, pointing to incomplete and biased information that patients received from their physicians about treatments (Radcliffe 1999), the neglect of environmental contamination as a contributing cause of cancer (Melamed 2000), and the pressures that the ever-rising prices placed on the treatment system (Batt 1999). I discuss two organizations that delineated certain types of corporations from which they would not accept funds and at the same time actively opposed the trend towards corporate partnerships within the breast cancer movements in Canada and the US. I then describe three case examples of Canadian breast cancer organizations that entered into formalized partnerships with the pharmaceutical industry. In two cases the decision to do so met with internal contestation; in the third

group, members found pharmaceutical company partnerships unproblematic, both in theory and practice.

### 5.3.2 Government and Policy Actors

Throughout the latter part of the 1990s, international trade agreements continued to reshape national policies in Canada, including the regulation of pharmaceuticals. In 1998 the federal government reviewed and decided to renew the 1993 law that had abolished compulsory licensing and set up the Patent Medicines Review Board (Cohen 2004, Carter 1999). Broad-based concerns about the health care system prompted the establishment of two large inquiries: a Royal Commission headed by former Saskatchewan premier Roy Romanow (Romanow 2001) and a Senate inquiry led by Senator Michael Kirby (Kirby and LeBreton 2002). Pharmaceutical policy was a dominant theme in both reports, in part because drug costs were among the fastest-rising costs in health care, but also because pharmaceutical policy in Canada is a patchwork that lacks the coherence of health care policy in general (Sketris, Bowles and Manuel 2004). A complicating factor was the pressure on Canada to align its pharmaceutical policies with standards set by the International Conference on Harmonization (ICH), a regulatory unit formed in 1990 by the pharmaceutical industries and governments in the United States, the European Union and Japan, to provide a transnational regulatory framework for drug approvals and post-market reporting of adverse reactions. The ostensible purpose of the ICH is to serve the public by freeing up new funds for drug development and by making drugs available to patients more quickly; some pharmaceutical policy analysts dispute this claim, however, arguing that safety standards have been compromised and a

more likely motive is to maintain the industry's competitive position in the marketplace (Abraham, 2004, Lexchin 2008; 2011).

Throughout the period 1996-2001 the federal government under the Liberal Party leadership of Jean Chrétien continued the move begun under the Conservative regime of Prime Brian Mulroney, away from the welfare state and towards a trade-based, neoliberal model. Social and political analyses of the reconfigured Canadian state suggest the directions in which the growing patient group movement would groups evolve in the 1997-2001 period. Finance Minister Paul Martin had included a promise to review the federal government's policies on interest groups in his 1994 budget and the following year he announced that "[o]ur approach to interest group funding will change" with some groups moving to a matching funds policy, and some losing core funding altogether (Pross 2006:10). The result was that, by the end of the 1990s, the ability of public interest groups to participate in policy debate was severely restricted (Pross 2006:10-11).<sup>231</sup> Following the drastic budget cuts to social programs in 1996 and as the economy improved, the Canadian government began to borrow discourses and policies from Tony Blair's Labour Party government in the UK, including Blair's model of the "Social Investment State" (SIS) (Dobrowolski 2004). Under an SIS regime, state spending is acceptable when programs have perceived pay-back potential for the future. Policy areas in which the Chrétien government saw this potential for future return included investments in technology and innovation for health care and the environment.<sup>232</sup> Thus, under this policy regime, groups that raise money for research into new health care technologies, or that promote the use of these technologies once developed, might well

merit government spending, where as critics of these priorities and products could be seen as impediments to economic growth.

The Chrétien government did recognize that its relationship with the non-profit sector was badly damaged by earlier cuts and took steps to reconfigure it. A five-year, \$90 million Voluntary Sector Initiative (VSI) extended the concept of public-private policymaking and service delivery “partnerships” beyond business to the voluntary sector, but favoured organizations that posed no challenge the state. The state’s role in these partnerships is negotiated and directed, described as a “steering, not rowing” (Dobrowolski 2004). The VSI’s five-year process of government dialogue with the voluntary sector culminated in the Voluntary Sector Accord, signed in 2001. The Accord was adapted from a novel policy instrument developed by New Labour in the UK to facilitate constructive relationships between the government and non-profit groups (Brock 2003a, Phillips 2003a). The Canadian accord is much more ambivalent than its UK counterpart, however. The Department of Finance took a cautious approach which contributed to the Accord’s failure to address two key issues: the right of groups to engage in advocacy, and their claim to legitimately receive tax-funded grants (Phillips 2003b). These government programs redefined the concept of advocacy to mean evidence-based policy consultations with the state (Laforest 2004); at the same time, confrontational tactics that made claims on the state were delegitimized. “Toolkits” and funding programs encouraged the voluntary sector to develop management skills and build capacity in the areas of policy research and evidence-based expertise which the government needed. Actors that adopted this mainstream, professionalized model of advocacy were invited to collaborate in policy development and were sometimes held up

as models for other voluntary organizations to follow. By comparison, organizations that used mobilization tactics and media campaigns were not funded or included in consultations, thus encouraging other groups to adopt conservative, non-conflictual strategies. Furthermore, a series of seemingly unrelated federal regulations all acted to constrain advocacy (Pross and Webb 2003). Examining Canada's SIS state program through a feminist lens, Dobrowolski concludes that, "Realistically, the women's movement has been diminished by the neo-liberal cuts. Now the social investment state's focus on service delivery also puts the squeeze on women's groups" (Dobrowolski, 2004: 191). Thus, social-investment-state federal government programs were tailored to starve out the more activist residue of the women's movement and encourage those groups engaged in service delivery. Funding programs favoured groups that were uncritical of government policies and those whose members volunteered time to provide education and support -- service work which, in the welfare state, had been performed largely by paid professionals.

The new-labour concept of government "steering" the non-profit groups involved in cancer to donate their time to developing policies in a non-conflictual and economy-promoting way is an apt description not only of the reshaping of the breast cancer movement but of a major new initiative introduced in this section which I refer to as *Canada's Cancer Plan*. Within the cancer community a broad cross-section of actors began groundwork in 1999 to develop a comprehensive Canadian plan to control cancer. The *Plan* had support from Health Canada and included representatives from cancer patient groups; the pharmaceutical industry did not participate in this initial phase of development, however.<sup>233</sup> The goal was to develop a nation-wide, coordinated,



comprehensive master plan to improve the way all cancers were handled at all stages, from prevention to palliative care. The *Plan* would thus develop a systematic, comprehensive approach for cancer policies within the government but also in provincial screening programs, public education about cancer, treatment protocols and community supports. With respect to breast cancer, because the *Plan* brought all cancers under a single policy development umbrella, it would both build on and, in time, supplant the Canadian Breast Cancer Initiative, which had provided federal funding to some breast cancer groups.

### 5.3.3 Pharma Funding “Refusers” Go Public

In May 1997, a Toronto-based, federally-funded women’s health organization sponsored a panel discussion in which four people were invited to share their views on “Ethical Issues in Women’s Health: the Delicate Business of Funding from Drug Companies.” The event marked a turning point because it brought the issue out of the inner sanctum of group meetings and aired it publicly before an audience of about sixty people. Three of the speakers, health activist Barbara Mintzes, physician Joel Lexchin, and Harriet Simand of *DES Action Canada* opposed groups taking funds from pharmaceutical companies; the fourth, Darien Taylor of the HIV/AIDS group *Voices of Positive Women*, argued that the particular characteristics of AIDS differentiated members of her organization from those in feminist health organizations who did not take funding from the pharmaceutical industry. She explained that HIV/AIDS activists had worked closely with the pharmaceutical industry to promote research into new drugs and to ensure that women volunteered for clinical trials, while at the same time exerting

pressure on the companies to make still-experimental drugs available to them. The members of *Voices of Positive Women* had a different perspective from feminist health activists, she said, because they knew their disease was fatal and they depended on drugs for their survival. In addition, she said, the personal situation of the HIV-positive women was often dire; they were “marginalized, stigmatized, isolated, poor, suffering physically and emotionally” (Baraldi 1997). *Voices of Positive Women* could not afford to support all these needs without financial help, and the industry was willing to give it.<sup>234</sup>

Recalling that the analysis of drugs and women that feminist groups developed in the 1970s and 1980s had been based almost exclusively on the experiences of healthy women, the inclusion of Darien Taylor’s perspective can be seen as a step towards broadening the feminist perspective to include that of women with life-threatening illnesses.

Anne Rochon Ford, the executive director of the sponsoring organization, explained her reasoning in organizing a formal discussion with this particular roster of participants.

I had been hearing over and over and over the same phrases continue to come up in talking about [pharma funding]. And often things would just not go very far in terms of talking them through and figuring out all that was behind [the differences]. And so the hope for that evening was to try and get a little bit more nuance to the discussion and not have it just be a “You’re wrong, I’m right,” kind of focus.

Which [is what] things often end up being in organizations where you don’t have a lot of time and your board only meets monthly and you’ve got to make hard decisions under pressure because, “This company wants to give us money and if we don’t take it by next week, ‘There it goes, we’ve lost it.’” So the hope was that [the event] would pull out some of the key points in the debate and try to really get them out there. And I knew that by having Darien [Taylor] on the panel that she was a perfect sort of defender. Because she’d

really thought a lot about it and [her position] wasn't just knee-jerk.  
(Interview with Anne Rochon Ford, 2007)<sup>235</sup>

The other three speakers emphasized the need for extreme vigilance in dealing with an industry that actively strives to shape the way the public and physicians think about health. In doing so, they argued, the industry often misrepresents the potential benefits of their products to encourage a dependence on marketable technologies (as with the promise that hormonal pills enable women to “stay young”). All four speakers agreed that a mechanism was needed to distance the groups from an industry funder and they offered two proposals: a central, neutral body that would collect money from the pharmaceutical industry and distribute the funds among community-based health groups according to fair criteria and with the identity of donor companies kept anonymous; or a compulsory tax on drug company profits used to create a fund that distributed monies back into the community (Baraldi, 1997). Either mechanism would have to ensure that groups critical of the industry were not left to fend for themselves and, ideally such a structure would reduce the likelihood of other groups absorbing and disseminating a biased understanding about drugs.

Both these proposals for structural change drew from the same underlying assumption: that the public needs constant reminders -- to borrow Emily Martin's analysis (Martin 2006) -- that the pharmacopoeia's collective personality inherently embodies a duality of remedy/poison which the pharmaceutical industry and patients alike are reluctant to acknowledge; yet both moral and health imperatives demand that the poison side be confronted. In an account of the panel discussion in the *DES Action Canada* newsletter, DES Action member Rosanna Baraldi reminded readers that Eli Lilly

had yet to compensate the DES daughters and sons who were harmed by the drug prescribed in Canada to their mothers:

If the drug companies are serious about their role as good corporate citizens, then you would expect them to redress situations of marketed drugs that turned out to be harmful, rather than only providing token funding to groups which will not be critical of the industry (Baraldi 1997: no page).

After the panel discussion, Anne Rochon Ford decided to move the discussion still further into the public sphere, using the debate as the basis of a booklet directed to women's health groups. *A Different Prescription: Considerations for women's health groups contemplating funding from the pharmaceutical industry* (Rochon Ford 1998) put the commonly-heard arguments for and against taking pharmaceutical funding in a critical framework (see Table 7). Rochon Ford believes the publication filled a void:

Anne: We had a pretty good turnout [at the panel] and I could tell by the enthusiasm of the people in the audience that this is something that was really needed, that people wanted to understand. Because ... on a completely superficial level, to most people it looks like, "Well, why wouldn't you?" "Why wouldn't you take the money" right? And it isn't until you start to really unpack it, which was what I tried to do in the way I did the booklet. [I would] have the pat phrase that we keep hearing over and over again, and then have the argument against it. And after the booklet was produced and we got it out there I got a lot of thanks.

Sharon: Really?

Anne: Oh, more than anything I've written. People sent e-mails and notes and stuff to me saying, "This is exactly what we needed." Or, "We had a board meeting last night. I was the only person arguing this and I lost, but boy, I sure appreciated your [booklet]..." -- that kind of thing. ...So I think it's good that there's that tool out there. (Interview with Anne Rochon Ford, 2007).

Panel member Barbara Mintzes moved the discussion to an international audience the same year in a booklet written for Health Action International. *Blurring the Boundaries: New Trends in Drug Promotion* discussed the pharmaceutical industry's covert use of promotional strategies, including the sponsorship of patients' groups. Although much of her research was Europe-based, the section on patient groups drew examples from Canada. Mintzes found evidence that drug companies sponsor patient groups selectively and as part of a carefully thought-through product-promotion strategy. As an example, she described Glaxo Canada's launch of Imitrex (sumatripan), a new treatment for migraine. John Martens, a pharmacist responsible for patient education in British Columbia at Glaxo told Mintzes that the company found a patient group which had been dormant and began giving it substantial grants and holding public meetings in the group's name, although the meetings were actually organized by Glaxo as part of a pre-launch promotional campaign. Eventually the organization objected to the company's heavy-handed involvement at which point Glaxo simply found another organization to fund.

“What companies would do and I was actually part of the process, is create a demand for a product before it was actually released,” states Martens. “We went around to various communities and organized public health education seminars on migraines and that topic was really popular... seminars that we actually charged five dollars for, another marketing tactic that makes the patient think that this thing isn't being funded by a major pharmaceutical company. We held these seminars right across Canada.”

With global sales of US\$ 600 million for sumatripan in 1995, the financial rewards of intense promotion to “carve a niche in the migraine market” for this product were considerable. (Mintzes 1998)

Mintzes explained in an interview that when she began her research for *Blurring the Boundaries*, she came across press reports and reports in the pharmaceutical

marketing literature, about organizations that had been started by pharmaceutical companies as part of a marketing campaign. This augmented her concerns, based on her knowledge of patients' groups that had been funded by the pharmaceutical industry in the 1980s:

Certainly the first examples that I saw, the type of information that came out of fertility and menopause groups, they were problematic. It was very clear that the information that they were providing to people that were affected, to women that were looking for help and trying to figure out what to do with their situation -- certainly with infertility, dealing with emotionally difficult situations -- that the information that was being provided was biased and promotional. And it was out of that concern, and then I guess coming across the discussions about this being used as part of a marketing strategy, in some specific campaigns where a new group would be formed with the launch of [a] drug. (Barbara Mintzes, interview 2008)

Mintzes emphasizes that patient groups provide an important service to patients, a fact that makes the debate about alliances with pharmaceutical companies a difficult one, to be embarked on with extreme care.

I think it took a while for these kinds of questions to be raised about pharmaceutical funding of patient groups, because patient groups are such a mixed bag. [Mixed] in the sense that there are groups that have been started by people who have been affected by a horrible disease and who then have provided support and information and, basically, a service to other people who have also been affected. And that they've come out of their experience and made it something positive in the senses of helping others to go through a similar thing. And that's a crucial, important side of patient groups! ...

I think the criticism of the industry funding of patient groups is totally necessary and [so] I always try to separate that critique from the sides that are positive. (Barbara Mintzes, interview 2008)

This separation is difficult to achieve as the Canadian group *Critical Advocacy to Prevent Cancer* and the American group *Breast Cancer Truth-Tellers*, with whom it had ongoing ties, discovered. Both organizations developed similar corporate contributions

policies.<sup>236</sup> I return to *Critical Advocacy to Prevent Cancer*'s decision below, but first I examine the process that led *Breast Cancer Truth-Tellers* to adopt a formal policy on corporate donations.

Concurrent with its decision to adopt a policy, the American group tried, with little success, to open a critical public discourse about the issue. *Tanya*, who became the executive director of the *Breast Cancer Truth-Tellers* 1995 when the organization was about four years old, was instrumental in initiating the policy adopted in 1998/9. She described the process in an interview.

*Tanya*: [In 1994] the board had a very clear statement that “We cannot be bought.” And it wasn’t that pharmaceutical companies were flooding us with money, mind you ... But members of the board were very clear that it would be ok to take pharma money and it wouldn’t affect our position.

Sharon: What was the meaning of that statement?

*Tanya*: The meaning was that we were going to say what needed to be said. We were going to tell people what was going on with treatments or real prevention, no matter who gave us money. I think that was the premise of that statement. People really believed it, and I think they acted consistently with it. (Interview with *Tanya*, 2008)

The board had periodic internal conversations about whether it was appropriate to accept funds from drug companies but the issue was not seen as pressing. The organization had received only one pharma grant (which they had asked for, to pay for a meeting) -- from Genentech, the company that at the time was conducting clinical trials for the biologic breast cancer treatment Herceptin®. The group took the money, a cheque for \$1,000. Although they continued to revisit the question occasionally and continued to say, “We can’t be bought,” nothing really changed until 1998, when what *Tanya* calls “a great controversy” erupted and prompted the group to consider formalizing its policy.

We struggled with this for about a year, at the board level -- not with what we should do, but how we should say it. Should we have a more detailed policy? Should we actually start to say “No”? Should we openly say “No”? And at that point, Genentech sent us another cheque for \$1,000 and we sent it back. (Interview with *Tanya*, 2009)

The decision to move the discussion into the public arena was not made “willy-nilly,” *Tanya* explained, but was an attempt, “to have a conversation that’s really important to the movement,” prompted by an event within the movement. The event in question involved an article that another west coast cancer group published in its newsletter discussing funding from corporations as a move that could potentially be contradictory to the organization’s *raison d’être*. The article sparked an internal exchange among the leaders of several local groups, one of whom felt that her organization had been unfairly criticized. The discussion escalated and culminated with a passionate letter written by a prominent environmental and cancer activist, coming down on the side that opposed corporate funding.

And basically her message was, “Silence is the sound of money talking.” I then shared [the letter] with my board President and said, “It seems to me it’s time for us to look at this again. This the best articulation we’re likely to see of an argument for taking a strong policy position and we should just decide if we’re going to do it.” (Interview with *Tanya*, 2009)

The board then began a discussion that led to the adoption of a policy stating that the organization would not accept money from any company that profits from cancer (e.g., drug companies and cancer treatment centres) or contributed to the cancer epidemic in any way the organization knew of (e.g., companies whose products had been shown to be carcinogenic).



Not because the money's bad and not only because we need people to trust what we say, but we're working in alliance across issues and people [in other organizations] have to know that you're trustworthy. And that's very hard to do if you're taking money from the industry. (Interview with *Tanya*, 2009)

After adopting its corporate donations policy, *Breast Cancer Truth-Tellers* published a series of articles in its newsletter, explaining the group's decision and the reasons for it.

And people responded in very interesting ways. There were people who wrote to us and said, "Are you people out of your goddamn minds?" And then there were the people who wrote to us and said, "If I had a million dollars I'd give it to you!" Now, unfortunately nobody with a million dollars has found their way to us, so we're still struggling [laugh]. But there are many people who believe that we're doing the right thing. (Interview with *Tanya*, 2008)

Although the group succeeded in generating a discussion within its own membership, it was unable to persuade the groups that were taking money from the industry to engage in a public debate over the issue. The discourse thus became one of critique on one side and silence on the other. At the same time that the group adopted its policy, the board decided *Breast Cancer Truth-Tellers* would not be a member of any coalition that accepted money from pharma or from other corporations precluded by its policy. It therefore resigned its membership in the national organization *Breast Cancer's National Voice* that did accept pharma funding. The corporate funding issue thus became one that defined *Breast Cancer Truth-Tellers'* identity and determined with which other groups it would formally affiliate. This process reconfigured alliances within the American movement. Since few other breast cancer groups had, or went on to adopt, a "no pharma funding" policy, *Breast Cancer Truth-Tellers'* found itself relatively isolated within the breast cancer community; it redirected its energies towards pursuing ties with

organizations that shared its perspective on corporate funding, including feminist health groups, environmental groups, and consumer protection groups.

When the Canadian group *Critical Advocacy to Prevent Cancer* decided to adopt a corporate donations policy in 2001, its board referred to Anne Rochon Ford's booklet, as well as to the *Breast Cancer Truth Tellers'* document, from which it borrowed the clauses that prohibit accepting fund from pharmaceutical companies and other specified classes of corporations (See Appendix A). *Critical Advocacy to Prevent Cancer's* rationale was that the policy was needed to avoid real or perceived conflicts of interest that could undermine its credibility and political legitimacy as a group that speaks publicly about breast cancer prevention, diagnosis and treatment. The policy also served to maintain the integrity of *Critical Advocacy to Prevent Cancer's* information service. *Critical Advocacy to Prevent Cancer* went public with its policy, posting it prominently on its website with a notice in its newsletter.

As in the U.S., moving the critical discourse about pharma funding into the public arena proved to be divisive for the community. *Critical Advocacy to Prevent Cancer*, like *Breast Cancer Truth Tellers*, belonged to a national umbrella organization, *The Hub*. Although the group did not resign from *The Hub* when it adopted its policy, the decision to adopt a formal policy arose from a discussion the board members had about a booklet which *The Hub* had published with funding from Janssen-Ortho Inc. manufacturer of the anti-anemia drug Eprex®. Subsequent to adopting its policy, *Critical Advocacy to Prevent Cancer* wrote to *The Hub*, expressing the view of its board members that the company's sponsorship presented a conflict of interest. The group also wrote to other *Hub* member organizations and urged them to oppose the national group's use of

pharmaceutical money, an initiative that served only to isolate the local group from other members. At the same time, in adopting the policy, *Critical Advocacy to Prevent Cancer* solidified its ties with the minority subset of patient organizations and other health-related groups that were sounding alarms about pharmaceutical company funding in the community. In 1998, the group had become a member of a Canadian coalition of women's health advocates that formed to monitor the federal government's drug regulatory reform.<sup>237</sup> *Critical Advocacy to Prevent Cancer* also became a member of the *Prevent Cancer Without Drugs Group*, a coalition of health organizations that had testified at the 1998 FDA hearing to discuss whether the early results<sup>238</sup> of the Breast Cancer Prevention Trial warranted approving tamoxifen as a preventative treatment for women deemed at high risk for breast cancer. All had urged to FDA to refuse Astra Zeneca's application to market Nolvadex (tamoxifen) to healthy women (Klawiter 2008, Ley 2009, Woodell 2004). All of the groups had policies against accepting funds from the pharmaceutical industry.

As the above discussion implies, their resistance to taking funds from the drug industry made *Breast Cancer Truth Tellers* and *Critical Advocacy for Prevention* outliers within the patient group communities of their respective countries, where accepting industry funds was becoming a common practice. Before I discuss case histories of several groups that made the move to industry funding, I move inside the pharmaceutical industry, where a new discourse on the potential value of alliances between the industry and patients' groups was taking shape.

### 5.3.4 The Pharmaceutical Industry Creates a Strategy

In the period from 1997 to 2001, the pharmaceutical industry began to recognize patients groups as influential actors worthy of attention, but also as a foreign territory in need of special navigational tools. This recognition is reflected in a wave of conference presentations, books, reports, and journal articles that began to appear in the late 1990s and early 2000s, featuring case studies of successful alliances and developing typologies of the forms they could take. The tenor of these documents is reflected in the five examples presented in the lower half of Table 6. The format, venue, institutional origin and geo-political provenance of the documents varies but the overlap in content is striking. They comprise: a 1999 talk titled *Strategic alliances between disease-specific non-profit organizations and private sector pharmaceutical companies* by two researchers from the global professional services and accountancy firm PricewaterhouseCoopers, presented to a Toronto-based corporate think-tank, the Canadian Institute (Rule and Chapman 1999);<sup>239</sup> a book, *Patient Groups and the Global Pharmaceutical Industry: the Growing Importance of Working Directly with the Consumer*, by a former industry insider of 17 years experience who headed a UK-based consultant consultancy firm with leading pharmaceutical companies as clients (Mills 2000); an article, *Patient Advocacy: for the Love of the Game*, in the monthly industry magazine *Pharmaceutical Executive*, profiling an organization for patients with multiple myeloma which was founded by a former pharmaceutical industry employee diagnosed with the disease (Breitstein 2001); a talk, titled “Patient Advocacy: Leveraging the Newest Dimension of Health Care Public Relations,” presented at the 2000 World Conference of the Public Relations Society of America by an employee of the UK-based

pharmaceutical company, Astra Zeneca (Miller 2000); and a Canadian poster shown at the 8<sup>th</sup> Cochrane Colloquium in Cape Town, South Africa titled “NGO and Industry Partnerships: Lessons Learned” (Whamond and Wong-Rieger 2000). The latter featured guiding principles for successful partnerships based largely on a case study of a Canadian breast cancer group’s alliance with a pharmaceutical company and was presented by two participants in that partnership.

All five documents imply a shift in relationships between pharmaceutical companies and non-profit organizations, captured in Miller’s (2000) challenge to the “myth” that industry alliances with patients’ associations are a one-way street, with all the benefits flowing to the group. Rule and Chapman likewise state, “Traditionally the relationship has been based on sponsorship but now pharmaceutical companies are ensuring that the partnership is tied to business objectives” (1999: 21). Although AIDS organizations are recognized as the game-changers in patient advocacy, and patients’ groups in the US are seen as global leaders in organized lobbying, the documents collectively take note of the diversity of diseases now represented (Rule and Chapman 1999, Mills 2000, Breitstein 2001) and the range of countries in which political advocacy by patient groups has become a fixture (Mills 2000). Speaking from a Canadian perspective, Rule and Chapman’s (1999) study found that the growth in such alliances in Canada was driven by very different forces in each of the two participating sectors. Non-profit groups were looking for sources of income in the face of government cutbacks and stiff competition among the ever-growing field of charities; companies were under pressure of increased competition in their own sector, both from generics and from other major brands launching similar products within therapeutic categories. The industry was

also facing the financial pressures of rising overhead costs and declining profit margins. Government intervention in the industry was increasing, but so was customer power, along with a demand for choice, according to this study's findings.

All the documents stress the potential gains for industry in engaging in successful partnerships and heading the list is faster drug approvals. Advocates' knowledge of the patient's perspective, the ability of their groups to function as an information hub, and the shared goals such groups have with the industry – especially the desire for new, successful drugs -- are critical assets, the article in *Pharmaceutical Executive* pointed out:

“The industry is starting to see that we [patients groups] are the link for getting information about their products and clinical trials to the patient communities,” says [Kathy] Giusti. “They realize that link can really speed the drug's approval process. That's the driving factor for the pharma industry.” (Breitstein 2001: np)

Other corporate goals which patients groups had the potential to help industry achieve included, increasing the industry's influence with governments, improving a particular company's image, providing it with access to new markets, and gaining access to data (Rule and Chapman 1999); more specifically, groups could increase pre-market awareness in targeted patient groups, set the stage for “reimbursement issues and lobbying activities”, establish a “reliable/ credible vehicle for product information distribution;” provide “firsthand insight into needs, issues, concerns and trends of target customers;” and form a bridge to “key community leaders who influence national policy, research, drug approval and care delivery” (Chapman, 1999:9). Karen Miller's list included faster approvals but also, “recruit patients into clinical trials, reinforce patient decisions to try a drug, boost product sales, and build compliance” (2000: slide 38).

Several documents make the point that the two sectors have different cultures and

alliances often fail; each side must understand the other if an alliance is to work. Trust, communication, and cultural compatibility were identified as among the keys to workable relationships (Rule and Chapman 1999). Whamond and Wong-Rieger asserted that, based on their research and experience, failed partnerships were perhaps, unfortunately, more common than successful ones. Among their guidelines for successful partnerships were:

... clear terms of engagement; incremental approach that allowed for development of trust and understanding; mutually-defined goals and objectives for each project; and control over the relationship (established boundaries and ability to terminate, at will). Written agreements were not as important as mutual respect and open communications. (Whamond and Wong-Rieger, 2000)

Fred Mills' book-length analysis provides the most thorough discussion of "restraining forces", both legal and ethical. These include legal restrictions on organizations with charitable status, as well as "the issue of retaining their independence, being unbiased and avoiding the perception that sponsorship equals ownership by the drug company" (Mills 2000:31). Although Mills' references to breast cancer organizations are sparse, the discussion of legal and ethical obstacles closely parallels the discourses in the groups I studied, suggesting that these concerns have resonance across disease groups and national boundaries. He notes that:

Many countries are now developing a set of criteria to guide NGOs [non-governmental organizations] in forming relationships with pharmaceutical companies. Although these differ in detail from country to country, they are all similar in their broad aims, which comprise equity, transparency and mutual benefit. (ibid: 31)

Mills acknowledges that pharmaceutical companies have been known to take "the unsophisticated and simplistic" view that "the NGO could be given some money and would then campaign on behalf of the company's product(s)" (ibid: 69). This approach,

he asserts, is now discredited and most companies act with greater “transparency and altruism” (ibid: 69). Despite a generally optimistic perspective on the ability of groups and industry to form relationships that meet the necessary ethical standards, Mills is sympathetic to the idea floated in the debate sponsored by the Canadian panel (page 327) of independently administered blind trusts, with money from the pharmaceutical industry and other sources (Mills 2000: 70-71).

Collectively, these presentations and documents identify relationships between pharmaceutical companies and patient groups as an emerging area of knowledge. The near-simultaneous appearance of so many prescriptive documents, both for and against pharma funding of patient groups, signals a stage of discourse in which the practice is no longer a novelty but is not yet normalized as a practice. Insiders recognize the phenomenon as widespread and, whether they favour the alliances or seek to discourage them, they are actively working to elaborate and disseminate their arguments to a broader community. In actor-network terms, this is a period of *enrollment*: parties on each side are defining the roles of various actors and striving to have these roles accepted.

### 5.3.5 Inside the Groups: Debates about Pharma Funding

In the cases described in 1991-1996, funding between breast cancer groups and the pharmaceutical industry suggest an environment in which decisions on both sides were made in the absence of formal policies and involved awards of \$1,000 to \$5,000 for single projects. In the period between 1997 and 2001, larger sums of money came into play, particularly in alliances with the national or umbrella organizations. These amounts are difficult to document but in some cases were in the hundreds of thousands of dollars



(Case 2, below; Nebenzahl 2003, Picard 2001).<sup>240</sup> In this section I discuss the move within breast cancer groups to adopt formal policies, and the beginning of public discussions. I begin with case descriptions of two groups that engaged in partnership arrangements, *Helping Hand* and *The Hub*.

**Case 1:** *Staff at Helping Hand contest a shift in board culture.* Virginia was hired to work on the staff of *Helping Hand* in 1995, when the organization began setting up a telephone peer support and information service which it began the following year. Her job was to train and supervise the volunteer peer counselors -- breast cancer survivors who responded to questions from the public based on a detailed training manual; she also took many calls herself. The staff and volunteers answering the phones took enormous pride in the impartiality of the information they dispensed, much of which was concerned with breast cancer treatments. The organization's board had no part in the phone service or daily running of the organization but took care of the finances and other business functions. All the board members were volunteers. By the organization's bylaws, half of the board's members had to be "survivors," i.e., they had had breast cancer. The others were brought onto the board because of their high profile, connections and fundraising potential. As discussed in the last section, the early years of *Helping Hand* had seen some tumultuous discussions on the board about pharma funding, with one member leaving in part because she felt the board was moving to accept funds from drug companies. When Virginia began working at *Helping Hand* in 1996, however, the organization had put in place a policy that ruled out funding from the pharmaceutical industry. The policy was based largely on concerns about *Helping Hand's* need to maintain high standards in the information dispensed, but also on the personal convictions of the organization's

Executive Director at the time. By 2000 the Executive Director had changed several times and *Virginia* began to notice a subtle shift in the organizational culture on the question of pharma funding.

*Virginia*: The makeup of the board became more corporate-oriented. And that's where the change really happened. But as far as I know, it didn't make any difference to the actual on-line support and what we taught our volunteers to say and do, and not say and do.

Sharon: You mean corporate in the sense that they were from the corporate world?

*Virginia*: Yes, from the corporate world. Nothing wrong with that; as I said, I lived in the corporate world myself. So, it's not like I felt that they were the antichrist or anything. It was that they looked at the organization from a very corporate point of view. And remember that we're dealing with a nonprofit. And that sometimes the thinking was around, "Well what are the results here?" "What's our profit on this [activity]," in other words. And "How can we make the books balance?" What changed, in my mind – and this is purely subjective – was a greater preoccupation with how *Helping Hand* looked in the community and who *Helping Hand* was associated with, rather than the ground work -- what was really happening in the trenches. (Interview with *Virginia*, 2008)

In *Virginia*'s perception, the organizational structure created an "upstairs-downstairs" divide between the organization's board and its staff. As the organization grew, the issue of pharmaceutical company funding was a fracture line.

*Virginia*: To use corporate-speak, we were losing our market share because more and more services were being provided elsewhere for breast cancer survivors. ... And I think the shift was that two things happened at the same time. What came first? In my mind, it was the change in the makeup of the board. The board started attracting, one after another, so-and-so referred so-and-so, and so-and-so came on the board. So the makeup of the board became more women who came from a corporate world, came from a fundraising mentality that did not have the same ethical values, or ethical – [I don't] mean that they were immoral; they were just different from those that we had started with.

And at the same time, the persistent knocking at the door from the pharmaceuticals: it was a question of, “Well, why not? Why shouldn’t we?” ... So it was the two things happening. The pharmaceuticals were always knocking at our door, but the door was being answered by the people now who didn’t see anything wrong with that. (Interview with *Virginia*, 2008)

Even more problematic than the shift in the culture of the board members who raised money, *Virginia* felt, was an absence on the board of critical voices among survivors who could raise ethical issues at board meetings.

*Virginia*: And the problem at *Helping Hand*, I feel, was not so much that we had these go-get-’em women who would bust their ass for *Helping Hand*. I mean, many of them worked hours and hours to do stuff. But it wasn’t tempered by the kind of survivor that would, that could bring a voice to the board that would show the other ethical sides of it. And it was difficult getting breast cancer survivors to go on the board at *Helping Hand*. It was very hard, very, very hard....

Sharon: Why do you think that was?

*Virginia*: I think that the kind of women who were interested in *Helping Hand* were often women that just wanted to be in the trenches and do the phone work. And, you might have different experience than I do, but my feeling was often, even with a survivor peer-support volunteer, that people sometimes wanted to volunteer in a breast cancer community group for a period of time and then, once they moved on in their treatment, they wanted to leave it behind....

And a lot of these corporate women did it because they truly believed that this was a thing that they should – some of them had sister-in-laws, or people that they’d lost in their lives. None of them were survivors. Yeah. But they had an attachment to the issue. .... And, they worked tirelessly to bring money in. And some of them got tired and said, “Okay, well, why am I busting my ass to do this when I think it’s okay just to take this money from pharmaceuticals? Why wouldn’t we? I don’t get it.” (Interview with *Virginia*, 2008)

The written prohibition against taking money from pharmaceutical companies began to erode, *Virginia* recalled, not by discussion or an overt, formal decision, but when the rules were bent for a highly successful annual fund-raising event called *Give and Gorge*, which was the brainchild of two board members from the corporate culture.

*Virginia*: It's an eating extravaganza. And volunteer chefs from all over town, from all kinds of different restaurants and catering services, come. They have a table and they serve samples of their food. And they donate their time and all of the food. ... It was the single largest fundraising project of *Helping Hand*. I mean, it brought in, at one time, over a third of our operating budget in one event. So [it was] very, very dicey. [Was the] weather bad that year? You know, if there was something that happened, it was really risky, Sharon. But it never bombed.

... Now, the way they evolved with it was, in the beginning it led; it stood for itself. These women that ran it had a separate committee, the *Give and Gorge* committee. And they would get people to donate. ... [The board members] went around finding this stuff, they worked really hard. Then they started to get a bit nervous about this. So, as we know, fundraising events have a life-span. And so because they wanted to pre-empt the loss of income from finding stuff, they went looking for corporate funding of the event so that they would know that from the get-go, [that] whatever they took at the door, they would have a certain amount aside to cover costs.

This was very, very careful spending. And a beautifully run fundraising event, without question; very ethical. But then, they started looking around for headliner sponsors. So it would be, the headline sponsor would be in for fifty thousand dollars.

Sharon: Hmm!

*Virginia*: And that's where they caught the pharmaceuticals. That was the first time the pharmaceuticals came in and started funding. And initially they said, "Well, it's a Give and Gorge function! It's not really direct funding to [*Helping Hand*]." And I think after the first year of them doing that, that's when they changed the funding policy. Because [the staff] were saying, "You know what? You're breaking the rules here. Don't we have a funding policy?" You know, "I'm a little uncomfortable with this." And that's when

they said, “Okay, well, we’ll relieve your discomfort and change the policy.”  
[laugh]

Sharon: [laugh]

*Virginia*: “We’ll make it legit so you won’t feel uncomfortable anymore.”  
[laugh] ... And the only rule with the headline sponsorship was that you didn’t have two pharmaceuticals vying for the same position. Or two banks. ... So that’s how they got in. It was, sort of, “Well, we’ll just give you some [money].” First of all they were buying tables at the event. And then it was a headline sponsor thing. (Interview with *Virginia*, 2008)

Realizing the board was about to change the policy, the staff made a last-ditch attempt to intervene:

*Virginia*: During the time when we knew that it was on the cards to be changed, we got wind of this, as a staff, and we asked to present to the board on it, because we felt that maybe they hadn’t had enough information. We were still in that twilight zone where we thought, “Maybe these people can be convinced that is not a good thing for the integrity of a so-called unbiased organization.” And a couple of us sent memos containing a lot of the criteria and saying, “Can we come and make a presentation to a board meeting...?”

[Because] although *Helping Hand* maintained a 50/50 survivor/non-survivor ratio, many of the survivors on the board were not women in the trenches, I mean they had their own experience with breast cancer but were not necessarily *au fait* with the community feel, or had not been active volunteers in the community. And so perhaps, we thought, maybe they haven’t got the understanding of how this might affect our community -- which was very naïve of us. And they refused to take a presentation from us.

Sharon: Wow.

*Virginia*: So, we knew at that point it was done and dusted.  
(Interview with *Virginia*, 2008)

Once the policy was changed, *Helping Hand* entered into an agreement with Astra-Zeneca<sup>241</sup> which the staff asked to see, but they were refused on the grounds that the agreement was privileged information. “Which did nothing to make any of us feel

particularly confident about what that arrangement was” said *Virginia*, “If it’s open and honest, why can’t we see it?”

At its base, the dispute between the board and staff levels is about the acquisition, transmission and blocking of knowledge. The staff prides itself in its knowledge of “the community feel,” in particular, of “knowledge-hungry” patients who face treatment decisions. The board has knowledge about the agreement with the company which it won’t relay this to the staff. For *Virginia*, the ethical dilemma that pharma funding posed at *Helping Hand* was intimately tied to the organization’s pledge to give unbiased information in their peer support service. And the fact that the demographic that most typically used the group’s services was “knowledge-hungry” only underlined the imperative that the information be free of outside influences, in both fact and appearance.

*Virginia*: ...we’re talking with a population now that is, you know, a baby boom population, women that are hungry for information, that look for stuff, that aren’t going to trust everything their doctor says. And in a sense, to me, although these are perhaps more well-informed people, it also leaves them vulnerable to an insidious form of persuasion. Am I making sense?

Sharon: Yes.<sup>242</sup> And was that -- how much of that was your analysis and thinking and how much of it was part of the training that *Helping Hand* developed over the years?

*Virginia*: Well, in the beginning, that was exactly what *Helping Hand* said it would be. ... The training manuals said that all the way through.

Sharon: Um-hmm.

*Virginia*: You know, “We will not give advice.” “We will not be tainted.” “We will not have ...” and even after *Helping Hand* started taking pharma funding, I wasn’t doing so much phone work then, but I know the women who were training the women to go on the phone and that was made abundantly clear. I mean, you can’t control everything; you might get a peer support volunteer who decides that the be-all and end-all advice is to take

Adriamycin®. But if she was heard saying something like that, she'd have been yanked pretty fast. We had a pretty high bar with the screening on the volunteers for the time, over the ten years I was with *Helping Hand* [the bar] was very high, very high. And they were watched.

(Interview with *Virginia*, 2008)

*Virginia*'s reasoning that the obsessive, knowledge-seeking of the stereo-typical boom generation patient was a source of *vulnerability* to biased knowledge -- and thus an argument against the use of pharmaceutical company funding for a health information service – contrasts with the counter-argument cited by proponents of pharma funded information. In the latter case, the well-educated, knowledge-seeking patient-of-today needs, demands and has a *right* to information from all possible sources, including pharma. She is far too savvy to be misled by advertising hype and efforts to protect her from misleading claims are framed as condescending.

**Case 2: *The Hub's Board Splits over Pharma Funding.*** About the same time that the tension over pharma funding split the staff and board members at *Helping Hand*, the board of a second group split internally over the same issue. *The Hub* was established in November 1994, a year after the National Forum, with support from the federal government. It was intended as an organizational support that would provide information for local and regional breast cancer groups, and also act as the “voice of breast cancer survivors,” that is, an advocacy group. From 1995 to 1999 the group relied primarily on a 5-year commitment of federal government funds. The group was then told that this money would be gradually phased out and the organization would have to become financially self-supporting.

In 1999, Janssen-Ortho (a subsidiary of Johnson & Johnson), which markets Eprex® through its subsidiary Ortho-Biotech, invited *The Hub* to enter into a partnership

arrangement. It was a federal election year and *Helen*, the newly elected president of *The Hub*, felt it was important for the group to lobby to have its funding renewed.

Furthermore, as a strong environmentalist, she was eager to move the group into environmental advocacy on cancer prevention. None of the federal money could be used to support advocacy but the biotech company was more than willing to fund this activity. The board voted to accept the money. The company provided an “unrestricted educational grant” of \$65,000 for three workshops, to be held at sites across the country. An additional \$25,000 was granted for a breakfast with women Parliamentarians; and further funds were provided for a special advocacy issue of the organization’s newsletter.

This initial arrangement had no written contract and the money was to be “no strings.” Although the company made several “after the fact” demands, from the perspective of the group’s board, the arrangement worked well. The workshops were well-subscribed, participants’ evaluations were positive, and the organization recruited twenty new members to its advocacy committee.

In early 2001, Ortho-Biotech’s Community Relations Director proposed a second round of funding, this time over a period of three years. The money would support more advocacy workshops and a needs assessment survey of the group’s members. This time, however, the company wanted a written agreement specifying that the workshops would include information on anemia (anemia was the main indication for the company’s biologic, Eprex®); because anemia is a side-effect of many chemotherapy drugs used to treat breast cancer, Ortho-biotech hoped to have chemotherapy-induced anemia approved as an additional indication for its drug. As well, the company would provide questions to be inserted in the needs assessment questionnaire. A representative would be invited to



the group's Annual General Meeting and other events, and the group would thank the company on its web site, in its newsletters and in other publications. This proposal split the board.

The money, at \$75,000 to \$100,000 annually for three years, was significant. For the most part, the funding could be used for purposes agreeable to the group. A number of members, however, including the president, balked at the demand for reciprocal benefits. Negotiations and discussions continued for several months, with special meetings of the executive, conference calls, revised contracts, and lavish lunches and dinners with the company's representatives. The president attempted to remove or modify the troubling demands while the company ratcheted them up. New requests included promoting a web-based decision tool for patients that included an anemia assessment questionnaire; participating in and endorsing Anemia Week, recruiting the group's members to a study of anemia and fatigue, publishing articles about anemia and fatigue in its newsletters, and co-hosting, with the company, a reception for survivors at an upcoming international breast cancer conference.

The president, *Helen*, strongly opposed the contract:

*Helen*: To me it was like, we might as well put a big sign up on our website, "we're now promoting Eprex®." I mean [the drug] wasn't really mentioned, but all this stuff about anemia -- there was only one reason to do that, as far as I was concerned. It wasn't just [that] they said, "This is information that women need to know" -- and some of that was ok. But when you got down to it, it was all about drugs that in a round-about way they were promoting. So that was when we did the survey with the board. (Interview with *Helen*, 2007)

In October 2001, the full board voted on each component of a new draft partnership agreement. The majority rejected the most blatantly promotional items and accepted others, but views were divided on every item. Opponents to the contract had

three main concerns: *The Hub* could be perceived as working for Ortho-Biotech Ltd. and would lose credibility; the name of the company's drug might come up at the workshops, which would contravene a commitment the organization had not to promote specific drugs; and the group could lose control of the organization by focusing excessively on one issue among the many that concerned its membership. (Notable by its absence in this list of concerns was the possibility that the drug might do women who used it more harm than good; as discussed below, clinical trial results showed this was in fact the drug's effect on women with breast cancer.) Defenders countered that the organization would be providing a much-needed service – that patients were upset because doctors didn't talk to them about anemia and fatigue; that the offer was an opportunity for *The Hub* to improve its shaky finances; and that the company's representatives had proven their trustworthiness.

Board relations became bitterly factionalized and the question of the partnership remained an open sore. The president felt the contract was tantamount to selling out the organization; the vice-president felt that the organization's very existence was in jeopardy and that this partnership, on balance, was an excellent opportunity to secure the group's future by working with a trustworthy company that cared about patients. Soon after, the president's two-year term expired and the vice-president assumed the presidency, as per the organization's bylaws. Within a few months, the new president signed a three-year agreement with Ortho-biotech, including most of the disputed terms. The past president resigned, calling the contract a sellout of the organization. Two board members subsequently resigned in support. In her letter of resignation, the past president voiced her belief that, while she was president the company's representative had "cut her

out of the loop” by not returning her calls, dealing instead with the sympathetic VP and biding her time until *Helen*’s term as president expired.

Looking back, *Helen* felt she had been naïve:

I’d never dealt with being president of an organization at the national level and I didn’t realize they could be nice and court you and give you what you wanted -- which was money to do advocacy [on prevention and the environment] -- and then come back at you with their own agenda. I should have known better; so I blame myself, in some respects, for getting involved and then having to fight a battle the second year. (Interview with *Helen*, 2007)

An additional factor however, was the difficulties they had experienced in the funding arrangement with Health Canada:

We always had trouble getting our funding from the government on time and we were dependent on [Health Canada] for operating [funds]; they were always a couple of months late. Once we had to shut down the office for a little bit and we had to let a couple of staff go because we just didn’t have the money to pay them. So when [Ortho-Biotech] offered us all this big money, the lights with the board went off all over the place, because they said, “we’re always having trouble with money, Health Canada’s always late with their payments, it’s always a problem whether our funds are going to be renewed.”

So they didn’t look at it from an ethical standpoint, as [in] what taking money from [Ortho-Biotech] and doing what they wanted would do to our reputation or our image. All they thought about it was, “It’s money. Let’s take it and run.” But there were strings attached as to what that money was going to go for. (Interview with *Helen*, 2007)

Within a few years, concerns about Eprex® itself were making headlines. In 2003, a report published in the medical literature associated Eprex® treatment with *shortened* survival in patients with advanced head and neck cancer (Henke et al 2003). A subsequent study with breast cancer patients similarly found that Eprex® hastened death (Leyland-Jones 2005) and studies with other types of cancer arrived at the same

conclusion, possibly because the agent stimulated tumour growth (Khuri 2007). Additional concerns with Eprex®, and other agents in the same class<sup>243</sup> were “the hyperbolic advertising by the companies that make ESAs [erythropoiesis stimulating agents] and the substantial profits accrued by physicians who use such agents aggressively” (Khuri, 2001:2448). The same author pointed out that the U.S. Food and Drug Administration had approved ESAs to reduce the number of blood transfusions required to treat extreme anemia brought on by chemotherapy; the drug was not approved “to alleviate fatigue or weakness or to improve a patients’ quality of life” (ibid: 2445).

In 2008, I interviewed *Hanna*, a former member of *The Hub* board who had remained on the board following *Helen*’s resignation. She was pleased with the relationship the group had with Ortho-Biotech on several levels. First, they had provided money at a time when funding from Health Canada had been unreliable, and second, with the money the company provided *The Hub* was able to produce a diary and appointment book in English and French which she described as a “neat” decision-making aid for patients undergoing treatment that pulled together information from different sources.

I asked her if she had had any reservations about the fact that Ortho Biotech, at the time the group received funding, was promoting one of its drugs for use with breast cancer patients. Her response was based in part on the fact that she had worked in a hospital setting where she saw the dangers of blood transfusions (a treatment for extreme anemia), but also on her comfort with the relationship the group had with the company:

*Hanna*: At no time did we have to, nor would we, endorse, OK? I think, personally, Eprex® was a good idea at the time.

*Sharon*: It hasn’t worked out very well though.

*Hanna*: It hasn't. But then again, if you look at blood transfusion, you know, if I had my druthers I'd rather have Eprex® than a blood transfusion. I used to work in blood transfusion. You know, it's not what they know what's in it [the blood], it's what they don't know. And they had been using [Eprex®] for renal transplants and renal dialysis for years at this particular point!

Sharon: Well, I thought they found that women who were taking it died sooner -- women with breast cancer.

*Hanna*: Hmmm. Not with renal. And it's not something that you would need a lot of if you're in treatment; you want something that boosts your white cells and boosts your red cells because you really want to continue your treatment. And, I mean personally, I still think transfusions are not the best solution. You get other people's problems with it. ... You know, it's a choice out there what we believe. But we would never endorse ... we would never endorse any product. ... Other people assumed we did, but that was their problem.

Sharon: Well, it's also a problem for the group if there's an appearance of closeness.

*Hanna*: Well, you know, we've also learned through the years that people can think what the heck they want. And if people are looking [for problems], I mean you could do that with any project. So, if they want to think it, fine. (Interview with *Hanna*, 2008)

Soon after she left *The Hub*, *Helen* started a new organization, focused on cancer prevention and the environment. *The Hub* continued its relationship with Ortho Biotech and co-hosted a reception with the company at an international breast cancer conference in 2002. Another board member, who later resigned as well, characterized Ortho-Biotech's behaviour as "really unethical":

I think they gave the [international conference] something like \$110,000, like a *huge* amount of money ... and they were doing such outrageous things to the board, taking the board [of the *Hub*] out to dinner, just spending money left, right and centre. So that was really bad. (Interview with *Martha*, 2007)

In October 2001, *The Hub*'s board of directors adopted a set of guidelines for entering into corporate partnerships which described nine expectations that would be fulfilled by any partnership agreement the organization entered into, including: that the partnership would benefit breast cancer survivors; that it would be compatible with *The Hub*'s goals and meet *The Hub*'s social and ethical obligations; that it would avoid endorsing specific products, treatments and the like; and that the organization would be prepared to disclose publicly any responsibilities it had to the partnering corporation. As I discuss in the next section, on the Partnership Period, *The Hub* subsequently entered into relationships with other pharmaceutical companies and continues to do so.

**Case 3: A Pharma-Funded Advocacy Group Faces a Media Watchdog.** A new Canadian cancer organization, *All-Cancer Advocates*, held its launch in 2000 with *Eve* at the helm and backed almost entirely with Unrestricted Educational Grants from pharmaceutical companies. As with *The Hub*'s alliance with Ortho-Biotech /Janssen-Ortho, the impetus behind the new group was a felt need for advocacy. Whereas the debates over pharma funding at *The Hub* and *Helping Hand* were internal, *All-Cancer Advocates* brought the question of pharma funding into the public arena, albeit inadvertently.

Following the meeting *Together to an End*, *Eve* brought together advocates from a variety of patient cancer groups with health professionals working in the cancer field to form an organization dedicated exclusively to cancer advocacy; their focus was all cancer sites, not only breast cancer. The impetus, she told me in an interview, was the session at the *Together to an End* conference titled "How can we reduce breast cancer mortality in the next ten years?" (see pages 310-312) at which an oncologist who was a delegate at the

meeting, presented data showing provincial disparities in survival rates of women with breast cancer.

He presented this data that showed – and this is in '96 – women in British Columbia who were treated for breast cancer in a five year period had a 27 percent improvement in overall survival than Ontario. ... And what was going on was that in BC ... they never limited what the treatment options were that they offered women. They had an organized system. They were more aggressive. They offered the full range of treatment options. They were more aggressive in providing women with information about that. And women tended to make choices for more aggressive treatment. (Interview with *Eve*, 2008)

As mentioned on page 311, a recommendation at the session Dr. Hryniuk convened was to form “a national volunteer coalition to continuously lobby the Provincial and Federal governments for improvements in outcomes” (Kelly, Condy and Harder 1997: 70). *All-Cancer Advocates*, an organization built on the idea of addressing provincial disparities, was set up to do precisely this. *Eve* and Dr. Hryniak were among its founders and one of their strategies was to produce an annual Report Card that would rate provinces on various aspects of their performance in treating cancer.

*Jillian*, another early member of this group, had been diagnosed with a form of cancer when she was still a university student. She heard a radio interview in which *Eve* talked about her experience with the cancer system.

I sought her out and I found her. I said “Look, I’m really interested in your approach to the larger systems problems, is there anything I can do?” And she was having a meeting a couple of weeks from then and I became involved because there was a kind of passion, an alignment [in our perspectives] of wanting to change things at a systems level. (Interview with *Jillian*, 2008)

As a member of *All-Cancer Advocates*, *Jillian* designed and wrote the organization’s first Report Card. When the group tried to gather the data, however, they

found that provincial data sets were not sufficient to allow them to make meaningful comparisons. The lack of comparative data thus became an advocacy issue and was a featured article in *Cancer Care in Canada*, a 24-page glossy magazine-format publication that the organization used to launch its advocacy efforts, in the fall of 2000. The publication featured a cover headline, “Report Card 2000”, and a three-part article on “The State of Cancer Care Today” (Anonymous 2000a: cover). As a whole, the dozen or so short articles were a collective call to action to deal with a mounting crisis in cancer care in Canada. A statement on the back cover of the organizations first publication explained that, “To maintain its unrestricted ability to engage in advocacy, *All Cancer Advocacy* does not have charitable status and donations are therefore not tax deductible” (Anonymous, 2000b:back cover). The same statement said the organization’s funding came from “annual membership fees and unrestricted educational grants from corporations” (ibid.); however, the fact that the corporations were drug companies is not specified. I asked *Jillian* about the origins of the organization’s pharma sponsorship

Sharon: How did it come about? Did they approach you, or did you approach pharma, or ...

*Jillian*: Well we approached everybody. But pharma was really the only industry that would fund that kind of work. And at that point we were purely doing advocacy, so there was no possibility of getting charitable status. So very quickly you get into the kind of contradiction game. So if you want to do pure advocacy work you don’t really have any other option. (Interview with *Jillian*, 2008)

Thus, organization’s structure as a not-for-profit organization which had opted not to apply for charitable status meant that, unlike cancer organizations set up as charities that can devote only twenty per cent of the money they raise to advocacy, *All-Cancer Advocacy* was free to spend 100 per cent of its annual revenues on advocacy.



Two prominent interrelated themes that ran through the articles reprised the discourse from the *Together to an End* session on reducing cancer mortality, that is, that Canada lagged behind the United States in providing patients with the latest treatments, and that patients had a right to these treatments.<sup>244</sup> The claim that Canada's system for providing cancer treatments is backward was illustrated most dramatically in an article on breast cancer treatments, titled "New chemotherapy regimen out of reach for Canadian women." The article compared the rapid adoption in the U.S. of a new chemotherapy treatment as the standard of care with the much different situation in Canada. The treatment in question was the combination AC+T (i.e., Adriamycin®, cyclophosphamide, and Taxol®) for node-positive adjuvant breast cancer. In the United States, AC+T had been adopted as the new standard of care after preliminary results of a clinical trial were presented at an ASCO meeting in 1998. A Canadian oncologist quoted in the article argued that American oncologists considered AC+T to be "the single most significant advance in the treatment of breast cancer in the past 20 years" (Leyland-Jones, cited in Anonymous, 2000c:22). In Canada, the article pointed out, the federal government had not approved paclitaxel (Taxol®) as an adjuvant therapy for early-stage breast cancer until April 2000 and that, according to the article, was in 1999, after *Eve* and other Canadian breast cancer advocates who had followed the American case applied pressure.

In the United States, opinions on whether the rapid embrace of AC+T was in the best interest of patients were far from unanimous. American physician and historian Barron Lerner frames the turn in which American oncologists adopted AC+T as standard treatment as part of the cultural predilection in the U.S. to welcome aggressive treatments for breast cancer:

This desire for potent chemotherapy was recently demonstrated when a new combination of drugs – Adriamycin, cyclophosphamide, and paclitaxel (Taxol®) – became the treatment of choice for breast cancer based largely on one presentation made at an oncology meeting and a marketing campaign by Taxol’s manufacturer, Bristol-Myers Squibb. (Lerner 2001: 254-255)

*All-Cancer Advocacy*’s Canadian lobby to promote AT+C thus accurately presented AC+T as a “treatment of choice” in the United States, but Lerner’s account underlines that this status was the result of clever marketing, not superior performance as demonstrated by scientific evidence. Survey data support *All-Cancer Advocacy*’s claim that women *want* such treatments (Coates and Simes 1992, Ravdin et al 1998). Less convincing is the claim that AC+T is “the best” treatment for breast cancer, or one that one that should be adopted in a healthcare system based on what will most benefit patients, rather than what they want.

Returning to *All-Cancer Advocacy*’s publication *Cancer Care in Canada*, the claim that patients have a right to new treatments was put forward in a one-page feature headed Cancer and the Law. A brief article by McGill bioethicist Margaret Somerville highlighted three points from Canadian court decisions related the question of whether Canadians have a right to “the best cancer treatments.”<sup>245</sup> She concluded that the term “standard treatment” could include a treatment not available in Canada but that was standard in another country with “comparable health care” (Somerville 2000:6); that “cost alone” could not mean a treatment is not medically necessary (ibid:6) and that physicians have a primary duty to care for an individual patient, not to save resources for others. A complementary article on the same page highlighted the case of a Quebec lawyer who went to New York for treatment of metastatic colon cancer because his doctor said the delay to receive treatment in Montreal would be unreasonable. When the

provincial insurance plan refused to reimburse the costs of his treatment he sued and won. (He also lived, and went on to found a national advocacy group for patients with colon cancer.)

Notably, an article on why people with cancer in BC “appear to do better” than their counterparts in other provinces, made no mention of more aggressive treatments; rather, extensive quotes from Dr. Jack Critchley, a Vice-President of the BC Cancer Agency, stressed the province’s integrated system.<sup>246</sup> The claim that breast cancer mortality was lower in that province because of a more aggressive use of chemotherapy appears in a small sidebar to this two-page feature. The sidebar highlights a 1998 book by newspaper journalist Lisa Priest, titled *Operating in the Dark: the Accountability Crisis in Canada’s Health Care System*.<sup>247</sup>

Whether these articles alone would have pushed the organization’s launch into the media headlines is uncertain. Just before they were ready to publish the magazine, however, an American cancer association published data on cancer mortality in American states from a U.S. cancer data registry and included data on Canadian provinces from Canadian registries. This gave the organization a stunning hook for media coverage. *Eve* explained:

All the Canadian provinces were piled up on the bottom of the list. We had fifty-two reporting agencies and all of the Canadian provinces were coming out, in terms of outcome data ... on the male and female survival rates, and the Canadian provinces were the worst. ... Afterwards, when it was attacked, when we took this and published it – because the media went ape-shit with it, as you can imagine, because ... what we were saying was, “This is evidence, when you benchmark us against seemingly the best in the world and the worst, we’re not doing so well, and we’re so proud of all of our cancer data.” ... So that was kind of our first foray, and that was funded by the pharmaceutical industry. (Interview with *Eve*, 2007)

*All-Cancer Advocacy's* Report Card, and the Canada-U.S. comparison in particular, caused a media sensation when it was released on September 25, 2000 (e.g., Branswell 2000, Buist 2000, Murray 2000, Foss 2000, Evenson 2000), although coverage was not universally positive. Some stories questioned the claims of regional and US-Canada differences in cancer rates and the interpretation that linked any such difference primarily to under-spending on cancer treatments was also challenged. Several cancer epidemiologists quoted in the articles stated that smoking, diet and other lifestyle factors were far more important than treatments in accounting for cancer mortality rates (Branswell 2000; Buist 2000).<sup>248</sup> Experts quoted in two articles even claimed that the data set on which *All-Cancer Advocacy* based its assertion showed that Canada's cancer survival rates were slightly *better* than those in the U.S. (Buist 2000, Murray 2000). Another characterized the group's source, North American Association of Central Cancer Registries, as "an obscure data base" (Evenson 2000:A4). Throughout the stories, quotes from *Eve* continued the theme that Dr. Hryniuk put forward at the 1996 conference: that patients were dying needlessly because they were being denied new, effective therapies which were available to American cancer patients.<sup>249</sup> Although many media sources, in keeping with standard journalistic principles of balance, sought views that questioned the organization's conclusions about the quality of cancer care in the US, the sheer volume of stories and their prominence in mainstream media virtually ensured that the perspective that the organization put forward would enter the popular discourse.

The controversy over *All-Cancer Advocacy* and its critique took an unexpected turn in November 2000, two months after the report's release. The CBC weekly consumer rights television program, *Marketplace*, ran a feature titled "Promoting Drugs

through Patient Advocacy Groups” that prominently highlighted *All-Cancer Advocacy* and made much of the fact that the organization was funded by the pharmaceutical industry. A transcript posted on the CBC’s website of past shows captures the segment’s critical tone:

The group swept into the media spotlight in the fall of 2000 when it released a controversial study on cancer deaths. The coalition is advocating faster approval of costly cancer treatments. It also wants governments to cover expensive new drugs.

What the media did *not* report was where the group was getting its money from.

(Johnson, 2000)

Eve and *Jillian* both appeared on the program, although only *Eve* was interviewed. She acknowledged on-air that the organization was almost entirely funded with money from the pharmaceutical industry. The two felt unfairly set up by the television show, however, as *Jillian* explained when I interviewed her:

*Jillian*: Their thesis was that we were this well-heeled advocacy organization that was running on all this pharma funding. And they were looking for a big kind of opulent, excessive expression of it, and I was doing this work out of my office on the second floor of my little house in High Park. It was a very seat-of-the-pants kind of operation. They had no evidence for any of the accusations that they were leveling. But they started with a very adamant thesis that we were this dark force of patients doing the mouthpiece work of pharma.

Sharon: But it was a pharma funded group wasn’t it?

*Jillian*: Absolutely! But it was no interference. And even then we had pretty strict guidelines of educational non-interference written into all the agreements.

Sharon: You mean an unrestricted educational grant?

*Jillian*: Yes.

*Jillian*, who had worked on a variety of pharma-funded projects when I spoke to her, was adamant that the industry partners did not dictate or influence the content of the *All-Cancer Advocacy's* work.

*Jillian*: They wouldn't be funding it if they didn't have a vested interest, but it's whether they have a direct influence that I think is more the issue.... I think the biggest criticism that's been leveled against organizations that take pharma money is that they're somehow extensions of the minds of pharma. Pharma may see that there's a long term interest in having patient groups educated and funded and arguing [in favour of having access to their drugs]. But it's more that kind of grey zone of -- it happens to be an area where patients have the same long-term interest. It may not even be an exact alignment of interests, but that the pharmas see it as an investment in having a voice that will support their long-term goals.

There's no question in my mind that pharma is highly self-interested. But I've never been in a situation where I've been *asked* to do anything that offended me in an editorial sense.

-- Interview with *Jillian*, 2008

The idea that patients and the industry share an interest in drug development and the rapid uptake of new products resonates with both *Jillian* and *Eve*. In an interview, *Jillian* described herself as fundamentally a pragmatist who owed her life to drugs. Although she felt it was important to have multiple sponsors for a project, she was impatient with those who used the pharma funding issue as a "crowbar".

I tend to ... focus on the outcome. You can pull apart the politics of everything and it will crumble. ... Opponents to pharma funding are using that as a lever to make themselves more worthy of funding. Pharma becomes this unfortunate armature for fractiousness. ... I know how hard most patient groups work – it's really hard! And I'm as skeptical as everyone else. Where is the real evidence that bad things have happened? Ninety per cent is on the up and up. It all depends on one's optimism. I feel the same way about government – [you need] to have a civic infrastructure... to have people not experience negative parts of the disease.

-- Interview with *Jillian*, 2008

Shortly after the launch of *All-Cancer Advocacy*, *Eve* joined a coalition of patient's groups that wanted to speed the approval of new drugs at Health Canada, *New Drugs Now!* – a group also funded by the pharmaceutical industry.

*Eve*: And *All-Cancer Advocacy* led to the *New Drugs Now!* conference. Because one of the things just surfaced was how long it took. Waiting times for drugs were longer in Canada at that point, for Health Canada to approve, than anywhere in the G8. You know, the Health Products and Food Branch was taking 600 days to approve a Herceptin® or something. And the FDA had just started a fast-track program for oncology agents. And [a prominent Canadian AIDS activist] was out there and had asked me to come to this conference that she did on reform of Canada's drug review system. And I think the Herceptin® book<sup>250</sup> had just been published, and so, anyway, I got involved with pulling together again another group.

-- Interview with *Eve*, 2007

As was the case with *All- Cancer Advocacy*, the main advocacy target of *New Drugs Now!* was Health Canada's Health Products and Food Branch, not the pharmaceutical industry; so from the organization's perspective, government money posed a more serious conflict of interest than money from the industry.

*Eve*: When we [*New Drugs Now!*] first started, it was about getting Health Canada to perform at the level that they said they would, which was that new cancer agents would be approved within 180 days so that they would meet their own performance targets.

If chemotherapy is only curative once,<sup>251</sup> there is, there ought to be a sense of urgency to get it right. ... and this is where I want to make the distinction – I'm only talking about cancer drugs. Because I don't know about anything else, for one thing; but again, it goes back to that sense of urgency. With cancer you get one shot at getting it right. ... So for me, Joel [Lexchin]'s argument about, 'we need to be cautious because there can be harm done' -- for the most part, with the new cancer agents, these are people for whom there aren't, there is no other option available to them! And so, we're holding back on something for this group of people who may benefit from it, but who certainly can't be harmed by it.

Sharon: Well, I don't know that fast is necessarily better.

Eve: Well, it's not fast though. I mean it's just, it's not.

The belief that no harm can be done by providing a new treatment to a person with terminal cancer is widespread. The examples of high-dose chemotherapy and Eprex® show, however, that drugs can severely compromise a patients' quality of life while providing no survival benefit (as was the case with high-dose chemo) or actually shorten the person's lifespan as recent studies of Eprex® have shown. Nonetheless, people with advanced cancer are indeed predisposed to want a potion to treat their problem and are inclined to try whatever is available. Studies of breast cancer patients have documented a willingness to accept extraordinary risks for very unlikely odds of benefit, or with a very small benefit-to-risk ratio (Coates and Simes, 1992; Ravdin, Siminoff and Harvey, 1998). This finding has important implications that I discuss in the concluding chapter. At this point I simply draw attention to the three urgent appeals to make new therapies more quickly and readily available that I described in Period One,<sup>252</sup> which illustrate the point. Each appeal was advanced by advocates with no apparent links to pharma funding: thus, while patients who spearhead drug access lobbies may be well-matched partners for the pharmaceutical industry, one cannot assume that all such lobbies are pharma funded; nor can one assume that those that are industry funded have been scripted by the pharma partner.

### 5.3.6 Canada's Cancer Plan and Pharma Funding

In 1999, a broad spectrum of health professionals, cancer agencies, and patients involved in cancer advocacy came together in an initiative called *Canada's Cancer Plan*.



As part of its contribution, in 1999 Health Canada recruited a scientist, *Gordon*, to coordinate the new inter-sectoral effort:

*Gordon*: ...the actual job title was Project Manager. And I was recruited to a part of the small unit that was obliged to manage the setup ... *Canada's Charity for Cancer Research and Support*, the Canadian Association of Cancer Agencies and some of the non-governmental organizations, such as *The Pink Foundation* ... wanted Health Canada's support. So the division within Health Canada, Population Health -- that had already set up the Breast Cancer Initiative was responsible for being the department to engage with all the stakeholders to set up a plan.

... there were just two of us [Health Canada staff] there and then we started that by engaging with all the stakeholders, in particular the very high level leaders in the cancer sector. So what I was tasked with was setting up all the committees, engaging with all the stakeholders, and preparing recommendations to the federal government. That started in 1999 and then by 2002 the strategy for the [Cancer Plan] in Canada -- which was set up by a staff of bureaucrats, very few of us, in Health Canada -- and about 700 to 800 volunteer staff, not just medical staff and researchers, but patients, survivors, volunteers and charities, etc., so that strategy was set up formally in 2002. (Interview with *Gordon*, 2008]

The pharmaceutical industry was absent from the three-year intensive planning stage but was brought in once the strategy was formally launched, according to *Gordon*, who continued to play a coordinating role. Two breast cancer activists whose engagement with breast cancer groups dated back to the early '90s assumed leadership positions in two separate organizations connected to the Plan: *Patients for the Cancer Plan* and *Advocate 4 the Cancer Plan*. The latter group had pharmaceutical companies as its main income source, while *Patients for the Cancer Plan* adopted a policy of not accepting money from the industry.

*Paula*, who had been involved in breast cancer activism since the Forum in 1993, became a co-chair of *Patients for the Cancer Plan*, a group within Canada's Cancer Plan

which represents 15 or so cancer organizations.<sup>253</sup> It functions to raise issues relevant to cancer patients and their families within the Cancer Plan. *Paula* explained her decision to transfer her energies from breast cancer groups to the Cancer Plan this way:

I felt that breast cancer had had its day in the limelight. I would never have said that at the time of my diagnosis but I felt the other cancers had not had the same attention as breast cancer and why not use the experience I had gained from working in breast cancer to help even things out? (Interview with *Paula*, 2007)

*Patients for the Cancer Plan* started as the *Cancer Patients' Advocacy Network* but changed its name because, *Paula* explained, "We wanted to take government money and we couldn't do that with 'advocacy' in the name." She and her co-chair agreed they would not take pharma money despite the fact that this limited what they could do:

*Paula*: [We] have always wanted to avoid pharma funding. Now that doesn't apply to our member organizations [i.e., groups representing various cancer disease sites – breast, prostate, leukemia, etc]. Many – I would guess most -- of our members do take pharma money. But at the higher level, we've said "No." That makes the member organizations happy because we're not in competition with them for funds.

You don't bite the hand that feeds you, or if you do, they won't fund you the next time you ask for money. Many organizations say, "They're unrestricted grants." They probably are, and probably in the case of most Unrestricted Educational Grants they don't interfere; but you know if you speak out [against something they want] they will cut you off. (Interview with *Paula*, 2007)

A second organization involved in the strategy, *Advocate 4 the Cancer Plan* does accept pharma funding and uses the money to undertake advocacy work. *Eve*, the founder of this group, did not believe that funding from the industry was a problem for a group whose mandate was to promote the broad goals of a national cancer strategy with a large cross-section of the cancer community behind it.

*Eve:* Because what we're trying to advance is the strategy. It's already determined. You know, it's seven hundred people working together over three years. ... Because the cancer strategy is actually – I don't know if you've read it or not.

Sharon: I've read parts of it.

*Eve:* So it's not about drugs. It's about a comprehensive approach to controlling cancer that includes primary prevention. ... And then it has the whole palliative care, end of life program that was developed by the National Hospitals Association. So it plugged everybody in and said, "A rising tide lifts all ships."

Sharon: But don't you think that the drug companies still expect to get something from it? I mean, it's not an altruistic arrangement.

*Eve:* Yeah. I think the shift is that groups like ours [*Advocate 4 the Cancer Plan*] really do bring an added value to the table, and that is because we brought a collaborative effort across the cancer community to bear on a change in public policy. And that wasn't directed towards [drug] access but was a comprehensive approach. ... And so, the priorities – I mean if it had been primarily pharmaceutical industry interests, you'd probably see -- that would be the focus. Well, who's going to buy that? That's pretty easy to dismiss. ... I don't think you'd get much buy-in that this is in the public interest.

I think most people would say, one, it's shareholder interest they're promoting. And there's a point where shareholder interest isn't the same as public interest. So we [in *Advocate 4 the Cancer Plan*] represent sort of, I think a mediating impact on what the pharmaceutical industry would be asking for, which I think is basically a wide-open formulary: anything that they invent that's new, every government should approve it.

(Interview with *Eve*, 2007)

*Jillian* became involved in Canada's Cancer Plan as part of *Advocate 4 the Cancer Plan* and she felt a palpable tension between the pharma-funded advocates and those who opposed pharma funding.

*Jillian:* There's always been a huge war between people within the community, between those who accept pharma funding, as if it were black

and white. You know, the pharma-takers, and the sanctimonious ones on the other side who feel they've never been tarnished by that conflict. And the *Cancer Plan* was kind of a classic war of those oppositional views.

Sharon: I don't think I've ever heard anyone say it that strongly, that there's been a "huge war." I mean did you sense it as really that strong?

*Jillian*: Absolutely! I felt that there were patient groups that, I mean, I remember [another advocate] being incredibly sanctimonious about saying, "You just can't touch pharma funding," and taking that to an extreme level within the *Plan* itself. Those were the dividing lines. (Interview with *Jillian*, 2007)

*Advocate 4 the Cancer Plan* continued to have pharma funding as its main revenue stream and took a lot of heat for that, says *Jillian*. She feels, however, that the patient groups that were part of *Patients for the Cancer Plan* were hamstrung by their own embeddedness within the *Plan* itself.

Sharon: Can you explain that a little bit?

*Jillian*: Well it was seen by Health Canada that if the patient component was being funded by public dollars, that advocacy was not part of their activity menu. So even though you have patient representation, you don't really have an effective public voice.

Sharon: And that's because of the government's views on advocacy?

*Jillian*: Yeah. And that was told in no uncertain terms to the patient groups, like *Patients for the Cancer Plan*, the patient arm of the *Plan*.

Sharon: So what did they expect *Patients for the Cancer Plan* to do?

*Jillian*: They expected a kind of patient pool to provide a volunteer advisory service to confer credibility on the process.

*Gordon* remembers both the contestation between the groups representing patients' interests on the *Plan*, and the prohibition against the government funding a

group engaged in advocacy. The *Canadian Cancer Plan* had a large number of committees developing action plans in different areas and each one needed volunteers who were either ex-patients or current patients, or family or friends of patients, he told me.

*Gordon:* So what I did was I got all the other organizations to agree to combine into a network and I then got them to vote for its committee who could then decide on who would be attending ... It was called at the time *Cancer Patients' Advocacy Network*. And then I suggested that they call it something else, because it's not allowed for the federal government to provide any funding for an advocacy network. So I said, "Okay, well, I can only have meetings for cancer patients' networks. So, you can attend those meetings and then I can fund." So I set up the meetings a couple of times a year. ...

And early when I was working there, the *Cancer Patients' Advocacy Network* were trying to get me to try and obtain funding for them, because they wanted to do a lot of advocacy. And I had to do lots of lectures then, explaining the federal government cannot fund advocacy projects.

Early in the interview, *Gordon* had explained to me that he immigrated to Canada in 1991. As we talked about the government's prohibition on funding advocacy I realized he might not be aware of the earlier policies that nurtured organizations to speak on behalf of marginalized populations within Canada, so I asked him about this.

*Sharon:* When I've looked in the literature on funding of groups, it used to be that the government would fund, basically, advocacy groups.

*Gordon:* Well, they would fund charities, and then there was a change, where the government stopped funding charities a lot. But then it started putting in a lot of tax benefits for donations to charities. ... I think that's what changed. Because I remember when I entered Health Canada, I'd be dealing a lot with charities who were moaning about not getting a lot of money from Health Canada. But there were some grants, very small grants that they could apply for, for particular projects.

*Sharon:* Yeah. But they became much more tied to doing service work.

*Gordon:* Yes, likely because maybe when they got a lot of funding from the federal government, then they were happy: “Okay we can provide services, a lot of services.” But then that must have changed.

Sharon: I mean there used to be funding to give the groups so the groups could actually do the preparatory work and the research that’s necessary to advocate effectively. And then that became no longer acceptable within the government.

*Gordon:* Absolutely not! Because one of the things I set up when I was doing the, working on the *Cancer Plan* was, we definitely needed patient survivors, or people who were focused on patient outcomes, or patients to be part of our committees. ... Because you want to have that kind of perspective when you’re discussing things and making decisions, to understand what it is to be a patient, what would be the impacts, etcetera. And in all the committees across the cancer control continuum that we set up ... we had to decide on how we can find particular volunteers who are either ex-patients or current patients, or family or friends of patients. And even when I decided to leave the Public Health Agency, early when I was still working there, The *Cancer Patients’ Advocacy Network* was trying to get me to try and obtain funding for them.

Sharon: Yeah. Well, it used to, though, that’s the thing. ... It was seen as part of democracy, that groups that don’t have the kind of funding that, say, a corporation would have, should also have a voice in the system and that that makes things more democratic.

*Gordon:* Oh?

Sharon: And so, yeah, that’s actually something that’s quite interesting from the perspective of my project.

*Gordon:* Yes, that is very interesting! So now they have to get funding from those industries. ...

Sharon: Yes. Yes, or raise it having runs and breakfasts and who knows what kinds of things they have to do to try to scrape together funding. But that used to be considered democratic, to have these groups that were actually funded to do advocacy. ... So it’s just interesting that, it sounds like you take

it as a given that the government wouldn't do that, when in fact it's a sort of a ...

*Gordon:* Well, they would have to have a very good process of deciding what can be funded and what cannot. And also of course what the benefit for our country -- not just democratic thought.

Sharon: Um-hmm.

*Gordon:* But actually, it would enable us to get a better perspective of what our, our whole country's humans want and desire. So that would make sense to fund advocacy if a lot of the groups or actions of a country are unable to be communicating to the country and government because they cannot apply for funding just to be advocates. ...

Sharon: Well, some of the people I've talked to have said that *Patients for the Cancer Plan* is actually pretty ineffective because they don't have a budget.

*Gordon:* Well, they don't. And the only money I provided was to set up meetings. And even then, they wanted, "Oh, we need consultants or managers. We need to hire [them] to do advocacy work." And I said, "No. I cannot apply for funding for that."

Sharon: And what, where did you get that? Was that something that was told to you, or was that a written rule or what?

*Gordon:* Oh yes. I think it's a written policy. Yes. Or it was told to me, within the Public Health Agency that no, we can't fund it. I don't know if I saw a formal written policy. Maybe there was somewhere, but maybe I hadn't seen it.

### 5.3.7 Interpretation of the Contestation Period

The Contestation Period reflects a shift within the pharmaceutical industry from the sporadic, small grants to patients' groups that I described in the Grass Roots Period to a practice of long-term alliances and larger grants given to groups that share the perspective of the industry. Whereas in the Grass Roots Period, groups responded to

industry overtures with a degree of confusion and debated the issue internally based on experiences and knowledge (or lack thereof) from other contexts, in the Contestation Period, the discourse within groups begins to take formal shape with the production of documents and debates in public venues. Within the industry, the norms for ethical and successful relationships also develop a formal structure, in which “best practices” are discussed and codified. Industry documents, books and conference presentations show that the practice of funding organizations is developing into a valued area of expertise. The contrasting discourses within breast cancer organizations that favour or oppose pharma funding begin to restructure the community itself, as the issue becomes one basis on which groups form or sever allegiances. These group allegiances cross disease boundaries; patients’ organizations and patients interested in advocacy begin to regroup into coalitions defined, not by disease but by their understanding of the ethics of pharma funding and whether such funding expands or undermines the community’s knowledge of medications.

At the core of the contestation are different understandings of the meanings of the risks and benefits of cancer medications, about patients’ rights with respect to medications, and of advocacy. Do rights revolve around rapid access to new medications and access to all who might benefit regardless of price? Or are rights with respect to medications defined in terms of safety, protection from fraudulent claims and equitable access to a limited basket of drugs that fall within budgetary constraints? Can these contrasting perspectives be balanced? How is “truth” about a drug’s risks, benefits and monetary value determined? What is advocacy, who gets to engage in it, and how should such work be funded?



The developing discursive theme that patients have a right to new medical treatments coincides with evidence that the industry has begun to take a systematic approach to funding patients' organizations that will advance their corporate goals and is willing to invest relatively large sums of money over long periods to do so. In three of the organizations I discussed (*The Hub*, *All-Cancer Advocacy*, and *New Drugs Now!* the pharma funding aligns with messages that promote faster approvals and adding drugs to formularies. Despite challenges, both *the Hub* and *All-Cancer Advocacy*, succeeded in mounting campaigns to promote awareness and acceptance of novel treatments for breast cancer patients. *The Hub's* agreement with Ortho-Biotech, to highlight anemia as a problem from which its members might suffer, did not promote the company's drug Eprex® directly. Rather, the promotional strategy was based on the same principles as what the industry calls a "help-seeking ad." This type of campaign raises awareness of a condition and encourages those who might be suffering from it to seek medical help, just when the company is promoting a drug for the conditions among physicians. *All-Cancer Advocacy's* campaign advanced on a number of fronts and was designed in part to position the group as an opinion leader in cancer policy. Its advocacy campaign was framed to raise the public's anxiety about the adequacy and accessibility of cancer treatments in Canada general, and new chemotherapy treatments in particular. I focused on the group's advocacy to promote a particular new chemotherapy regimen (AC+T) onto the menu of standard adjuvant therapies for breast cancer. In the case of *Helping Hand's* shift in position to allow pharma pharmaceutical company, a staff worker involved with the organization's peer support and information system expressed concern

that this transition could affect the quality of information, but did not believe this had occurred at this point.

A discourse separating patients' groups into those that are pharma funded and free to engage in advocacy, and those that are government funded and better suited to service provision, was reinforced through the *All-Cancer Plan*, a broad-based coalition of cancer researchers, cancer treatment specialists, cancer policy makers, and cancer patients' groups. A network of groups that received very little funding from government and (by choice) none from industry provided volunteer consultation services to the Plan and lent it a legitimacy based on including "the patients' perspective" in the Plan. This organization was not allowed to engage in advocacy however; a second Coalition, which included patients but also members from other sectors, was funded by the industry and given the specific mandate of being an advocacy group for the Cancer Plan.

In short, the Actor-Network translation developed at the *Together to an End* conference has continued the process of *enrollment*, in which the lead actors define the roles of others in a manner that helps align scientific truth with the vision and interests of those actors. The actor-network begun at *Together to an End* has effectively *mobilized* by founding several important new organizations (*All-Cancer Advocacy* and *Advocate 4 the Cancer Plan*) that subscribe to and promote its discourses. While the contestation period was one of internal disruption for both the *Hub* and *Helping Hand*, by the end of the period both groups have effectively converted to a funding model which includes pharma sponsorship as one source of funding (these groups are arguably the two most important breast cancer organizations that emerged from the post-Forum expansion: the *Hub* because it remains the national coordinating body and advocacy voice for the local and

regional groups, and *Helping Hand* because of its role in providing information to women making decisions about breast cancer treatments. *Helping Hand* began as a Toronto-based Ontario service but by the end of Contestation Period has begun to expand its service to other provinces.

## **5.4 2002-2011: THE PARTNERSHIP PERIOD**

### **5.4.1 Introduction**

In this section I discuss the Pharma Partnership Period (2002-2011), the third phase of the translation. Funding from the pharmaceutical industry becomes the norm among Canadian breast cancer organizations for their advocacy activities, with only a small number of groups resisting the practice wholly or in part. Critical events include the production of documents that provide a consensual platform on which many breast cancer patients' groups make common cause with the industry and a parallel counter-discourse documenting resistance to pharma funding; the creation of documents and practices that normalize partnerships with the industry; and a struggle over the meaning of patients' rights and the right to medications. The appearance of *aromatase inhibitors* as new entries in the field of costly new treatments for breast cancer provides a case study in translation with respect to patients' groups and breast cancer drugs.

I first summarize a number of changes in the socio-political landscape in which the groups are working. Second, I present two types of evidence of normativity: the proliferation of prescriptive texts which detail how the partners on both sides – the industry and the groups – should proceed to build a successful partnership; and actual examples of partnership arrangements and projects which were entered into in a routine

manner (Table 5.6). The dominant discourse assumes that such partnerships are a fact; the discourse of the Contestation Period, on the potential advantages of pharma-patient group partnerships, shifts to incorporate the awareness that such alliances are potentially risky to the partners. The emphasis the Partnership Period is on how the groups and companies can configure their relationships to avoid the pitfalls, meet ethical standards and ensure lasting, mutually beneficial alliances. I document examples of resistance with texts and cases that show the impact on treatment advocacy of this new configuration. These examples reinforce my interpretation that contesting the ethics of pharma partnerships and their benefits for patients is now an outlier position.

I relate the shift in emphasis over partnerships to a parallel discourse over breast cancer drugs, drug prices, and whether access to expensive new drugs is a right. By the end of the Partnership Period, the absence of funding sources for groups that played an industry watchdog role all but silences any critique of pharmaceutical policies from the civil society sector. I argue that, meanwhile, the partnership projects directly or indirectly have reconfigured the discourse on patients' rights with respect to drugs, away from safety, efficacy, affordability, and accurate information, to a rights rhetoric that emphasizes rapid access to new drugs regardless of cost and before scientific evidence has met the standards generally agreed on in the scientific community. I examine this *translation* of rights rhetoric in relation to patients' rights documents developed by the federal and provincial governments. Finally, I draw on actor-network analysis to assess the transformation in group discourses on pharma funding, drugs, and pharma policies over the three periods.

#### 5.4.2 The Drug Advocacy Discourse Changes Course

##### *Pharma's prescriptive texts on successful patient-group partnerships* A

characteristic of the Second, or Transitional Period was the appearance of prescriptive texts on why and how pharmaceutical companies should and could go about forming partnerships with patients' groups. Evidence that these relationships are an accepted practice by the beginning of the Partnership Period, in 2002, is found in documents that continue this theme, but with a shift in tone. Rather than reporting on the phenomenon as something new, to be explained and promoted, texts now assume companies have some familiarity with the concept but need to improve their game. One way to do this, two articles in *Pharmaceutical Executive* explain, is to take a third party on board, the public relations (PR) company (Cox 2002, Brietstein 2002). The PR company is described as a kind of matchmaker, someone with contacts throughout the corporate and non-profit communities who can help "introduce [a company] to the right partners" (Brietstein, 2002: 68). These matches depend on identifying common terrain for the two sector and, at the beginning of the Partnership Period, PR companies help steer the industry to the specific areas of mutual benefit for companies and patients' groups. One twenty-year veteran of the PR firm Hill & Knowlton, who is both a former cancer patient and a one-time press agent for the FDA, identifies this common ground as access to expensive treatments:

The middle ground came about with baby boomers who, unlike older patients, felt they should be involved in their healthcare and should challenge physicians' decisions.

Pharma companies, particularly those with state-of-the-art treatments, recognize that empowered patients are more likely to want the best treatments

and the newest therapies, even though they might be the most expensive, and will readily engage physicians in getting that care. (Breitstein 2002: 68).

Beyond the one-on-one encounter with the doctor, the same PR veteran explains that advocacy organizations can further advance this common interest by virtue of the fact that they understand the options and resources available to patients: “With that information, patients might decide they want the more expensive therapy, and if needed, advocate access and reimbursement to get it” (Breitstein, 2002: 68).

Once public relations (PR) companies were recognized as integral to the success of a pharma company/patient group partnership, these companies began to produce documents of their own, designed to establish their reputations as knowledgeable, successful matchmakers. Like pharmaceutical companies, many PR companies have a global reach. One example is Cohn & Wolfe, a PR company with offices in Europe, Latin America, the Middle East and North America, including three in Canada. In 2004, the company’s Toronto office conducted a Partnership Survey of twenty Canadian organizations, including corporations in the pharmaceutical sector, and non-profit organizations in health, among other sectors. The purpose was to gather information from companies and non-profits which had experience working in these arrangements that would “help its clients navigate the shifting landscape of partnerships” (Cohn & Wolfe 2004: 1; also, see summaries in Reed, issues No. 3 and 4, undated). The survey asked respondents what they perceived as the greatest barriers and challenges to success, as well as the greatest opportunities; the Cohn & Wolfe report then mapped emerging “best practices,” and identified distinctions between “challenging” partnerships and those that worked. The 40-page report emphasizes the company’s “more than 13 years of experience creating such partnerships” (ibid: 1). The fact that a major PR company would

invest in such a study implicitly signifies that corporate non-profit partnership brokering is an expanding business opportunity for the companies, and one in which Cohn & Wolfe seeks to establish itself as a leading actor.

The report affirms that corporations are adopting a more strategic approach to choosing partnerships, discarding an outmoded type of “cheque book philanthropy” (ibid: 15) -- also characterized as “spray and pray” (ibid: 11) -- to a focused model that might mean writing fewer but larger cheques, and seeking “two-way ... reciprocal partnerships” (ibid: 10) that satisfy “broader corporate goals, such as enhancing corporate reputation, obtaining assistance with government relations, or building a customer base” (ibid: 1). These relationships were more likely to be ongoing than one-off and “multi-layered,” involving decisions made by committees within the company that represent more than one department.

For non-profit organizations, the report notes that ethical concerns are at the forefront; they realize their credibility is “their most valuable asset and they don’t want to jeopardize it” (ibid: 37). In recognition of this more engaged, often long-term type of relationship, companies and non-profit groups alike had developed tools for regular, honest communications. These might include written agreements or (because agreements were sometimes seen as too rigid) a looser document outlining “principles of partnership” along with a checklist to evaluate the potential partner against criteria such as ethical considerations, shared values and goals, credibility, and influence with, or access to, key stakeholders (ibid:28) In addition, all the companies in the survey expected the groups to measure the impact of the program they were supporting, by showing in advance that it had:

...put meaningful metrics in place. Not only do businesses want to know how a partnership will affect their bottom line; they also want to see the non-profit demonstrating a positive impact on those communities it serves. (ibid: 19).

Cohn & Wolfe's report suggests that, not only are corporate/non-profit partnerships evolving as area of expertise in which actors on both sides must become well-versed if they are to successfully navigate its hazardous shoals, but such partnerships themselves are sites of knowledge production and knowledge-sharing that help the two parties maintain a leadership edge in their respective communities.

Other industry publications reinforce the assertion that maximizing sales is not the only motive for working with patients' groups. The pharmaceutical industry learned from the attacks of some early AIDS groups on pharmaceutical companies that patients' groups had the potential to damage the industry's reputation; thus, as the phenomenon of patient power spreads to other disease and conditions, the pharmaceutical sector has recognized its collective interest in cultivating relationships with the patient group sector and in demonstrating sensitivity to patients' needs. Thus, Karen Miller, AstraZeneca's "director of ally development", relates that when the company began marketing tamoxifen as a preventative they "authorized an ad agency to develop patient education materials for Nolvadex (tamoxifen) before getting patient input. 'By the time the materials were created we realized they contained wrong information,' Miller says. 'We learned our lesson. For Arimidex®, we worked with the advocates.'" (Brietstein 2001:6).<sup>254</sup> In this spirit, the company Novartis carefully managed its relationship with patients during the development and launch of Gleevec, an expensive treatment for the relatively rare cancer, chronic myelogenous leukemia (CML):



The early example of AIDS patients transformed into activists against pharmaceutical enterprises who thought they had done a great thing in bringing the first AIDS drugs to market gave all of us at Novartis pause. We had to display our concern for CML patients; we had to show them that Novartis was doing all that it could to speed the production of ST1571 [i.e., Gleevec]. (Vasella and Bloomgarden 2003)

Such articles<sup>255</sup> depict today's "knowledgeable patient," who monitors websites and knows when a promising new drug is in clinical trials, as an entity to be respected and even feared within the ranks of industry. From this perspective, pharmaceutical companies have little choice but to understand what patients and their organizations value and to build and maintain their trust.

Like the Cohn & Wolfe report, a 60-page guide titled *Patient Advocacy & Professional Organizations: Building Effective Relationships*, published in 2004 by a pharmaceutical research firm in North Carolina called Best Practices, LLC, underscores the point that the practice of partnerships with patient groups was well-entrenched within the industry in the early 2000s (Anonymous 2004). As advertised on the company's website, the book boasts a price tag of U.S. \$4,950.00 and for this reason I was unable to obtain a copy. The promotional text on the company's website<sup>256</sup> is detailed however, and lists the book's table of contents, charts and exhibits, leading companies profiled,<sup>257</sup> the questions the study set out to answer, and key findings. The following promotional text describes the importance of knowledge as a reciprocal commodity in the partnership arrangement:

This Best Practices Benchmarking® Report includes best practices and case studies to help companies create internal structures, mechanisms for coordination and operational tactics that lead to successful relationships with key patient advocacy groups and professional organizations. By reaching patient advocacy groups and professional organizations, companies inform thought leaders, prepare the marketplace for upcoming products, impact

policy, gather market intelligence, and gain valuable feedback from patients.”

Website of *Best Practices, LLC*®

One “Key Finding” for building successful relationships listed in the promotional blurb is the value of having a consolidated unit within the company responsible for interacting with the groups (it recommends that the in-house unit be “housed in marketing or corporate affairs”). Companies are also advised to develop criteria for ranking the groups by their “strategic importance.” The advertisement identifies patient group relationships as essential to a company’s marketing strategies and promises to spell out criteria for sorting through the large and confusing array of patient groups so that companies can “target efforts toward organizations with the greatest potential impact” (ibid).

In the dominant discourse, however, the question of whether the partnerships are intrinsically beneficial or ethical is no longer a preoccupation; the central questions are how to make them succeed, to define what ethical standards they should meet, and to determine how these two goals should be accomplished.

*Cancer groups develop an ethics rationale for pharma funding* Within groups that had formed alliances with pharmaceutical companies, parallel discussions took place to identify strategies for success and to respond to ethical concerns. Pat Kelly, one of the founders of *All-Cancer Advocacy*, played a lead role in advancing these discussions. In 2002 she completed a Master’s thesis titled, *Begging Your Pardon: Exploring the Impacts of Pharmaceutical Industry Funding of Non-Profit Organizations*. In it, she examined the debate in Canada about pharma funding of non-profit groups from her perspective as an advocate and former cancer patient who chaired the board of an organization (“*All-Cancer Advocacy*”) that received most of its funds<sup>258</sup> from the

pharmaceutical industry; she also identifies *All-Cancer Advocacy* as the sponsor of her thesis research project.<sup>259</sup> Interviews with key informants from seven other organizations that receive funding from the industry, and with seven representatives from two pharmaceutical companies that fund non-profit organizations, provide a detailed picture of how participants in these alliances understand and address the ethical issues.<sup>260</sup> *Begging Your Pardon* thus serves as a comprehensive articulation of the perspective of these actors *vis à vis* their industry funding and their critics at the outset of the Pharma Partnership Period.

A recurring theme is a sense of grievance on the part of leaders within pharma funded organizations who believe they have been unfairly attacked by those opposed to industry funding; they are presumed guilty without evidence. Several who, like Kelly herself, had agreed to appear in the *Marketplace* program felt they had been set up and humiliated to the detriment of their organizations. In Kelly's view, such tactics reflected a cultural malaise one writer has dubbed *The Argument Culture*,<sup>261</sup> a mode of interaction that fosters a "spirit of attack."

Groups established to respond to the needs of people harmed by pharmaceutical products, or advocating for primary prevention of disease, might understandably oppose pharmaceutical company funding, she observes, but they can't and shouldn't speak to needs of people who need pharmaceuticals to treat their conditions. Critiques of pharma funding, when aimed at groups with a different purpose, can thus "contravene the democratic and social justice principles that NPOs [non-profit organizations] share" (ibid: 74). She argues that such injustice is done when these groups "undermine public confidence in NPOs that have received funding from pharmaceutical sponsors, while at

the same time these NPOs can and do clearly demonstrate accountability and transparency in relationships” (ibid: 74). She suggests that groups critical of pharma funding “may have a stake in manufacturing conflict and polarization” (ibid:74); by contrast, alliances between non-profit organizations and the pharmaceutical industry strive to “foster the values of trust, collaboration, information sharing, horizontality, networking, negotiation, consensus and flexibility” (ibid: 40).

Using “*All-Cancer Advocacy*” as an example, she locates the eye of the storm in the interest pharma funded groups have in gaining access to new drug therapies.

The intersection of interests between “*All-Cancer Advocacy*” and pharmaceutical sponsors is specifically in the area of timely access to evidence-based treatment and diagnostic therapies. As such, “*All-Cancer Advocacy*” members advocate for changes to the drug review system and to provincial formularies such that cancer patients will gain safe, efficient access to evidence-based therapies .... While “*All-Cancer Advocacy*” does not limit advocacy efforts to improving access to drug treatments, it is because of the overlap of interests between the goals of “*All-Cancer Advocacy*” and the pharmaceutical industry that controversy arises. (Kelly, 2002: 6-7)

Her research found that non-profit organizations had indeed collectively mobilized their resources to reduce federal and provincial barriers to accessing new drug treatments, acting for the “repressed interests” of patients and their families:

These advocacy efforts have arisen in response to both member demand and public expectations that NPOs act to serve as public champions, especially with regards to complex health policy. (Kelly, 2002: 101)

From the perspective of the groups that receive pharma-funding, those that refuse funds from the pharmaceutical industry but accept funds from the government (Kelly cites *Learn from Drug Tragedy, Critical Advocacy to Prevent Cancer and Pharma Policies to Protect Women’s Health*) are not only privileged, but their own funding

source represents a conflict-of interest that undermines their ability to criticize government policies. She identifies the government's ten-percent rule limiting the amount of donated money registered charities can spend on advocacy as a further barrier for groups with charitable status that see their mandate as advocating on behalf of patients.<sup>262</sup>

The central claim of Kelly's thesis is that pharma-funded organizations like *All-Cancer Advocacy* can, and in her experience do, function ethically and maintain arms-length relationships from their industry sponsors. She also concludes that the phenomenon of the so-called "Astroturf" groups -- industry-created organizations that lobby for corporate interests under the guise of being a community-based, public-interest organization -- is largely mythical, but has nonetheless tarnished the partnership concept (she was aware of only one organization in Canada that she considered an Astroturf group).<sup>263</sup> Participants in her study could cite only a few instances in which companies committed "infractions," such as efforts to control editing of materials or to use logos inappropriately (ibid: 94); with one exception, the organization was able to resolve the conflict through discussions with the company in question. Public opinion, she asserts, is moving to a position of support for the partnership model as a way that corporations can demonstrate social responsibility. A society that promotes capitalism, she argues, by extension, "promotes a social contract imposing an obligation [on corporations] to consider public interest" (ibid: 110).

Although she concludes that the alliances between pharma companies and non-profit groups in Canada have shown they can function accountably under a self-regulating model, Ms. Kelly notes that "broadly recognized Best Practices" are lacking in

both sectors (ibid: 100). She proposes that groups and pharmaceutical companies alike should work to further develop “frameworks for principled relationship-building” (ibid:110), to defend themselves against media challenges, and to maintain public trust.

Despite the growing trend of cross-sector partnerships, it is not enough to welcome the new hybrids with open arms. For those groups who choose to pursue corporate alliances, it will be necessary to clearly articulate the terms and the outcomes, and be prepared to develop effective, flexible self-regulating mechanisms. Distinct boundaries must be maintained to safeguard against the “Astroturf” phenomena that drives media rhetoric and undermines public trust. Accountability and transparency in these transactions are the methods that will safeguard and justify public confidence. (Kelly 2002: 122)

*Moves to transparency and disclosure by pharma and the groups they fund* In keeping with these calls -- from within the industry and from the community of pharmaceutical groups -- for more systematic attention to ethical principles, the Partnership Period saw the development of formal disclosure guidelines. Non-profit organizations, the industry and the federal government all created such documents (see Table 8).

Among non-profit groups, *The Hub*, as mentioned, had introduced Guidelines for corporate partnerships in October 2001 and *Advocate 4 the Cancer Plan*, a group which *Eve* co-founded in 2001, has a Sponsorship Agreement which it uses to spell out the terms under which it accepts funding from corporations. Both agreements include a clause saying the organization will not endorse or promote a particular product; *The Hub* further states that the organization “will be prepared to disclose publicly any responsibilities to the partnering organization”.

Within the industry sector, in January 1, 2009, the lobby organization for the Canadian brand name pharmaceutical industry, Canada’s Research-based Pharmaceutical Companies, (known by the acronym Rx&D and formerly known as the Pharmaceutical

Manufacturing Association of Canada or PMAC<sup>264</sup>) similarly responded to criticisms about conflicts of interest and lack of transparency, issuing “Guidelines for Transparency in Stakeholder Funding” (Rx&D, 2009a). The content had been ratified at the November 2008 Annual General Meeting. Along with an “Interpretation Document” (Rx&D, 2009b) and an additional explanatory “Q&A” document (Rx&D, 2009c), the guidelines were framed particularly to apply to relationships with “patient groups, consumer groups, advocacy groups, associations of health care professionals and the not-for-profit business sector” (Rx&D, 2009c).<sup>265</sup> A preamble listed seven Principles and eight Guidelines which addressed many of the issues that had been raised in texts critical of the industry. The preamble asserted that it was “natural” that the pharmaceutical industry should work together with stakeholder groups, given the range of their mutual interests (Rx&D, 2009a); however, it stated, the industry realized that the potential existed in these relationships for real or perceived conflicts of interest and was therefore committed to “transparent, trustworthy and credible” relationships (ibid:1). *Principles* affirmed the priority of the health and wellbeing of patients, the independence and integrity of stakeholders, the need to avoid conflicts of interest in interaction with stakeholders, the transparency of funding relationships, and the need for clearly delineated parameters for joint activities. *Guidelines* advised companies to disclose lists of stakeholders to which they gave direct funding, to avoid joint activities designed to promote specific medications, and to avoid creating patient groups for the sole purpose of furthering market access (what pharma critics refer to as Astroturf groups). The interpretive *Guidelines* and the *Questions and Answers* included the specification that projects and agreements that began before January 1, 2009 would be grandfathered and that Rx&D

would not (“for now”) monitor companies or penalize those that did not comply. The *Guideline* was meant as a “living document,” subject to modification as the industry lobby group receives feedback and requests for clarification (Rx&D 2009c).

In separate interviews, *Eve* and *Jillian*, two of the activists who had worked in alliances with drug companies using formal agreements, discussed how they had experienced the process working in practice.

*Eve*: When we meet with them, we say we’re looking for funding for particular projects. For *Advocate 4 the Cancer Plan*, we develop our own business plan every year and we use the Project Logic Model. I don’t know whether you’ve seen it.

Sharon: No.

*Eve*: It’s just a quick one-page charting that shows, “These are our program areas, these are our targets, these are our messages, and these are our outcomes.” And it sort of gives you a nice flow: “That’s what we’re going to do for the next two years, and this is what we’re asking *you* for.”

So they don’t get to cherry-pick. [They don’t get to say,] “Yes, I want my name on your web site but I really don’t want to fund a meeting in Kakabeka Falls. We’re not really interested in that.” You have to do the whole ball of wax. And you can do it at different levels, but you don’t get to say what part you can do or don’t do. So we don’t change what we’re going to do based on your involvement or your money. We just let you know, “This is what we think needs to be done in the next year or so.” So that’s what they get.

Sharon: When you say the groups should make their agreements public, what would a typical agreement be like?

*Eve*: Basically it says, “This explains who we are and what our values are. And this is what our project plan is going to be for this year. This is our track record. This is how we have influenced government. This is the metrics, the outcome of this group for the last three years. And this is what it costs.” So you publish your financial statement and you say to them, “and this is what we’re asking you for, and this is what you get in return for that.”



Sharon: So what *are* they getting in return?

*Eve*: They get to be part of the *Canada's Cancer Plan*, same as anybody else.

Sharon: They get their name on the ...

*Eve*: Same as every other group. So, I hear what you're saying. You would assume if they're there, and they're fat and influential, they're going to demand return on their investment. They get what everybody else gets – better cancer control. They get their name on the list.

(Interview with *Eve*, 2007)

*Jillian* had been involved in cancer activism for about eight years when I interviewed her and had worked with a number of groups and projects that were funded by the pharmaceutical industry, as well as participating on a variety of government-run cancer committees and forums. Because the companies usually have a one-year or two-year corporate plan, the non-profit organization would usually meet with the company a year ahead of a project they were asking to have funded.

*Jillian*: In the early days, I would help with fundraising so I would attend some of the [discussions]. And it was really hard work to get money out of those people.

Sharon: Oh really?

*Jillian*: Oh, yeah, absolutely! And you have to present yourself as a well-run business. You have to show the kind of work that you're doing, and that it's got accountability and coherence. It's tough work. (Interview with *Jillian*, 2008)

As a precaution, the groups she was involved with always obtained funding from more than one source to mitigate the potential for any tendency a funder might have to push a point of view or product. And, she emphasized, in none of these projects had she ever been asked by a pharmaceutical company to do anything that offended her editorial

sense; in fact, she had “never been asked to do anything by a pharma company” (interview with *Jillian*, 2008).

*Canada’s drug regulator responds to the pharma funding issue* Within Canada’s federal government as well, the idea of alliances between non-profit cancer entities and the pharmaceutical industry gained normative status during the Partnership Period. Health Canada’s regulator, the Health Products and Food Branch developed a document titled the “Voluntary Statement of Information Form for Public Involvement,” designed to “recognize the importance and value of openness and transparency in public involvement activities and decision-making processes” (Health Canada 2008). The Branch, which is responsible for evaluating and approving new drugs and medical devices, had set up an Office of Consumer and Public Involvement (OCAPI) in 2001 to demonstrate its commitment to public involvement in its activities and decision-making processes. The (VSI) was instituted, at least in part, in response to criticisms from groups that saw pharmaceutical funding as a conflict-of-interest. Groups like *Pharma Policies to Protect Women’s Health* noted that the individuals selected to represent the public on panels, committees and other forms of consultation related to drug regulation were often from organizations sponsored by the pharmaceutical industry.

The VSI, which went through several iterations (Health Canada 2004, Health Canada 2008), asks a series of questions, including whether the individual, and/or an organization to which she belongs, has either a direct or indirect financial interest in “an organization or company likely to be affected by the outcome of this public involvement activity” (OCAPI 2008: 5). The form remains wholly voluntary, that is, an individual can decline to respond to any or all of the questions and still participate in the public

involvement activity; or, s/he can fill out the form and decline to give the Health Products and Food Branch permission to make the information public. According to a preliminary version of the form, Canadian law required the form to be voluntary because the federal Privacy Act obliges the government to make disclosure of personal information voluntary. According to OCAPI, this constraint on transparency precludes the government insisting on information about funding to an organization with which the individual is affiliated, even if that person is participating in a consultation process that could have an impact on the public's health (OCAPI 2004:3, Note 1).

The *Canadian Cancer Plan*, set up in 1999 with logistical support from Health Canada, also adopted a policy that allowed it to accept funds from the pharmaceutical industry. *Gordon H.* (pseudonym), who was hired by Health Canada to coordinate the various volunteer committees of the Plan, described the reasoning behind the policy and the process by which it was adopted.

*Gordon H.*: So the decision was that yes, we should not ignore ... the private sector, or we should not keep them out of the Cancer Plan completely. ... But what our [Governing] Council decided was, if the pharmaceutical industry [should] say, "Yes, we're able to provide you some funding for your clinical guidelines group," then we do have some acceptance: "OK, you can provide us for [that] just as a generic grant support." They can't insist on any outcomes or intellectual property [reverting] to them, it's just a free grant. And that's something that a lot of the cancer agencies in this country have accepted. ...

Sharon: Is that the same as an "unrestricted educational grant"?

*Gordon*: Exactly, yes. And there could be agreement – they could say, "Oh, we'd really like to be told what your committee eventually decides on something, just out of interest, as long as it's ok for you to provide it to our industry" – those kinds of collaborations, so that's fine. (Interview with *Gordon H.*, 2008)

The federal government's embrace of corporate partnerships as a normalized means of supporting civil society groups complemented the process of stripping equality-seeking civil society groups of government funding. While the Liberal Party, which held power from 1993 to 2006, had defended the defunding of civil society groups as a necessary cost-cutting measure (Smith 2005), it also recognized the political and social toll this strategy had taken. The five-year Voluntary Sector Initiative (1996-2001) was an attempt to repair some of the damage that had accrued by delegitimizing civil society groups (Brock 2003b). When the Conservative Party took power in 2006, the Conservatives revived the discourse of demonization which it justified with an overtly political motive,<sup>266</sup> a plan to incrementally shift the country's values from "liberal" to "conservative." Political scientist Tom Flanagan, a former advisor to Prime Minister Harper, explained in a book and subsequent radio interview that part of the Party's strategy for accomplishing this ideological shift was to defund groups that the Conservatives view as having been cultivated by the Liberal Party. Among the groups Flanagan termed "Liberal outrider organizations," which the Party assumed to be hostile to the Conservative ideology and agenda, were, "feminists, gay-rights activists, law professors, aboriginal leaders, environmentalists, etcetera" (Flanagan 2007:264).<sup>267</sup> In an interview on CBC radio's political affairs program *The House*, Flanagan elaborated on this strategy:

Over decades, Liberals built up these kinds of organizations. It's partly a question of who gets money. It's also a matter of giving access: who gets to have meetings with Ministers? Defunding is part of it .... It's not something that's going to happen all at once, but I think we want to get back – I hope we'll get back – to more of a situation of neutrality where civil society organizations are expected to make it largely on their own resources...". (Petty 2007).

Consistent with this position, in the Partnership Period women's organizations that had depended wholly or in large part on funding from the federal government had their funding sharply reduced or eliminated entirely, particularly if they had been involved in advocacy – a shift that encountered resistance from many community organizations, as well as from Opposition parties in Parliament (Status of Women Canada, 2007). Several women's health groups that had focused on pharmaceutical policy lost funding they had received through programs at Health Canada: *Learn from Drug Tragedy* ceased operations in 2009 and *Pharma Policies to Protect Women's Health's* had its funding from Health Canada cut in half in 2009 and 2010 and eliminated entirely at the end of March 2011. *Buyer Beware*, a national consumer watchdog which had been an influential force since the 1950s, was crippled by the loss of its core government funding (Church and Armstrong 2011). Funding for *The Hub*, which had originally been funded through the Canadian Breast Cancer Initiative (from Health Canada) was transferred to the Public Health Agency of Canada (PHAC) when the new agency was set up in 2004, a move that coincided with a redefinition of cancer as a chronic, rather than an acute, disease.<sup>268</sup> *The Hub* was threatened with loss of its funding in 2008 but support was reinstated when opposition parties, rallied to the organization's support.

#### 5.4.3 Pockets of Resistance to Neoliberal Policies

To some extent, this environment of funding cutbacks simply continued the neoliberal hostility of the Chrétien and Martin eras (from 1993 to 2005) towards government programs that were not in direct support of business or trade objectives. In

2004, for example, the federal government under Liberal Prime Minister Paul Martin launched a broad restructuring of regulatory policy called the Smart Regulations strategy, which promised to “streamline and speed up approval for new drugs, foods, biotechnology products ....and ... harmonize standards, especially between Canada and the United States” (Graham, 2005). When the Conservative government took power in 2006, the restructuring process continued but under the name “Cabinet Directive on Streamlining Regulation” (Health Canada 2007). Public consultations were held across the country; a government report on the consultations took note of a discursive divide on the draft proposal between consumer advocates and those from the business community. Members of non-profit groups that were not pharma-funded, including the breast cancer group *Critical Advocacy to Prevent Cancer*, raised concerns about the initiative. A government report described the perspective of the non-profit sector as follows:

Participants from public advocacy groups worried that the Smart Regulation Initiative, and by implication the draft Directive, was being driven by international trade considerations and North American integration, which they saw as a move toward deregulation and the lowest common denominator in protection for the environment, health and safety of Canadians.

Generally speaking, participants from the public advocacy sector felt strongly that the draft Directive subscribed to a business/**economy**-first paradigm ... (bold in original).

Treasury Board of Canada Secretariat, 2007

Business interests that took part in the same consultation voiced a contrasting point of view:

Many participants, primarily from the industry, business and natural resource sectors, expressed strong support for the overall approach of the draft Directive.

Treasury Board of Canada Secretariat, 2007

The strategy, part of a 10-year plan to advance the country as an “innovative economy” on the world stage, gives lip service to health and public safety but its main purpose is clearly to promote trade and innovation (Bibeau, Graham and Fleising 2006; Treasury Board of Canada Secretariat). In 2007 the federal government released a blueprint for modernizing drug regulation that it described as “proactive” and “enabling” (Health Canada 2007). One aspect of the new model was a reformed drug regulatory system designed to bring Canada’s review times in line with international benchmarked performance standards. Called “progressive licensing”, the new “life cycle” system of licensing was designed in part to speed up availability of new drugs; to this end it incorporated a lower standard for drug approvals. A second component was an improved system of post-marketing surveillance, to be achieved by a number of means, including collaboration with the FDA and other international drug review agencies (Wright 2007; Yeates et al 2007).

Even within the government, resistance to applying the trade agenda to health and drugs remained strong in some quarters. In 2004, a Parliamentary Committee released a report, *Opening the Medicine Cabinet*, on Health Aspects of Prescription Drugs, which made a series of strong recommendations on the questions of clinical trials, post-market surveillance and direct-to-consumer advertising. The report supported safety measures and openness over commercial interests in clinical trials. The committee also stressed the need for independent information about drugs and expressed concern that industry promotion was contributing to inappropriate use of drugs and excess expenditures. It recommended major improvements in the reporting of adverse drug events, including heightened surveillance of drugs after licensing with public disclosure of adverse event

reports; and recommended tightening the ban on DTCA and enforcing violations (Brown 2004).

With respect to health care more broadly, most Canadians – a proportion as high as 90 per cent according to one poll, continued to support the single-payer health system, despite a rising rhetoric of “unsustainability” from elites wanting tax cuts and a private system that would prioritize access on the basis of ability to pay (Evans 2010). In 2004, the federal government committed to a large transfer funds to the provinces, but did not enforce breaches of the Canada Health Act (Armstrong and Armstrong, 2008). The cost of new drugs to the system continued to make headlines, with cancer drugs drawing particular attention (Kondro and Sibbald, 2005; Vogel, 2010; Sherman, 2011; Smith and Hillner, 2011; Pollack, 2011; Editorial, *New York Times*, 2011; Walkinshaw 2011)

Pockets of resistance to the wave of pharma partnerships remained within the breast cancer movement. Most prominent, *Critical Advocacy to Prevent Cancer*, which, as described in Chapter 3, had brought in a Policy on Corporate Contributions in 2001, promoted its stand on pharma funding with a banner on its website. *Critical Advocacy to Prevent Cancer* attempted, unsuccessfully, to have other breast cancer groups adopt the same ban on funding from pharmaceutical companies, and other corporations that had a direct financial stake in cancer and/or that contributed to the cancer problem. The group made willingness to endorse the policy a pre-requisite to joining the organization’s board of directors or its small staff. When other organizations, including *The Hub*, rebuffed *Critical Advocacy to Prevent Cancer*’s attempts to have the prohibition of pharma funding adopted more widely, the group was increasingly isolated from the broader Canadian breast cancer movement. *Critical Advocacy to Prevent Cancer*’s loan wolf



position on pharma funding contributed to the organization's identity as a breast cancer group that was different from the others, both in its commitment to promoting a carcinogen-free environment, and its willingness to adopt positions critical of drug promotion and of the use of the breast cancer cause to market consumer products ("pink marketing"). The group's discourse and its social world became more strongly aligned with that of environmental activism and of pharma-critical health organizations like *Remedy & Prevent Drug Harms*, *Pharma Monitor*, *Pharma Policies to Protect Women's Health*, *Buyer Beware (Alberta)*, the American group *Breast Cancer Truth-Tellers* and *Women Advocate for Women's Health* and the US/Canada feminist health coalition *United for Disease Prevention*. These groups continued to produce texts that discussed financial conflicts of interest as a problem for health policy (Armstrong 2007, Batt 2004, 2009; Mintzes, 2007). As stated above, however, many of the groups disappeared or were severely weakened during the Partnership Period for lack of funds. In parallel with the cuts to government funding in Canada, the U.S. Canada coalition of health organizations, *Prevent Cancer Without Drugs Group*, disbanded in 2003 after its funding from the American foundation that had supported the coalition expired, although individual member organizations continued.

*Pharma-free zones within a pharma-funded group* In some organizations, resistance to pharmaceutical funding was expressed within the group although the policies of the group itself endorsed accepting funds from drug companies. In Chapter 3, I discussed the ambivalent, "case-by-case" policy of the group *Down-home Peer Support and Education*. Within that group, the strongest resistance emerged from a web-site Forum that attracted women many dealing with treatment issues. The web-mistress

actively protected that project from the incursion of pharma funds, but her paid position was eliminated in 2007 when foundation funding was discontinued for that project and she left the organization. (The group's Internet Forum lost momentum and was abandoned in 2010.) A similar case of a staff member creating a "no pharma money" zone around a project she had nurtured occurred at *Helping Hand*, when that organization changed its policy to accept funds from the pharmaceutical industry in 2000. *Virginia*, who had strongly opposed the policy because she felt pharma sponsorship would undermine the credibility of the group's peer support service (in particular, the information provided to patients about drugs), continued to work for *Helping Hand* until 2006 when she and three other staff members were laid off. By the time the group began taking pharma money, she was spending most of her time in a teaching program of her own creation which involved educating nurses about the concerns of women with breast cancer. She explained her attempt to isolate her project from the group's pharma funding policy in an interview:

*Virginia*: They [the executive director and board of *Helping Hand*] knew I wouldn't take pharma funding for my program, so in a way there was some small part of me that felt that I was upholding what the original beliefs were - - which were still my beliefs -- that we should not be taking money from pharmaceutical companies.

Sharon: How did you work that out, that you didn't take money for your own program?

*Virginia*: Well, obviously, if *Helping Hand* was receiving money into its general funding from any pharmaceutical company, then I couldn't keep myself completely untainted by this. My salary had to come from somewhere.

Sharon: Right.

*Virginia*: For the large part of my work, for the last five years that I was there, I was doing the teaching [to nurses] program. For a couple of years in a row

we got funding from *The Pink Foundation* for the second and third year, and then we got money from the Bank of Montreal for a year -- that kept me going. And then by default, I persuaded them to hang onto the teaching program and put it in core funding, so I wasn't dependant on an outside funder.

And even though fundraising wasn't my job, I made it quite clear that I wouldn't represent the program to a pharmaceutical [company], but that I would do what I could to try and bring somebody else on to fund it. And it was a difficult sell to funders. It never got funded by an independent again after that.

Sometimes [the executive director] would throw out this, "Well, you won't take pharma funding!" and sort of grin at me, so it was quite punitive, in a sense. And I used to smile back and say, "You're right, if I have to stand up in front of a classroom of nurses and tell them that I'm here by virtue of Astra Zeneca, I'm going to throw up. I'm just not going to do it. So if you want to take the money take it, but Astra Zeneca or anybody else is not going to get their logo on my stuff. And I won't mention it."

Whereas when I was doing it [the nurses' education project] for Bank of Montreal or *The Pink Foundation*, I would say very briefly at the beginning, "I'm here because *The Pink Foundation* gave me the money." Or "I'm here because Bank of Montreal gave us a grant." And that's it. I wouldn't sell a bank account for the Bank of Montreal -- you know, there's no clean money in the world. But that was something I was able to live with, and I wasn't prepared to head it up with a pharma name.

Sharon: Can you explain a bit more how you draw that line? And the distinctions you see?

*Virginia*: [Laughs] It's a bit like ethical investing, when you start investing your RSPs. ... And if you want to be completely pure about this, are you actually going to question every individual donor, where they got their money from? How far back do you want to go on this tree of money? And I guess that's how I learned to live with Beemo [Bank of Montreal] money. I decided, 'Okay, well I think I don't want to know where Beemo has its money invested.' ... But the difference between that and pharma funding was they [the pharmaceutical companies] had an immediate agenda [i.e., selling drugs to patients].

-- Interview with *Virginia*, 2008

When *Virginia*'s job was terminated, she did not know whether her stance against pharma funding was a contributing factor: "And [the board's] argument against it all the time was it should be self-funding. And at the end of it, how much incentive in getting rid of me was that I was a loudmouth that didn't fall into line, and how much of it was a purely fiscal decision?"

Even a "purely fiscal decision" can't be untangled from the issue of pharma funding, however, because *Virginia* (who had worked herself in private industry and was no stranger to this world) had been unable to find an alternative sponsor for the project. The claim that the pharmaceutical sector was virtually the only industry willing to provide substantial funding for breast cancer projects is a consistent theme in the interviews with women involved in projects for which members of a group attempted to find alternative commercial sponsors. Furthermore, this claim resonates with the shift in strategy for funding non-profit groups throughout the private sector, in which companies in all major sectors abandon their traditional "spray and pray" funding approach to favour alliances with groups that could benefit the company in some way (Cohn & Wolfe 2004).

The Partnership Period is characterized by a discourse that treats partnerships between breast cancer groups and pharmaceutical companies as evidence of a constructive willingness to cooperate. As government restrictions on advocacy by non-profit groups tightened, pharma funding became particularly central to groups that see advocacy as part of their mandate. Although several organizations critical of pharma funding remain, and continue to develop and promote a counter-discourse, government policies restrict the few sources of funding available to them and their numbers have dwindled. The question remains whether this changed landscape has any importance to

Canada's pharmaceutical policies or to the health care system. I explore that question in this section, under three themes: the social construction of the breast cancer pharmacopoeia, silences, and patients' rights regarding medications.

#### 5.4.4 The Social Construction of Four Drug Treatments

In Chapter Four I discussed Emily Martin's analysis of drugs as having personalities that are susceptible to social construction. Her observation that the word "pharmakon," used in ancient Greece to mean both "remedy" and "poison" (Martin 2006), underlines the two poles that an effective social construction process must recognize. I draw from four examples to explore whether pharma funding might affect the way patients' groups construct the personalities of breast cancer drugs.

*Erythropoietin (brand names Epogen® and Eprex®)* In my three-stage chronology, the drug Eprex® first surfaces in the Grass Roots Period at the Parliamentary Hearings, as Epogen®. Sylvia Morrison cited the drug as central to her desperate attempt to obtain access to the experimental process high dose chemotherapy with autologous stem cell rescue (ABMT-ASCR), a procedure which she ultimately had performed in New York, paying for the procedure and the drugs herself. Yet when Johnson & Johnson, and subsequently Ortho-Biotech, approached *The Hub* with a partnership proposal, the same drug was known in Canada as Eprex®. The explanation for this discrepancy in nomenclature lies in erythropoietin's complicated legal history. The American biotech company Amgen manufactures the drug but Ortho-Biotech, a subsidiary of Johnson & Johnson (also called Johnson Ortho), sells it through a licensing agreement. In the U.S.,

Ortho-Biotech sells erythropoietin as Epogen®; in Canada, the same company sells it as Eprex®.

As I described above (347-353), when Ortho-Biotech provided funding to *The Hub* for advocacy, the negotiations set off an internal dispute within the organization and ultimately led to the resignation of the president, *Helen*, who had initially agreed to the alliance. To this point, if Eprex® has a poison side to her therapeutic personality it is not apparent,<sup>269</sup> although some, like *The Hub*'s former president, find her tactics of self-promotion manipulative. In the Partnership Period, however, new data surfaces to suggest that Eprex®'s therapeutic identity does indeed include a poison side. In 2002, the drug was linked to a small but significant number of cases of a life-threatening condition, pure red-cell aplasia, in which the body loses its ability to produce red blood cells (Pollack 2002); subsequently, preliminary results from a clinical trial showed that patients with metastatic breast cancer who took the drug died sooner than those who did not (Leyland-Jones et al 2005). Eprex® also has a complicated corporate history, entailing a bitter lawsuit over competition for the cancer patient market. Additionally, the advertising of EPO is characterized as "hyperbolic" (Khuri, 2007:2448) and in the U.S., the profits to physicians who use these drugs are said to be "substantial" (ibid, 2007:2448).

When evidence of EPO's risks to cancer patients became apparent, the FDA placed a black box safety warning on Amgen's two drugs Aranesp® (darbepoetin alfa) and Epogen®, as well as on Ortho Biotech's Procrit® (epoetin alfa) (Medscape 2007; NEJM 2007).<sup>270</sup> Health Canada issued a safety advisory about the medications on April 16, 2007, noting that the drugs were sold in Canada under the names Aranesp® and Eprex® (Health Canada/Amgen/Janssen-Ortho, 2007). While the safety warnings

covered uses for a variety of cancers, the evidence that the drug was harmful to women with breast cancer undergoing chemotherapy is most relevant here. A randomized controlled clinical trial involving 939 women with metastatic breast cancer was undertaken with the expectation of showing that those given Eprex® would survive longer than those given a placebo. Instead, after four months, the reverse was true and the trial was terminated. The drug had two adverse effects: it promoted both tumor growth and fatal thrombotic events (Leyland Jones et al, 2005).<sup>271</sup>

The findings thus reveal a dark side to Eprex®'s personality, not evident when *The Hub* entered into its alliance with Orth-Biotech. As a result, the organization may have inadvertently encouraged use of a drug that hastened the deaths of members who trusted the organization for information. Importantly, at the time *The Hub* engaged in its relationship with Ortho Biotech, no evidence existed to suggest this poison side to the personalities of Eprex® and similar drugs. Health Canada and the FDA had approved the drug for use in breast cancer patients suffering from severe anemia, although not for “fatigue” or to improve quality of life.

In the business press, Eprex® was touted as a major therapeutic success story, as well as being a financial blockbuster for both Amgen and Ortho-biotech/Johnson & Johnson (Real Time Traders 2007). Even at the time of the safety advisories, the question remained whether the danger was dose-related. But the nature of drug trials and the drug approval process is such that the existence and extent of drug harms invariably takes longer to establish than a drug's benefits. Furthermore, the safety advisories indicated that the regulatory agencies suspected the drugs were being used for purposes beyond their approved indications, a practice known as “off-label use.” In this case, the drug was

approved for *severe anemia*, either induced by chemotherapy or caused by the cancer itself. In practice, however, the drug was being prescribed simply to alleviate chemotherapy-induced fatigue (Abel et al 2006; Mintzes et al, 2009; Stupak 2009). Drug company promotion is often designed to encourage off-label use, by implying the drug may benefit patients other than those with the precise condition that has been studied in clinical trials. In the U.S., where direct-to-consumer advertising (DTCA) is legal, Procrit® was advertised for seven years to treat “cancer fatigue”, although the drug was not approved for this purpose. Furthermore, the ads did not mention that, in clinical trials, the drug caused tumors to swell -- an indication that the drug might be stimulating cancer growth (Stupak 2008).

*The anti-hormonal drugs: Nolvadex™ (tamoxifen), Evista™ (raloxifene hydrochloride), Arimidex® (anastrozole) and Letrozol* Estrogen is known to stimulate tumour growth in the majority of breast cancer cases and a number of breast cancer treatments have been developed that reduce estrogen exposure. The U.K.-based company Astra Zeneca introduced the now-classic breast cancer treatment, tamoxifen (brand name Nolvadex®) in the 1970s. Tamoxifen is still widely used as an anti-estrogen to treat breast tumours that respond to the woman’s endogenous estrogen. Initially, tamoxifen’s success rested on the fact that the drug dramatically reduced the woman’s chances of developing a second cancer in the opposite breast to the one in which she had cancer; it was not until 1998 that the drug was shown to save lives -- the ultimate benefit in a cancer drug (Fisher B, Costantino JP, Wickerham L, et al, 1998). Although tamoxifen is generally considered less toxic than cytotoxic chemotherapy, it has many side-effects that affect quality of life and several that can be life-threatening.



AstraZeneca's patent on tamoxifen expired in 2002<sup>272</sup>, setting the stage for a race between two drug giants to capture tamoxifen's market. AstraZeneca's entry was Arimidex® and Novartis's was Femara®. The early clinical trial results from the drugs suggest both drugs have fewer serious side-effects than tamoxifen -- neither causes endometrial cancer although both weaken bones causing fractures and joint pain -- and they seem to be more effective in preventing recurrences. Neither drug has yet been shown to reduce mortality so neither can definitively be said to outperform tamoxifen. Reduced mortality takes longer than do so-called surrogate end-points (showing a reduction in recurrences or a reduced time to recurrence); similarly, long-term toxic effects take many years to document. Both drugs for now exist in the grey zone of "promising, but more research is needed."<sup>273</sup> Even less certain is whether one of the new entries was superior to the other. In July 2004 Health Canada gave AstraZeneca's Arimidex® conditional approval<sup>274</sup> as a treatment for early breast cancer in post-menopausal women; Novartis's Femara® was conditionally approved for the same purpose in October 2006.

Since AstraZeneca was one of the companies to support *Helping Hand* once the organization dropped its ban on pharma partnerships, I asked *Virginia* if she felt the group had engaged in any activities that might be seen as promoting the company's products. As with the decision to change the policy on pharma funding, she and other staff members were uneasy about the group's relationship with the company, but they were not privy to the discussions of the organization's board:

*Virginia*: [laugh] Funny you should ask....And this is where the secrecy comes in. After AstraZeneca started negotiations with *Helping Hand*, [the executive director] took up a relationship with them through what they call "patient information sessions." And to her credit, after she asked me once in

the very beginning, she never asked me again afterwards. Mostly she would fulfill this function. She would turn up different places in the province. There would be a patient forum. There would be a doctor and [the executive director], I don't know who else. And it would be advertised in the community under some kind of title like 'hormonal treatments' or something like that, and would be promoted through the local hospital. Usually the doctor would be a local doctor.

And what we were given to understand was these were sessions that were funded by AstraZeneca, but that we never knew what *Helping Hand* was doing or getting out of it. And when we questioned [the executive director], she would say, "Well, I'm just there to represent *Helping Hand's* services at these events, to balance it out." .... But Astra Zeneca I believe – I found out because of materials that she actually gave to me at some point – were training her to do this. And so whether or not the doctor or any other pharma rep at that event was talking specifically about a specific drug, I cannot swear would be the case. But it was my understanding that [she] became very *au fait* with some of the products or product that were being promoted at the time. ... So I can't say. I do know that the way it played out with us is she never told us what went on. We'd say to her at staff meetings, "So what is it? Why are we there? What are we doing?" Now [she would say], "Oh, well, it's just a patient information service." ... I mean, I'm trying to be fair about this, because I never went to one of these things.

-- Interview with *Virginia*, 2008

The format of these meetings strongly resembles that described in Chapter 3, in which Astra Zeneca funded an information meeting about treatment options with the collaboration of the provincial group *Down-home Peer Support and Education*, featuring a local oncologist. In that group, members did not feel the session were promotional; they became concerned later, however, when the company asked the group to link its website to that of the company (see Chapter 3). Unlike this regional group, however, the lead representatives from two national organizations were quoted in one of the company's press releases. On July 14, 2004, AstraZeneca issued a press release under the heading

“Health Canada Approval Paves Way for New Era in Breast Cancer Treatment” which began:

Marking the first major treatment advance since tamoxifen’s introduction over 25 years ago, Canada’s leading oncologists and breast cancer patient support and advocacy groups gathered to applaud a new era in treatment for early breast cancer. Women have the best chance of cure at this stage of disease. (Astra Zeneca 2004)

The breathless tone continued through the rest of the press release, with enthusiastic quotes from three Canadian oncologists supported by the executive directors of two national breast cancer organizations and by a patient from British Columbia. Neither of the women speaking on behalf of organizations endorsed the product outright; rather, they enthused more generally about dramatic advances in the treatment of the disease. The first commented:

Another breast cancer announcement? We say thank goodness for that ... While a cure for breast cancer is now on the horizon, investments in research, innovations and discoveries, along with the growing number of patients participating in clinical trials is paving the way.

-- Director of a national breast cancer group, quoted in Astra Zeneca (Canada) press release 2004

The executive director of the second organization made a similarly enthusiastic but generic statement: “A new era in treatment is dawning, with better, safer options available. On behalf of everyone touched by breast cancer, we applaud this advance.” In contrast to the group representatives, however, the patient quoted as an individual came out full-square for Arimidex®:

When I heard I had breast cancer, I was stunned. I’m so thankful that I was given the opportunity to take ARIMIDEX® ... Today’s news is encouraging for post-menopausal women with breast cancer because it gives us peace of mind that our treatment will reduce our chances of recurrences and, hopefully, let us lead a better, longer life [capital letters in original].

*Virginia* recalled, with chagrin, that *Helping Hand*'s Executive Director also attended international meetings paid for by Astra Zeneca.

*Virginia*: .... But, you know, she would end up at these international conferences as well in Europe. I mean, we used to say, "Ah, Christ, she's off to the south of France again!"

Sharon: [laugh]

*Virginia*: [laugh] Totally pissed off, we were! The furthest we got anywhere was probably Sudbury or something. And this was this side of the coin. They would send her off on these things, and it was all pharma stuff. It was all pharma-funded. It was a joyride. And we, I don't know that *Helping Hand* ever really actually saw a lot of money out of it. ... I mean this was something that was quite fascinating for us. Because we'd pore over the annual report and see whether or not we could find where this money – what was in it for us? If we were getting blighted by this, where's the money? ... But we, there was never any real evidence of that, just these mysterious patient information sessions, and these trips to Europe to be the Canadian representative. And at these things, results of trials would be announced. So, are we saying here that by being present at these events and travelling on Astra Zeneca's dollar are we – we being *Helping Hand* – are we endorsing this product? That to me is crossing the line. Then, you see, I'm a purist.

... And these international things: we'd say, "Well, what's the point? We're not even an international organization. We barely have a national mandate. We don't even have a national board of directors. ... We don't have a global mandate. We're not a policy-making organization. We're not an advocacy organization. We are a grass-roots support organization -- why should we care what goes on in Geneva?" Unless of course it was a world conference where you were sharing ideas about support provisions and stuff like that.

So the answer to that question is, "Yes, I think that there was a hand in." You know, this is around the time that there was competition. Tamoxifen was on the wane. And there were competitors going, there was a competition for the estrogen-receptor positive market [i.e., the aromatase inhibitors]. And yes, I think that that's what that was. But can I prove it? (Interview with *Virginia*, 2008)

To obtain an industry perspective, I interviewed Jim, a representative from Astra Zeneca Canada who was hired to work in Product Public Relations, building relationships with patient organizations:

Jim: And the background to it [the affiliations with groups] was that there had been all of these scandals involving other pharmaceutical companies like Merck with Vioxx® [rofecozib] and the whole thing that had broken with Celebrex® [celecoxib] and all of that.<sup>275</sup> And so the reputation of the industry had taken a serious hammering. And, I mean, to put it bluntly the pharmaceutical industry was -- people were looking at it with new eyes. And the whole concept of public relations and product public relations was transformed, I think, by the fallout from those -- from what happened there.

And I always felt anyway that good public relations had to be patient-centered. And with my senior managers, who also believed fervently in this, that we as a company had to put patients at the heart of what we did. And “product public relations” was very much key to that, was a litmus test to that.

We had to really reposition and re-think and redevelop all that we did here. And that, from traditional product public relations, which was all about product promotion, it should really be much more of a relationship-driven activity, taken in many ways outside of the mainstream of just promoting a product, much more around promoting mutually important things, like disease awareness, sharing of information on both sides that’s helpful. So, for example, clinical trials information, helping patient groups and patients be aware of our clinical trial programs so they could get on these trials and have an understanding of what was coming down our pipeline; because, particularly in the area of cancer, as you know, that’s so important.

Sharon: Um-hm.

Jim: To have the chance to get access to some of these new therapies. And, so this, this was really the driving force between the work which we, which I was involved in. ... So convincing senior commercial managers of the value of what we did was not easy because it didn’t have an immediate commercial payoff. I had to really work very hard to show them that this, that there was good business sense behind what we did. And for people who are very dollar-driven, that wasn’t easy. But we ourselves were coming out of the

situation where one of our products, Crestor® [rosuvastatin calcium, a statin, used to treat high cholesterol], you may remember – had had a serious blow to its reputation, through a whole series of what proved to be unfounded criticisms about its potential safety that we had struggled very, very hard to counter -- a blizzard, a blaze of bad publicity about this one product, and [we had to] stabilize the product. Because people had all these fears around its safety, because a similar type of product, another statin, had been withdrawn from the market; and that meant that all statins suddenly were under question.

And Crestor®, being the newest one of its type, took the brunt of a lot of that fear. And so people [in the company] really were looking at what we did in public relations with very skeptical eyes. Because, as is always the case, communications gets the kicking when things of that type seem to go wrong....

But we did have some good senior support from the head of the company. We had a very clear vision that we wanted to be, we set out with a vision to become the company that patients trust. And if you believe in trust, you have to believe in a relationship strategy, because trust can only come through good relationship building. ... You have to put aside some of your commercial agenda in order to build trust. You have to invest in trust. And that means putting aside some of the, the narrower, if you like, the immediate kind of pressures of making sales and product promotion to actually really build trust so that you can develop a mutual platform, is what I called it. And so that you could understand: what is it when you are developing new therapies, what is it about that therapy that patients value most? And very often, it isn't the product itself, it's all the services that you put around the product – the information you make available, the support –it's those things which are just as valuable as the raw product.

Sharon: Hmm.

Jim: And you're not going to understand that unless you have the relationship with patient groups.

(Interview with Jim, 2008)

### Case 3: The Hub's *Survey on the Risks of Relapse after Treatment with*

*Tamoxifen*. In September 2007, *The Hub* featured an announcement on its website about a survey “led by” *The Hub* and conducted by the professional polling company Ipsos-

Reid. “Despite ... the wealth of resources available,” the announcement stated, the survey had found that “only one in 10 woman surveyed are aware of their risk of relapse after five years of tamoxifen treatment”. The web announcement had links to series of additional resources: a more detailed press release, a one-page summary of the survey’s finding with three questions which women were urged to “ask your doctor,”<sup>276</sup> and a video posted on YouTube. The video was in the form of an extended piece of news reportage, including a series clips: first of *The Hub*’s president, then of a woman who had completed tamoxifen treatment but was not aware she was still at risk of a relapse, and finally of an oncologist who mentioned the option of taking an aromatase inhibitor, a drug that blocks or inhibits the enzyme aromatase.<sup>277</sup>

As a package, the resources characterized women’s lack of knowledge about their risk of relapse as “alarming.” Each component underlined the importance of women speaking to their physician, using terms like “essential” and “strongly recommend.” A medical oncologist quoted in the one-page summary referred to current treatment guidelines “such as those from Cancer Care Ontario.” These guidelines, she said, “...reinforce that modern post-surgical (adjuvant) therapy options such as aromatase inhibitors, including extended therapy beyond five years, can save lives.”

The entire package had all the hallmarks of a help-seeking ad, a type of direct-to-consumer advertisement (DTCA) that discusses a medical condition but omits the brand name of the product the company wants to promote. Instead of naming the product, a help-seeking ad urges the reader or viewer to “ask your doctor” for more information about available remedies. Although Canada, like most industrialized countries,<sup>278</sup> prohibits DTCA of prescription pharmaceuticals, the government has loosened its

restrictions on such promotions through two administrative shifts, one of which, in 1996, “redefined the boundary between ‘information dissemination’ and ‘advertising’” in a way that appears to give tacit approval to such unbranded “ask your doctor” ads (Mintzes, Morgan and Wright, 2009). Typically a company places a help-seeking ad if it has a new product that it is promoting heavily to physicians. By encouraging people who might suffer from the condition in question to see their doctor and ask about potential remedies, the ads alert the public to a potential new drug and increase the volume of patients making doctor visits. In this case, the encouragement came not from the company making the product, but from a breast cancer group which was, arguably, a more trusted source and also one in a position to target the message to the precise population the company wanted to reach.

*The Hub’s* web page did not identify a drug company as a sponsor. Instead, it credited the survey as sponsored by *The Pink Foundation*, a national organization that raises funds for breast cancer research and community-based projects. Puzzled, I asked *The Hub’s* Executive Director, *Hazel*, if a drug company had sponsored the initiative. She confirmed that “the risk of recurrence project” had been paid for by Novartis, the company that makes Femara® (*Hazel*, personal communication, March 16, 2009).

Health Canada’s approval of Femara®, Novartis’s entry into the aromatase inhibitor market for adjuvant use, came in the form of a conditional approval in April 2005.<sup>279</sup> A conditional approval is based on promising preliminary results in a clinical trial with the understanding that full approval depends on later results upholding the early trend. It seemed to me that Novartis had used the group as a vehicle for a help-seeking ad



that would stimulate the adoption of its recently-approved drug into standard use based on surrogate end-point results.

To understand how the group viewed the project, I asked *Hanna*, who had been on *The Hub*'s executive at the time the Ipsos-Reid survey was conducted, about the group's perspective in deciding to undertake the project. As she described the initiative, the group saw itself as assisting physicians in getting the word out about an important new therapeutic development:

*Hanna*: People weren't aware of it. ... And this new drug was so much more effective in stopping a recurrence.

Sharon: And this was one that you would take after five years [on tamoxifen]?

*Hanna*: Yes. And we did do some advocacy around that because people didn't realize... And it was for that reason, and they were going through the same thing at the cancer centre. The doctors thought, "How are we going to reach these people?" You know, because people go from doc to doc to doc, but if you have all the physicians informed, the patients are informed, that they need to explore this. "Ask your doc about it, it's important." And it *is* important! ... Nobody wants that [coming] back again. You know, if you've got something you can take ... for the people where you can say, "This is really going to decrease your chances of the ugly coming back," they had to know about it.

And the different cancer centres attacked this different ways. There were [a lot of] letters that went out, to all the patients that they could find – which is not an easy task! And the docs, they would have to comb through all the records. So there were information sessions on it. So, "This is what's here; as a patient you have to think about whether you want to do this or not." Some did, some didn't. But it was like, "Holy crap, this thing really worked. How are we going to let our patients know?" ... It was like, "Oh, my dear! How are we going to do this one?"

And that's why we did the video. It was like, "If we can get out there, [get] people to ask -- just go and ask!" ... And it was important. Part of this "informed patient." ... And it's a unique situation, for a drug to become that good. You know, all of a sudden, Holy liftin'! And it was not that tamoxifen

was bad, it's just that this one [Femara®] was so much better. And it was ... to be able to have a drug that would do that, and prove to be doing it? I say, "Bring it on!" You know-- because I've had a recurrence, and a recurrence is not a pleasant thing to go through. (Interview with *Hanna*, 2008)

I found *Hanna's* enthusiasm for aromatase inhibitors excessive, considering the still-preliminary status of the evidence and the relatively small (albeit statistically significant) advantage these expensive new drugs conferred, relative to tamoxifen. I would not discount her views as simply the result of corporate influence, however, since her perspective corresponds to that described in the research on breast cancer patients and their willingness to embrace the risks of additional new treatments, even if the gain over tried and true treatments is extremely small (Coates and Simes, 1992; Ravdin et al 1998). In the case of aromatase inhibitors, risks include a small increase in the risk of cardiac failure, and an increase in osteoporosis and bone fractures, as well as joint disorders such as arthritis (AstraZeneca Canada 2011; Novartis, 2006, 2010). *Hanna* did not agree with me, however, when I expressed concerns that patients might receive an overly-positive view of drugs from a group like hers; ultimately, she argued, the drug was prescribed by an oncologist:

Sharon: I guess one of my concerns is, and this has come up in some of the literature, and it's that if – I mean most drugs have side-effects which women want to be informed about when they are making their decisions or when they are going through treatment. Are you going to hold back in talking about those side-effects, even if the drug company doesn't ask you to, when you know that you are receiving money, or you have the potential of receiving money from the company? It's just the whole thing of information and presenting patients with unbiased information about a drug. It may have been hyped or are people excited about it or whatever? That's where I see some of the dangers of ....

*Hanna*: Well, in cancer care, any of the drugs that are prescribed are according to clinical practice guidelines that have been developed by the individual cancer agencies. That's part of informed consent and the side effects. And I've been in on conversations with people and sat in with them, and at least in this place [the hospital where she worked], they are well informed. Very well informed!

- Interview with *Hanna*, 2008

*Delays in drug access: The HUB's report card on wait times.* In 2008 *The Hub* published a 46-page report ostensibly on wait times for cancer diagnosis and treatments, a project supported by the GlaxoSmithKline Foundation (acknowledged on page 2 of the report). The first half of the report examines and compares wait times to breast cancer diagnosis, surgery, radiation treatment and chemotherapy in each province and territory, a discussion which corresponds to the usual meaning of "wait times." Another section of the report stretches this conventional meaning to encompass "drug availability," that is, drug approval times and the inclusion of drugs on formularies. Thus, report frames the interval between a company's submission to the regulator for approval to the time that the drug is put on all the provincial and territorial formularies as a "wait time" for patients (although not mentioned in the report, this interval is a critical "wait time" for the drug companies, who cannot begin marketing their drug until it gains regulatory approval; similarly, sales will be limited if insurance plans don't cover the drug). Indeed, the report argues that the "wait time" for a drug actually begins when the company submits its drug for approval. The section "Wait Times – Drug Approvals and Availability" is highly critical of the federal government processes for approval<sup>280</sup> and of the provinces for delaying formulary inclusion because of costs, noting that "Total time elapsed between the manufacturer's first application to Health Canada and final inclusion on a provincial or local formulary can be between 3-5 years or longer" (Anonymous 2008:25). The report

is entirely uncritical of drug companies for their drug pricing practices, and nowhere mentions misleading drug promotion practices, or that drug treatments may in fact shorten patients' lives as well as extend them. The latter reality was most dramatically seen with high-dose chemotherapy, (post-) menopausal hormone therapy, and Eprex®; however, even drugs like tamoxifen and Herceptin®, with proven benefits overall, are toxic for a subset of patients and sometimes result in fatal outcomes. The implicit assumptions are: that new drugs will be lifesaving, that patients will benefit if they are made available rapidly, and that full coverage for a drug that shows benefit -- even in a surrogate endpoint -- ought to be provided to all patients regardless of drug cost. The Wait Times report states, "... as new targeted and biologic medications that will actually save lives become available, women will be denied access to them." (Anonymous 2008:43).

At the time *The Hub's* Wait Times Report Card was published, GlaxoSmithKline (GSK), the company that sponsored the project, had a new, targeted biologic breast cancer drug, Tykerb™ (lapatinib), in clinical trials. Tykerb™ was designed to treat women with HER-2 positive cancers, the same sub-population now treated with Herceptin®. In a clinical trial, Tykerb™ was shown to improve *time to disease progression* in women with HER-2 positive cancers when used in combination with another drug, capecitabine, made by Hoffman-LaRoche under the brand name Xeloda® (capecitabine) (Geyer et al 2006). Time to disease progression is a surrogate end-point for drug efficacy, however, and does not actually demonstrate that a drug extends survival time (see Terms and Abbreviations). Compared to Xeloda® alone, the addition of Tykerb™ provided an expected gain of 0.12 quality-adjusted life years (Le and Hay

2009). The drug combination met the minimal standard of effectiveness and relative safety. On this basis, in 2009 and 2010 various national regulatory agencies, including the FDA in the United States, the National Institute for Health and Clinical Excellence (NICE) in the U.K., and Health Canada, approved Tykerb™ in combination with Xeloda® to treat women whose disease had progressed on Herceptin®.

Insurance coverage of the drugs was another matter, however. In the oncology literature, the approval of Tykerb™ was accompanied by several cost-effectiveness analyses which concluded the drug's modest benefits did not warrant its price-tag of US \$2,900 a month -- an estimated \$19,630 over a patient's lifetime and \$166,113 per Quality-adjusted life-years gained (Le and Hay 2009; NICE 2010). In 2010, NICE issued a guidance to say that its independent Appraisal Committee could only recommend the drug combination in the context of clinical trials, because "evidence suggests it only extends life by a small amount of time -- around 10 weeks (2.4 months) -- and costs thousands of pounds more than one of the more commonly used NHS treatments for this indication -- capecitabine on its own" (NICE 2010). *The Hub's* Report Card does not mention Tykerb™ by name but advances the argument that delays in the regulatory approval and formulary funding of "new targeted and biologic medications" -- a generic description that applies to Tykerb™ -- are detrimental to breast cancer patients. With no discussion of the implications for the healthcare system of funding high-cost treatments with unproven or modest benefit, the document outlines an advocacy strategy under which *The Hub* will "work collaboratively with other concerned organizations to ensure that breast cancer issues, including wait times and drug availability, remain high on the public agenda" (Anonymous 2008:27).

Whether the sponsoring pharmaceutical company had any direct participation in the Report Card on Wait Times project is not evident from reading the Report; two years later, however, in 2009, *The Hub* hosted a webcast sponsored by the same pharmaceutical company, GlaxoSmithKline, in which the company took a direct and leading role. “Understanding the Healthcare Environment in Canada and Atlantic Canada,” which was webcast September 14, 2010 as a service to *The Hub*’s members in Atlantic Canada, had two presenters, both employees of GlaxoSmithKline. One is identified as the company’s “National Reimbursement Strategist, Specialty Care,” with previous work for the company in “stakeholder relations, government relations, and market access”; the other is the company’s “Director of External Affairs” in Quebec and Atlantic Canada. Under the rather anodyne title, “Understanding the Healthcare Environment,” the web-presentation explains in detail the drug regulatory process in Canada and the drug reimbursement practices in the four Atlantic provinces, and claims that “All patients are not treated equally”; more specifically, “Access to cancer treatments is: variable, not universal, not portable, not comprehensive and not always publicly administered.” The language is carefully keyed to the Canada Health Act, implying that access to cancer drugs violates all key tenets of the Act. Faster drug approvals and full coverage of all new breast cancer treatment drugs by all provinces and territories is advanced as the answer to these inequities. The final section of the presentation presents advocacy by patients and physicians as the key to influencing the “scientific and bureaucratic roadblock” in the healthcare environment. The webcast lists audiences for groups to target with their advocacy, including the provincial ombudsman, human rights offices, Members of the Legislature, the Premier’s office, and key ministries, such as Health, and Status of

Women. The detailed outline for advocacy provides a 12-point action plan, with advice such as: “Develop and implement contact plan: key decision-makers, political staff in MOH [Ministry of Health], Premier’s Office, civil servants and champions inside Government public service”.

The webinar was advertised through *The Hub*’s general member list as well as through its regional member organizations. Thus an advocacy plan, developed and presented by a pharmaceutical company, that framed the discourse about access to new cancer drugs in terms advantageous to the industry, was given exposure to breast cancer patients through their network of organizations. Key sources for the presentation are the annual Report Card of the pharma-funded group *All-Cancer Advocacy*, a publication on drug access by the conservative think-tank the Fraser Institute titled *Access Delayed, Access Denied* (Rovere and Skinner, 2011),<sup>281</sup> and a 2009 report by the Canadian Cancer Society, titled *Optimizing Access to Cancer Drugs for Canadians* (Turner Associates, 2009). The Cancer Society’s report echoes the concerns of *The Hub*’s Wait Time report card, *All-Cancer Advocacy*’s annual report cards, and the Fraser Institute’s “Access Denied.” First, that coverage for cancer drugs is unequal across the country’s provinces and territories, as well as within a single jurisdiction (the latter depends on whether an individual has private insurance and if so, the terms of that coverage). And second, the Canadian Cancer Society’s report claims that the “costs [of the newer cancer drugs] are prohibitive to all but the wealthiest Canadians” (Turner Associates, 2009: i). Except for a single sentence on the last page of the report, that “twin drivers of spiraling drug costs – utilization and prices – must be examined to ensure that Canadians receive value for money today and so that future generations can continue to afford a high quality drug

funding system” (ibid: 39), the report nowhere suggests that pharmaceutical companies may bear some responsibility for access inequities by overpricing their products. Indeed, the Cancer Society commissioned its report from a healthcare consulting firm whose founder and president counts among her past positions, “vice-president of marketing with a major pharmaceutical company.”<sup>282</sup>

In January 2010, The Hub circulated an “Outreach” e-mail to members which included an account of its successful advocacy to convince the Ontario government to fund Xeloda® so that a patient with advanced cancer could receive the capecitabine (Xeloda®) + lapatinib (Tykerb™) combination treatment without charge. A December 18, 2009 story in the *Globe and Mail* had described the woman’s plight: she had metastatic cancer which was advancing rapidly and her oncologist had recommended Xeloda® + Tykerb™ as a treatment of last resort (Priest, 2009). GlaxoSmithKline offered her Tykerb™ under its compassionate access program but the Ontario government refused to fund Xeloda® under its Exceptional Access Program (the drug costs \$8,000 per month) because the province had not put the Xeloda® + Tykerb™ combination on its drug formulary. GlaxoSmithKline had submitted its application to the province’s Committee to Evaluate Drugs (CED) in July 2009 but the province was still studying the proposal (i.e., a delay of five-plus months). Prompted by the *Globe and Mail* story, *The Hub* wrote to the Ontario CED and the Ontario Minister of Health to urge them to approve Xeloda® + Tykerb™ for inclusion on the province’s formulary. The organization also orchestrated a campaign among its on-line communities to do the same. In late December, the Ontario government approved the drug combination for formulary inclusion. *The Hub*’s January 2010 Outreach e-mail to members concluded:



Health Canada approved this combination of drugs, *which is saving lives*. Surely the Ontario Committee to Evaluate Drugs (CED) process should have *put saving lives ahead of additional evaluation* and approved it immediately. This combination of medications is prescribed for patients with advanced or metastatic breast cancer as a last resort. Time is of the essence for these breast cancer patients. ...

The Ontario CED approval of these drugs is an important step in progress for Canadian women currently suffering from metastatic breast cancer. By approving this combination of drugs, it gives women with breast cancer and their physicians more treatment options. ... but more action is needed. We believe, *in conjunction with the International Federation of Pharmaceutical Manufacturers & Associations*, that each patient should receive the treatment that is best tailored to their profile instead of being *denied access to potentially life-saving drugs that are not yet approved*. (electronic Outreach announcement, *The Hub*, January 2010, italics added).

The Hub and its members, in concert with the national newspaper the *Globe and Mail*, thus succeeded in having a new drug combination placed on Ontario's provincial formulary and represented the decision-makers who delayed the decision as showing "lack of compassion" (Anonymous 2010). The international debate as to whether the treatment was cost-effective (Le and Hay 2009; NICE 2010) is not acknowledged; indeed, the appropriate stance of governmental decision-making bodies is presented as little more than to rubber stamp new drugs. *The Hub* also identified Xeloda® + Tykerb™ as a life-saving drug combination although the clinical trial results (Geyer et al 2006) had shown improved *time to disease progression* – a surrogate end-point. Indeed, it is widely agreed that advanced breast cancer is not presently curable, although treatments may extend life and/or alleviate symptoms (Love with Lindsey 2010: 584); in describing Xeloda® + Tykerb™ as "life-saving", *The Hub's* communication to its members thus reshapes scientific knowledge about the disease in its advanced form (asserting that metastatic breast cancer *can* be cured, with new drugs), about the meaning of clinical trial

results (surrogate end-points are a measure of efficacy), and about the particular treatment combination. Additionally, the communication to members overtly aligns the organization's policy position on treatment access with that of the International Federation of Pharmaceutical Manufacturers & Associations, the global umbrella organization representing the interests of the brand-name pharmaceutical companies.

#### 5.4.5 Processes of Social Construction

Despite the now-established practice of breast cancer groups receiving funding from the pharmaceutical industry, all of the representatives of the pharma-funded organizations that I interviewed insisted that the funding was given “strings free” via unconditional educational grants and that these donations did not influence their programming or advocacy. Based on the four case examples above, I argue that pharma-funded groups contribute to a social construction process in which patients and the public receive a biased understanding of new breast cancer drugs; furthermore, in concert with the companies and segments of the media, the groups exert pressure on the drug regulatory system and provincial drug formularies to speed the approval of new drugs and have them added to formularies. The following discussion outlines the processes by which the pharma funding of groups contributes to biases in the knowledge of breast cancer drug treatments.

*Accent on drugs as remedies.* In his history of breast cancer treatments, Barron Lerner notes that progress in breast cancer treatment has typically occurred not through the introduction of dramatic new innovations, but by incremental improvements, by “gilding the lily.”<sup>283</sup> As he points out, clinicians and clinical researchers, as well as

patients, often wax enthusiastic about “advances” that, in the light of more complete evidence and historical perspective, were not advances at all but wishful thinking. The promotional efforts of drug companies don’t fabricate an optimistic bias from thin air – the ingredients are already there because cancer patients desperately want to live. Furthermore, their physicians want them to live, and researchers want their work to yield useful results. The process suggested by these case examples is, rather, that the collaborations with drug companies reinforce the patients’ existing optimism with one-sided data (companies also genuinely want to believe their drugs will do good). The pharma/patient group partnership then allows the company to feed on the patients’ (now-enhanced) optimism by disseminating patients’ “applause” through press releases (as with AstraZeneca’s Arimidex® promotion) or with more complex, subtle strategies like *The Hub*’s coordinated package comprising professional survey documenting “uninformed patients”, and a two-part remedy: a YouTube video “ask-your-doctor” ad constructed as an informative news report, an instructional print-out page with “Ask Your Doctor” questions.

This interpretation fits the case of Taxol®, discussed in the accounts of the Grassroots Period and the Contestation Period. First, the optimism of patients and their support networks was manifested in the breast cancer patient who was prescribed Taxol® off-label, who then told her story to the women in the advocacy group *A Voice for Patients*, which took the case to the Provincial Legislature and to the media. The resulting public outcry exerted enough pressure to have the drug put on the formulary because the women believed Taxol® should not be denied to women who might benefit from it but couldn’t afford to pay for it (a social justice argument). In 1998, when preliminary

clinical trial evidence suggested Taxol® might be beneficial used in conjunction with the cytotoxic drugs Adriamycin® and cyclophosphamide (AC) for early-stage breast cancer, researchers presented the results at an oncology meeting, the company followed with an aggressive ad campaign in the U.S. (where such advertising is allowed) and the combination became the “treatment of choice” in the United States. Canadian advocates then demanded that Canadians have access to this drug combination here, because it would be unjust (and perhaps grounds for litigation) to deny Canadian women what Americans deemed to be the “best treatment.” Thus, Taxol®’s “personality” is co-constructed to emphasize its remedy side over its poison side by a mix of actors: the company that develops a marketing strategy, the researchers who investigate the drug in clinical trials and become vested in its success, the clinicians who want their patients to live, the journalists eager to report on the newest cancer “breakthrough” and to help save lives, a prominent ethicist, and the patients themselves, supported by patients’ groups, who believe that even a tiny gain is worth whatever risk and cost it might entail. Funding from the industry may enter this network at any point, in a variety of ways (for example, by enabling key advocates to attend international meetings where they become aware of new drugs in development; by paying for projects that disseminate early, positive clinical trial results throughout a network, or by presenting advocacy organization with a detailed plan for pressuring government decision-makers). These strategies help to amplify the actors’ voices and reinforce their already-favourable view of the drug.

*Buying Silence? The Unconditional Educational Grant (UREG)* A counter-discourse critical of the partnership model and its potential for biasing the drug regulatory process continued in the Partnership Period; the organizational structures supporting the

critique weakened progressively throughout this time period, however and so did the vehicles for promoting the critique. From its outset, the group *Critical Advocacy to Prevent Cancer*, profiled in Chapter Three, had engaged actively in the debate over cancer therapies and the way they are presented to patients and the public. This activity continued in the early part of the Partnership Period when the group was a member of the U.S./Canada coalition, *The Prevent Cancer without Drugs Group*, which billed itself as “an independent coalition” to signal that none of the members accepted pharmaceutical industry funds. Members of *Pharma Policies to Protect Women’s Health* continued to draw attention to the issue of pharma funding of patients’ and other health groups. Published articles appeared under the auspices of the organization (Batt 2005, 2009; Mintzes 2009), and as papers in scholarly journals (Mintzes 2007). The group also pressed for conflict-of-interest disclosures from advocates participating on advisory committees and public hearings sponsored by the Health Products and Food Branch. One result was the Voluntary Statement of Information Form for Public Involvement discussed on page387-388.

Despite the continued presence of these groups that were independent of the industry, a number of people I interviewed who had been involved in breast cancer groups or health-related advocacy over the years expressed concern that critical voices were now missing from the chorus. Anne Rochon Ford, who had been struck by the positive responses to her booklet on pharma funding to women’s health groups, noticed a palpable shift within the advocacy community towards an acceptance of pharma funding. She recognized that the dominant discourse now favours pharma partnerships and even

suspected that her booklet might have contributed the success of the opposing perspective:

Anne: .... And clearly [pharma funding] has become over the 10 years just a more and more difficult position to defend. ... So I think it's good that there's that tool out there [her booklet]. It's outdated [however] I think a lot of the main points still hold. But I think that the discussion has evolved further, too, the same way that [the level of debate] was kind of in baby steps when I was at *Helping Hand*. I think that we also have more evidence now. But the thing that's the most depressing is that it doesn't seem to be making a difference. ... There are more and more and more groups taking money. And the numbers that aren't, and are making a statement about it, you can count on one hand.

Sharon: Right.

Anne: And that I find really, that I find testimony to the industry's phenomenal ability to finesse the whole discussion around it, the ways that they present it. They know all our "con" arguments, right? They know them all! They've learned them. They've mastered the responses. And I knew that going into these debates. I knew that, [in] putting the booklet out, that this is going to be fodder for them.

*Virginia*, who had worked with both *A Voice for Patients* and *Helping Hand* also expressed concerns about the silencing of advocacy voices within the breast cancer movement:

*Virginia*: Where are all the advocacy groups now? ... For the last year and a half I've been out of the loop, but when I was in the community, I didn't really feel that the breast cancer community had a very loud advocacy voice.

Sharon: No, no [agrees].

*Virginia*: And I don't know why. Because I mean, you know, initially that's how we started out, wasn't it?

Sharon: Well, some of us did. I think advocacy is always a hard sell. I think there are always a minority of women who really want to get into advocacy

work. Most people are much more drawn to, as you say, doing some support work.

*Virginia:* Yeah, that touchy-feely stuff.

Sharon: And the advocacy stuff is hard, it's really demanding. And there's no money for it.

*Virginia:* No, well you can't get funding from government, obviously. And who wants to fund an advocacy voice? Because politically, people get scared. You're right. It's very tough.

Sharon: Wasn't that ultimately why *A Voice for Patients* went down?

*Virginia:* Oh yeah! Oh, they couldn't get any money. Because, how long can you get volunteers? You can't run an effective organization entirely on a volunteer basis. I feel that very strongly. I feel there is a strong role for volunteers, but I saw how we had to operate at *Helping Hand*. And we always talked about being volunteer-based -- well, that's bullshit. I mean the volunteers were absolutely integral to providing more of a choice in terms of who you phoned up and spoke to. But the thing would have fallen apart if we didn't have a core team of professional breast cancer survivors that answered the phone, because you can't always rely on people to turn up.

Sharon: Um-hmm.

*Virginia:* So any organization needs somebody on the payroll just to keep things ticking over. And *A Voice for Patients* didn't have that. And couldn't find anywhere that would provide funding that would allow them to do what they wanted to do. Because we couldn't go to -- we did get government money for one particular project, but it had nothing to do with advocacy. It was about diversity. But we couldn't use it for anything else, unfortunately. We thought when we took it we might be able to, but we couldn't.

But, yeah, you're right. From that point of view, it's hard. But even with that, I'm quite surprised, because the breast cancer community is now quite mature, that there isn't more. I mean in the beginning... maybe it's the reverse. Maybe in the beginning, that's when you get your loudest voices. But once things start, you become established and you have a profile and, you

know -- “Breast cancer’s come a long way, baby!” You know, where we get lots of money.

-- Interview with *Virginia*, 2008

In every partnership case I examined, the funding from the industry was designated as an “unrestricted educational grant,” a term which was generally understood to imply that the industry doesn’t predetermine or restrict what groups can say. Individual advocates had different experiences with -- and views of -- such grants. Some members of groups receiving pharma money took the label as reassurance that the money was “no strings” and therefore ethically unproblematic. As was seen in Chapter 3, however, the group *Patients, Know your Rights* had experienced a variety of administrative controls and actually battled with the drug company liaison to have the phrase included on the Patients’ Rights Charter that the company funded. *Virginia*, who had confronted the Executive Director and board members at *Helping Hand* over the issue of pharma funding, took a skeptical view:

*Virginia*: There’s this phrase that used to be bandied around a lot, which is, oh crumb, what is it? The “something educational grant”...

Sharon: Oh, the Unrestricted Educational Grant?

*Virginia*: Yeah! Oh, I love that phrase! (laughter) I *love* that phrase. So, there was a lot of emphasis placed on that from [the Executive Director at *Helping Hand*.]

Sharon: Oh really?

*Virginia*: Oh yeah, yeah, “unrestricted educational grant.”

Sharon: Is that how they would, they would couch their ...

*Virginia*: Yeah. What is that? Give me a break! It’s like, “I’ve given my son an unrestricted educational grant to go to university, but if spends his money on drugs and drink, I’m pulling it!” (laughs).



In science and technology studies, the concept of a “boundary object” is used to theorize something invested with multiple meanings which actors from different sectors use to help them collaborate across boundaries. The boundary object may have different meanings to the various sectors involved; furthermore, these meanings may be negotiated over the course of the collaboration. Depending on the way these negotiations evolve, the boundary object may enable the parties to work together or it may be a source of tension (Shostak, 2007; Star & Greisemer, 1989). The Unrestricted Educational Grant can be understood a boundary object because it allowed groups groups to accept funding from the industry on the understanding that the money had no strings attached, and allowed the industry to award grants without the appearance of bribery. A process of negotiation was most apparent in Group C, when the lawyer from Astra Zeneca advised James not to have the term printed on the Patients’ Charter, but the women in the Working group insisted it was necessary for the Charter to be taken seriously. James agreed and the group was satisfied; had he sided with the company’s lawyer, the collaboration would likely have collapsed at that point. Virginia’s interpretation illustrates a competing meaning assigned by an activist who is skeptical that pharma funding is ever without strings; for her, the Unrestricted Educational Grant is an instrument which companies use to buy the silence of patients’ groups. The concept highlights the role that documents with flexible meanings can play in mediating or exacerbating differences among actors. Exploring the multiple meanings of a boundary object provides insights into the ways that actors with different interests navigate and shape a contested reality.

*Jillian*, who vigorously defended the partnership arrangements of groups she had been involved in, described the pharma funded Report Card project that was criticized on

national television as “no interference ... we had pretty strict guidelines of educational non-interference written into all the agreements” (interview with *Jillian*, 2008), and affirmed that by this she meant they were “unrestricted educational grants.” Pressed about the imbalance in advocacy voices, however, she expressed unease with the status quo.

Sharon: I guess the question is whether patients and drug companies really have the same interests in all cases. In some cases maybe they do but in some cases they don't and I'm worried about when they don't.

*Jillian*: Yeah. Well I think maybe what you're pointing to is, there's a huge gap in the critical spectrum. Like, where are the patients who are standing up lobbying for lower drug costs, or for clearer information about how drug prices are determined? And that stuff is *really* hard! [laughs] I've just joined a research group that's going to be looking at underlying ethical issues around access to therapies, access to treatment. I feel like I'm in over my head. And I'm a bright, university-educated, quick study on most things. But when I look at the whole domain of -- the kind of ethics and the kind of societal obligation of treatment, I feel like I'm in over my head. It's not something that can be taken lightly.

Sharon: Oh yeah, for sure.

*Jillian*: It's a really complicated -- I don't really know how to answer your question because it's a much more complicated and nuanced issue than I could rhyme off the top of my head. There are so many interrelated factors that are related to kind of the shape of our health care system, our expectations as patients. I don't even know if I really believe that we should be investing the money that we're investing in the targeted therapies! Because in the end we can't really afford them as a society, so why would we bother? It's kind of like giving R & D [research and development] money to Rolls Royce to do a hybrid car. ...

Sharon: [laughs]

*Jillian*: ... Well, yeah, but nobody can afford [the product]! And is it really in the best interest of society? Because at that level, you have to be looking at the balance of things.

-- Interview with *Jillian*, 2008

*Francine*, a women's health activist with the group *Pharma Policies to Protect Women's Health*, felt that dissenting voices in the advocacy community were not alone in being silenced; she thought the Partnership Period was marked by a similar chill against dissenting voices within the government bureaucracies responsible for drug regulation:

*Francine*: I see individuals [in government] having a general orientation towards understanding the complexity of this issue [of pharma funding] and being muzzled. Particularly in the federal government, where I had more experience [i.e., meeting with officials as part of a non-profit group]. And I have this sense of a directive from on high that "working with industry is an important part of making this whole machine work." And, "we don't have excess funds to pay for the kinds of things that Canadians want and so we need industry to work with us." And so I think that, even if it's not blatantly stated, it's often stated in many ways in policies that come out, right? About cooperating with industry, even if it's not a directive, [even if it's not] that blunt, there's a general message within the federal government anyway, to employees that, certainly that you can't badmouth industry; and secondly, that cooperating with them is an important piece of how we do business now.

Sharon: Um-hmm.

*Francine*: So that when groups like us [*Pharma Policies to Protect Women's Health*] come along and we critique that, I think what it does is it scratches a nerve in the people who agree with us. I mean, I would put "Joan" at that end of the spectrum, with a small handful of people there with her. And people sometimes have completely surprised me [i.e., government employees who seem sympathetic] .... In some ways, the people who are higher up are going to be the ones who see it most directly, right? They're going to be at the meetings that industry comes to and I think they are the ones that must be the most caught, if they had any kind of consciousness, because they're seeing it firsthand.

And that's where people's real core beliefs, I think, get challenged. But if you're high up [in government], you've got to be careful how you talk about it. You better be careful what you say. I'm just continually amazed that the meetings I sit through with Health Canada people who just do not say a word about this stuff. They just will not pronounce on it. They won't react to you if you say something outrageous. They certainly won't volunteer a statement

about it themselves.

And I find that fascinating! And very much a testimony to the power that industry now has within - I'm just talking about within the area of drug regulation, where they have the most interest in having influence. So I don't know, at the level of individual bureaucrats if there's been any -- I think the cynicism is still there [among government employees] and they keep it carefully under wraps.

Sharon: Cynicism about?

*Francine*: About industry's involvement with what they're doing. Not just anything, but real worry, you know. ... And then, of course there are many who believe its fine -- who don't see any problem. But, I think that there [is] a core of people who truly have the badge of civil servant, [who] try to wear it, and try to view protecting health as their main reason for being there -- the health of Canadians -- and who put safety before industrial development. I think there is a core of them. And they seem to me to be muzzled.

-- Interview with *Francine*, 2007

Sometimes the silencing of critical voices was indirect, resulting from the disappearance of an organization. The group *A Voice for Patients* closed its doors in 1999 rather than take pharmaceutical company funding, and *Learn from Drug Tragedy* ceased operations in 2009. Although *Critical Advocacy to Prevent Cancer* has managed to remain solvent, it narrowed its focus to the environment and prevention out of recognition that it's not possible "to do the whole gamut" and do it well (see Chapter 3).

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The acrimony underlying the rift between the two sides in the discourse had also largely precluded any possibility of dispassionate debate among those who accepted pharma money and those who did not; the breakdown of discourse between parties on each side also made public discussion of the important policy issues bound up in the

stand-off difficult. Thus, *Jillian* referred to a “huge war” between the “pharma-takers” and the “the sanctimonious ones on the other side” (*Jillian*, quoted above).

*The Discourse of Rights and Cancer Drugs* the November 1996 meeting *Together to an End* was the site at which a new discursive theme was introduced (see pages 306-312), asserting the importance of giving cancer patients rapid access to new expensive drugs and linking geographical differences in cancer survival rates to the availability of more aggressive treatment regimens. Documents and practices reinforced and elaborated this theme in subsequent years. These include the documents produced by the pharmaceutical industry and public relations firms which defined the rapid approval of new drugs and patients’ access to new drugs as the key areas of overlap with the interests of patients and thus the most fruitful common ground on which the two cultures could meet; this claim of common interests was incorporated into the discourse of Canadian patients’ organizations and became a rationale for collaborations between the two actors (Picard 2001). *All-Cancer Advocacy*’s high-profile Report Card project, articles in the group’s magazine, and Pat Kelly’s Master’s thesis elaborated the discourse in important ways. Cancer survival rates in Canada were said to be poor compared to those in the U.S., with a further suggestion that the alleged gap was attributable to new medications being less available in Canada. Further, patients were said to have the basis for successful law suits if their provincial governments denied them treatments considered “best practice” elsewhere. The national coalition of patients’ organizations, Best Medicines Coalition, formed in 2000 with funding from the pharmaceutical industry, made rapid approvals of new drugs and their placement on provincial formularies its main objective. This coalition is an umbrella group for disease organizations and its representatives meet with

the federal drug regulatory agency to consult on patients' issues (Health Canada 2002).

The organization:

...advocates that Patients and consumers have the right to access the best medicines/drugs and health care, as health care services which are recognized under the Canada Health Act [based on the rationale that] patients have rights to new drugs that often provide benefits not afforded by previously available products (Kovacs Burns 2005: 18).

In Chapter 3, I discussed in detail the *Charter of Breast Cancer Patients' Rights*, developed with funding from Astra Zeneca Canada. Although the assertion that patients have the right to have new drugs paid for by provincial health plans that appeared in an early draft form of this document was removed, pharma-funded projects developed by other groups incorporate the same assumption --that patients have a right to expensive new drugs--into the patient group discourse in other ways. Indeed, in the Partnership Period, this assumption underlies virtually all the pharma funded projects with breast cancer groups that I examined. The company funding each project typically has a new drug in the review process; however, the particular project the company funds never specifically identifies that drug (the ethical guidelines of all the organizations I studied prohibit undertaking a project that required a group to advocate for approval of a particular drug); however, since all brand-name companies share the goal of rapid drug approvals and formulary placements, a project that aligns the group with this process cannot be seen as "favouring" one drug over another. When the sponsoring company's drug comes up for approval or formulary review, the organization can then advocate on behalf of that drug's approval without compromising its position of impartiality *vis à vis* the various companies and their drugs as was done in *All-Cancer Advocacy's* push to

have AC-T approved by Health Canada, and *The Hub*'s advocacy to have Tykerb™ and Xeloda® placed on the Ontario formulary.

The argument that patients' have a right to new treatments based on the standard of care in other countries, or without regard to cost, or the cost-benefit ratio is problematic on a number of levels. As the cases of AC+T and high-dose chemotherapy with stem cell rescue illustrate, a treatment may become the standard of care on the basis of aggressive promotion by the manufacturing and/or "hope" rather than on the basis of demonstrated benefits. Such promotion conflicts with the patients' right to accurate information about the treatment's actual demonstrated benefits (which may be limited or no better than less expensive treatments); and the patients' right to information about risks, which (as with high-dose chemo and erythropoietin) can include earlier death may be contravened. A lack of concern with cost-benefit ratios opens the door to patients' groups distorting the spending priorities of provincial health departments, and/or taking funds from other spending envelopes, such as education, based on aggressive lobbying tactics rather than the actual potential of the treatment to contribute to health.

## **5.5 CONCLUSION: THE MAKING OF TWO ACTOR-NETWORKS**

Throughout the past two decades, drug access has emerged as a central health policy issue in Canada and in other high-income countries and one on which opinion is sharply divided. This debate is closely tied to the rapid rise in the cost of drugs which has been particularly dramatic in the case of oncology drugs. When Herceptin®, the first biologic treatment for breast cancer initially gained approval, its cost immediately prompted concern (Sibbald, 1999, Martin, Pater and Singer 2001). The debate about the cost of cancer drugs has accelerated through the past decade (Goldman, 2007; Kolata and

Pollack, 2008; Dhalla and Laupacis, 2008; Smith and Hillner, 2011). An intersecting discourse suggests that patients' groups are destabilizing attempts to use scientific evidence as the basis for confronting the drug cost issue (Kondro and Sibbald 2005; Boseley, 2006; Hébert and Stanbrook, 2010; MacKenzie, Chapman, Salkeld and Holding, 2008; Rothman 2011). Writing in the British newspaper *The Guardian*, Sarah Boseley explicitly ties a campaign against cost controls on cancer drugs in Europe to funding from Roche, the European distributor of Herceptin® and Avastin® (bevacizumab) (Boseley 2006).<sup>285</sup>

The competing discourses over Herceptin's® cost can be seen by examining three flashpoints: first, Health Canada's initial approval of the drug in August 1999 as a treatment for women HER2 positive cancers whose cancer had metastasized (Sibbald 1999, Batt 2000), second, a renewed controversy in 2005 over whether the drug should be funded for women with early-stage breast cancer (Kondro and Sibbald 2005; Picard 2005; Priest 2005), and third, a public outcry in 2011, when the province of Ontario denied coverage to a woman whose early-stage cancer was deemed "too small" to justify treatment with the costly drug, only to reverse the decision in the face of public pressure (Picard 2011; Priest 2011a, 2011b, 2011c, 2011d). At each point actors from within various sectors have aligned themselves more or less consistently to debate the issue. In each instance, the scientific evidence needed to make a policy decision (to fund the drug or not) was preliminary and unclear. The drug's high cost raised a health systems question that had not been confronted so openly before, however: how could a system based on a principle of universal access to necessary treatments cope with a



costly cancer drug that appeared to have a benefit that was measurable but modest in relation to the price the company was charging?

Barbara Sibbald, associate editor of the CMAJ, confronted the dilemma when Health Canada first approved the drug for HER2-positive women with metastatic cancer, in August 1999. Referring to Herceptin® as “a \$2,700-a-month drug,” Sibbald noted that the drug’s approval was based on a clinical trial in which patients in one arm had shown an improvement in survival of on average five months over chemotherapy alone. Each of Canada’s provinces and territories now had to decide whether it could accommodate the cost of covering the drug for eligible women and by November 1999, only B.C. and Ontario had committed to doing so, decisions that set up regional inequalities in access. Under Canada’s health care system, she asked, was a province ethically obliged to provide a treatment that benefitted patients, regardless of cost? (Sibbald 1999: 1173).

Sibbald questioned the ethics of Genentech’s decision in pricing the drug so high. A spokesman for Genentech cited the drug’s high research and development costs; similarly, McGill oncologist Brian Leyland-Jones (a lead investigator in the clinical trials) vigorously defended the price on the grounds that the costs of bringing a drug to market were “phenomenal” (ibid:1173). Leyland-Jones also described the drug in terms that (recalling Emily Martin’s *pharmakon*) began to characterize Herceptin’s® personality, as viewed by one of the drug’s obvious admirers: Herceptin®, he said, represented the “tip of the iceberg” in the coming in advance in “selective, gene-targeted” therapies. He described this new generation of cancer therapy as “discriminate, selective drugs” with “negligible side effects” (Sibbald 1999: 1173). While women taking the drug

might have chills & fever on the first day, he said, “*patients said* it’s like taking water” (ibid: 1173, italics mine). By invoking patients as the authorities on the drug’s claimed superiority over old-style chemotherapies, Leyland-Jones bypassed the scientific record as set out in the company’s product monograph, a profile that included several uncommon but life-threatening effects of the drug, most notably, heart failure and severe respiratory distress, both sometimes fatal, and a long list of less serious effects fairly typical of cancer therapies that are not “targeted,” including nausea, vomiting, dizziness and rash (Genentech, 2005, 2010).

As of this writing, the breast cancer community’s perspective on drug access is dominated by the groups that receive funding from the pharmaceutical industry. Using actor-network terminology, this *translation* of scientific knowledge differs markedly from that developed concurrently by a different subset of organizations. First, the two groups diverge in the way they *problematize* drug access. I refer to The Hub’s problematization as “rapid access” and the competing problematization as “safety and cost-control.” Actors in both camps express many of the same concerns, but advocate different solutions, based on different assumptions. To capture the main elements of safety and cost-control problematization, I draw from a recent document titled *Life Before Pharmacare: Report on the Canadian Health Coalition’s Hearings into a Universal Public Drug Plan* (Anonymous 2008), jointly published by the Canadian Health Coalition (the CHC) and the Canadian Centre for Policy Alternatives (CCPA).

On the question of which drugs qualify as “essential”, this discourse, like the one it contests, deplores the patchwork nature of the current drug coverage in Canada, the lack of access to life-sustaining drugs, and the bureaucratic snafus that ensnare patients

and their families when they are facing an illness. At this point, however, the two discourses diverge. Whereas the “rapid access” discourse hinges on the need for more rapid approvals for new drugs and uniform cross-Canada formulary coverage for new drugs as soon as possible after they are approved, the safety and cost-control discourse emphasizes the need for a national pharmacare plan, integrated into the existing health care plan. A national formulary would “cover the complete cost of all essential drugs” (ibid: 30). The CCPA/CHC document recommends that the decisions on which drugs are paid for would be “based on *independent* evaluations of *safety*, effectiveness, and *value for money*” (ibid: 30, italics mine). Furthermore, the plan would include bulk purchasing to reduce drug prices, a national public information system free of conflict of interest with the pharmaceutical industry, strengthened enforcement of the direct-to-consumer drug laws, measures to improve the prescribing behaviour of professionals and, finally, “accelerated access to more affordable non-patented drugs and repeal of the regulations that extend monopoly patents beyond 20 years” (ibid: 20). The document thus departs from the discourse of *The Hub* and its allies in its assumption that drug pricing and the influence of the pharmaceutical industry are central problems. Remedies incorporate cost-effectiveness into the drug evaluation process and explicitly exclude the pharmaceutical industry as an actor in evaluating its own products. In the “safety and cost-control” problematization, the *obligatory passage point* for drug evaluation is thus comprised of researchers, policy makers, practitioners and patients’ organizations that are free of pharma influence. In the “rapid access” problematization, patients’ organizations comprising patients with chronic diseases are an *obligatory passage point* for drug evaluation (Kovacs Burns 2005). The groups in question acknowledge receiving

substantial funding from the pharmaceutical industry but they discount this funding as a factor in their organizational decision-making.

The documents backing the “rapid access” discourse and the CCPA/CHC report both list an impressive roster of groups and individuals who made representations at its hearings (*enrollment*). They include academics, physicians, union representatives, public health workers, members of community organizations, seniors’ organizations, and politicians from the left-leaning New Democratic Party. In short, advocates of the latter position are, broadly speaking, drawn from the left of the political spectrum (see Anonymous, 2008b: 32-34), whereas advocates of the former position are drawn from the corporate world, from right-of centre political parties, and from non-profit agencies such as the Fraser Institute that advocate less government, deregulation and a relatively unfettered free-market economy.

In sum, by 2011, the dominant discourse in the breast cancer movement about pharmaceutical policy corresponds closely to that of the pharmaceutical industry and to free-market actors in Canadian society. The earlier, intense internal debates over pharmaceutical company funding and the need to separate drug –related information from the potential effects of such funding have given way to a pragmatic acceptance of industry funding bolstered by a belief within the movement that mechanisms such as the unrestricted educational grant and acknowledgement of pharmaceutical gifts protect the organizations from industry influence.

## **5.6 SUPPLEMENT: A SOCIALLY CONSTRUCTED PHARMACOPOEIA**

A pharmacopoeia is intended as an authoritative reference that specifies for pharmacists and other users the herbal, chemical, or other ingredients that make up a drug remedy. In this Supplement, I use three examples from my research to show that, in addition to these tangible ingredients, a variety of social influences also “make up” the various breast cancer treatments discussed in the text.

Collaborative projects between drug companies and patients’ groups are only one aspect of the socially constructed portion of the pharmacopoeia. Clinical trials are increasingly “branded” to evoke positive imagery (Orlowski and Christensen 2002). Evocative acronyms for clinical trials testing cancer drugs include STAR (Study of Tamoxifen and Raloxifene) and ATAC (Arimidex, Tamoxifen Alone or in Combination). Hochhauser (2002) argues that branding a treatment with positive imagery before the process of testing it has been completed constitutes a form of doublespeak that masks the real risks of participating in experimental research projects. Similarly, companies rely on naming consultants to select trade names for drugs that will support their marketing objectives; Abel and Glinert (2008) found that the names of 60 commonly-prescribed chemotherapy drugs tended to evoke lightness, smallness and fastness.

The treatments selected for illustrative purposes in the Supplement are 1) high-dose chemotherapy with stem cell rescue, a risky procedure promoted in the absence of valid clinical trial evidence for over a decade 2) the three aromatase inhibitors Arimidex®, Aromasin®, and Femara®, promoted on the basis of surrogate end-point data as an advance over the drug tamoxifen; and 3) the social construction of Xeloda® + Tykerb™ as “lifesaving” based on surrogate end-point findings from an incomplete trial.

**Table S1 Social Construction of High-dose Chemotherapy with Stem-Cell Rescue**

<b>Scientific knowledge, questions and controversies</b>	
<p><b>Known facts about drugs and drug regimen:</b> drugs used, mechanism of action, mode of administration, clinical trial results.</p>	<ul style="list-style-type: none"> <li>• Details of procedure and specific drugs used vary but concept is to administer cytotoxic drugs from breast cancer repertoire (i.e., drugs that kill cells while they are dividing) at 2 to 20 times the normal dose in the hope of destroying all cancer cells in patients' system. The high level of toxicity destroys the cells in the patients' bone which are necessary for survival, so a sample of the patients' own bone marrow is removed and stored while the patient is treated with chemotherapy. The bone marrow is then replaced and given time to reconstitute. During this period the patient has no immunity to infection and is kept in strict isolation. As the procedure was developed, the drugs Eprex® and Neupogen®) were introduced to stimulate the growth of red and white blood cells respectively, speeding recovery and shortening hospital stays to as few as three weeks (from four to six weeks). (Love with Lindsey 1995).</li> <li>• The procedure entered usage in the U.S. in the late 1980s prior to clinical trial results. Canada and other high-income countries trials conducted clinical trials throughout the 1990s; most showed an initial but temporary response improvement over conventional chemotherapy. Toxic side-effects included treatment-related death in 5%-15% of cases (20% in early attempts). A South African research team reported the only positive clinical trial results from the procedure but in 2001 the head of the research team was found to have committed research fraud. These revelations, along with clinical trial results showing the procedure had no advantage over standard chemotherapy, effectively ended the procedure.</li> </ul>
<p><b>Key scientific question(s)</b></p>	<ul style="list-style-type: none"> <li>• Will extremely high doses kill enough cancer cells to improve survival in patients with a high risk of metastases?</li> <li>• If the procedure is more effective than conventional chemotherapy, does the advantage outweigh the considerable risks and monetary expense?</li> </ul>
<p><b>Source(s) of scientific controversy</b></p>	<ul style="list-style-type: none"> <li>• Initial controversy arose from the growing popularity and use of the procedure in the absence of evidence of efficacy, with high off-setting toxicities and costs.</li> <li>• Revelations of fraud by South African researchers constituted a major research scandal and suggested that conventional chemotherapy had reached its limits.</li> </ul>
<b>Factors contributing to social construction</b>	
<p><b>Multiple social factors combine to bypass clinical trials and push cytotoxic chemotherapy beyond its limits</b></p>	<p><i>Physician belief in extreme treatments for cancer:</i> cancer specialists administered the treatment outside of clinical trials in the hope it might work.</p> <p><i>Profit motive:</i> Secondary and tertiary US hospitals in particular were suspected of using the treatment as a cash cow, contributing to the high mortality rates;</p> <p><i>Culture of hope:</i> More than 20,000 eligible American patients refused to enter clinical for fear of being randomized into standard treatment arm and travelled to hospitals willing to administer the treatment. Clinical trials in the U.S. thus suffered slow accrual.</p> <p><i>Public pressure:</i> American insurers gave in to public pressure and agreed to pay the high cost of the procedure. (In Canada, the procedure was conducted within clinical trials, never as an approved procedure.)</p> <p><i>Media hype:</i> Media stories cited the procedure as giving hope to patients whose chance of developing metastases was high.</p> <p><i>Patient Advocacy:</i> U.S. advocates promoted the procedure and pressured to have it accepted as standard treatment (Mayer, 2005); in Canada, Sylvia Morrison, a patient who had the procedure performed in the U.S., pleaded at the Parliamentary hearings for adoption of the procedure in Canada on the grounds that desperate patients should not be denied access to a promising procedure.</p> <p><i>Scientific Hubris:</i> Dr. Werner Bezwoda, a South African researcher, published fraudulent research results (Weiss et al 2000) which lent credibility to the procedure despite the inability of others to replicate his findings.</p>

**Table S2 Social Construction of Aromatase Inhibitors: Arimidex® (anastrozole), Aromasin® (exemestane), and Femara® (letrozole)**

<b>Scientific knowledge, questions and controversies</b>	
<b>Factual information about drug and drug regimen:</b> mechanism of action, mode of administration, clinical trial results	<ul style="list-style-type: none"> <li>• In postmenopausal women, direct secretions from the ovaries are no longer the main source of estrogen; rather, the ovaries and adrenal glands secrete precursors to estrogen which the enzyme aromatase then converts to estrogen in sites throughout the body. Aromatase inhibitors are a class of drugs which block the enzyme and thus reduce levels of estrogen.</li> <li>• As a treatment for post-menopausal women with advanced (metastatic) breast cancer, Arimidex, Aromasin and Femara, all extend life longer than tamoxifen (Mauri, Pavlidis, Polyzos et al 2006).</li> <li>• As an adjuvant treatment for women with early estrogen-positive breast cancer, aromatase inhibitors are approved to be given after tamoxifen treatment or as a first-line treatment. They have an advantage over tamoxifen in delaying recurrence (a surrogate end-point) but have not been shown to extend survival. Side-effects include bone and joint pain, increases in fractures, hot flashes, weight gain and gastro-intestinal complaints and (rarely) heart attack, stroke and blood clots.</li> </ul>
<b>Key scientific question(s)</b>	<ul style="list-style-type: none"> <li>• As an adjuvant therapy, do aromatase inhibitors reduce mortality (a true end-point), as tamoxifen does?</li> <li>• Do the drugs used as an adjuvant therapy reduce quality of life to a greater extent than tamoxifen?</li> </ul>
<b>Source(s) of scientific controversy</b>	<ul style="list-style-type: none"> <li>• Early trial results of benefit are known to be an unreliable indication of long-term benefit;</li> <li>• Benefits demonstrated are for delayed recurrence only; trials have not shown benefit to survival;</li> <li>• Trials were stopped before meaningful results were obtained and early stopping of trials precludes obtaining clinically useful results (i.e., a useful risk-benefit analysis);</li> <li>• As an adjuvant therapy, as of 2011, none of the three drugs had shown significant survival benefit over tamoxifen.</li> </ul>
<b>Factors contributing to social construction</b>	
<b>A surrogate end-point and a clinical trial stopped early are used to imply evidence of benefit and to build a case for “patient information sessions” and “patient choice”; companies marketing the drugs fund groups to mount projects that support these objectives.</b>	<ul style="list-style-type: none"> <li>• Use of a suggestive acronym (ATAC) for the pivotal clinical trial comparing adjuvant use of tamoxifen and Arimidex implies unproven benefits (Hochhauser 2002, Orlowski and Christensen 2002)</li> <li>• Early stopping of comparison trials with tamoxifen for adjuvant use of all three drugs generates publicity and excitement but limits clinical usefulness of trial results</li> <li>• Lacking reliable evidence, the medical community invokes “patient choice,” a strategy which implies patients are being granted respect and autonomy; however, patients can no more make an “informed choice” in the absence of critical evidence than can their physicians; indeed, patients may mistake a surrogate end-point as evidence of survival benefit (Cannistra, 2007: 1544)</li> <li>• Astra-Zeneca and Pfizer sponsor public information sessions featuring a local oncologist and organized by patients’ groups with logistical support from a public relations firm. These bypass restrictions on venues in which drug companies can ethically convey drug trial information.</li> <li>• AstraZeneca funds the development of a Patients’ Bill/Charter of Rights by representatives of breast cancer groups from across the country; an early draft implies a right to formulary coverage of new treatments such as Arimidex.</li> <li>• A disguised “help-seeking” ad campaign run by <i>The Hub</i> and funded by Novartis urges patients who have taken tamoxifen to “ask your doctor” about additional possible treatment. The campaign capitalizes on the organization’s credibility with patients and its ability to target the audience for whom Femara® is intended and implies the drug “can save lives.”</li> </ul>

**Table S3 Social Construction of Xeloda® (Hoffman-LaRoche, capecitabine) + Tykerb™ (GlaxoSmithKline [GSK], lapatinib)**

<b>Scientific Knowledge, Questions and Controversies</b>	
<b>Factual information about drug regimen:</b> drugs used, mechanism of action, mode of administration, etc.	Xeloda® is changed in the body to 5FU which interferes with the growth of certain tumour cells. Xeloda, alone or combined with Taxotere®, has been shown in clinical trials to extend life in patients with advanced breast cancer by approximately three months. Tykerb™ is a kinase inhibitor that interferes with the growth of HER2 tumour cells and was designed to treat women with HER2-positive cancers. In August 2009 Health Canada granted Tykerb™ approval for use in combination with Xeloda® based on a single clinical trial in which patients with metastatic breast cancer who were HER2-positive received either both drugs or Xeloda® alone. Patients with the combination therapy showed improved time to progression (a surrogate end-point). The product monograph (dated September 6, 2011) specifies that approval is based on a surrogate endpoint “without demonstration of an overall survival advantage or palliation due to therapy” (GlaxoSmithKline 2011:3). In combination therapy, Tykerb™ and Xeloda® are taken daily as tablets. Common side-effects of the combination include diarrhea, nausea, vomiting, skin disorders and fatigue. Some patients taking Tykerb™ in clinical trials experienced cardiac arrest and sudden death (rare), or liver toxicity and death (also rare).
<b>Key scientific and/or policy questions</b>	<ol style="list-style-type: none"> <li>1) Does the combination Xeloda®+Tykerb™ extend life in women with HER2-positive metastatic breast cancer beyond treatment with Xeloda® alone?</li> <li>2) Does a modest <i>estimated</i> (based on improved time to survival) extension of life when Tykerb™ is added to Xeloda alone (expected gain of 2.4 months and 0.12 quality-adjusted life years) warrant the price tag (US\$ 2,900/month; estimated \$19,630 over the patient’s lifetime; \$166,133 per Quality-adjusted life-years gained)?</li> </ol>
<b>Source(s) of scientific and/or policy controversy</b>	Early stopping of the pivotal clinical trial limits the data for determining safety and efficacy. Furthermore, using estimates of benefit, Tykerb™’s price exceeds the international norms that insurers use to evaluate cost/benefit.
<b>Usage</b>	Health Canada approved the combination on May 15, 2009, for patients with metastatic breast cancer whose tumours are HER2-positive and whose disease had advanced after treatment with taxanes, anthracycline, and trastuzumab (Herceptin®).
<b>The Social Construction of Xeloda®+Tykerb™ as “Lifesaving”</b>	
<b>A patients’ group helps a costly new drug combination to leapfrog the drug approval process and gain provincial formulary status based on 4.4 months of delay to a surrogate end-point</b>	<ul style="list-style-type: none"> <li>• Investigators halt the sole, pivotal trial early based on the statistically significant finding of 4.4 months increased time to progression (TTP), a surrogate end-point, in the combination arm. Critics question the practice of early stopping on ethical grounds because it generates premature excitement by implying benefits that are unproven and precludes obtaining evidence of whether the treatment will yield actual benefits (life extension and/or reduced side-effects). (2006)</li> <li>• Health Canada refuses GSK’s application for drug approval on Dec. 13, 2007, claiming the data are insufficient to show safety and efficacy (HPFB 11/03 2009).</li> <li>• <i>The Hub</i> issues a “Wait Times” report, funded by Tykerb’s manufacturer, GSK, which criticizes Canada’s federal government for procedural delays in approving new drugs and provincial delays in adding them to drug formularies. (January, 2008)</li> <li>• The company resubmits its application on March 11, 2008, responding to safety issues; efficacy is still in question, however.</li> <li>• Health Canada convenes a panel of Canadian experts from outside the government to reconsider the application; the panel concludes that evidence of efficacy is sufficient and recommends the HPFB reconsider its decision; on December 4, 2008, the HPFB approves the application, granting a Notice of Compliance (NOC).</li> <li>• International cost-benefit assessments question the use of the combination based on the high cost of Tykerb™ and estimates of modest benefit. (2009, 2010)</li> </ul>



	<ul style="list-style-type: none"> <li>• A <i>Globe and Mail</i> story highlights the plight of an Ontario woman with rapidly advancing metastatic cancer who has been denied the combination Xeloda® + Tykerb™, recommended by her oncologist to delay time to progression. GSK has offered the woman Tykerb™ under its compassionate access program (i.e., without charge), thus deflecting the cost/benefit concern about Tykerb™; however, because the provincial government has not put Xeloda®+Tykerb on its formulary, the province denies the oncologist’s request for Xeloda®. Two ambiguous quotes in the article blur the distinction between time-to-progression and life extension/survival: the woman’s oncologist states, “The current process for accessing life-sustaining drugs for cancer patients is flawed”, while the patient says she should not have promised her 17-year-old daughter she “wouldn’t die ... because it isn’t under my control” (Priest 2009). (Dec. 18, 2009)</li> <li>• Promoted by the <i>Globe and Mail</i> story, in December 2009 <i>The Hub</i> writes to the Ontario Minister of Health and launches a national advocacy campaign among its members, urging the government to put Xeloda® + Tykerb™ on the provincial formulary.</li> <li>• The Ontario government approves Xeloda® + Tykerb™ for formulary inclusion in late December 2009.</li> <li>• <i>The Hub</i>’s executive director and president hail the decision, castigating the government for “bureaucratic red tape” and “lack of compassion”. In a bulletin to its members, in January 2010, the <i>The Hub</i> claims the drug combination “is saving lives,” despite scientific consensus that advanced breast cancer is presently incurable. The Hub explicitly aligns its position on treatment access to that of the International Federation of Pharmaceutical Manufacturers &amp; Associations.</li> <li>• On December 14, 2010, <i>The Hub</i> hosts a webinar narrated by two employees from GSK, Tykerb™’s manufacturer, which also sponsors the webinar. The two narrators explain to <i>The Hub</i>’s members the process by which Canada approves drugs and how drugs are placed on formularies. The presentation frames the drug approval process as contravening all five tenets of the Canada Health Act and details an advocacy plan that patients and physicians can follow to remove the “scientific and bureaucratic roadblock” in healthcare.</li> </ul>
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## **CHAPTER 6      CONCLUSIONS AND POLICY CONSIDERATIONS**

### **6.1 INTRODUCTION**

I decided to study the breast cancer movement for much the same reason I decided to start a breast cancer group after my breast cancer diagnosis, more than two decades ago: something seemed wrong. In 1988, I felt alone with the disease -- I wanted to talk to others experiencing the same trauma. I was frightened by the risks accompanying the chemotherapy treatments my oncologist recommended and wanted to know if following his advice was the right course of action. And, finally, as I became aware of the enormous, complex system of institutions developed to deal with breast cancer – clinicians, researchers, administrators, corporations and charities – it seemed unjust and counterproductive that patients were left out of the decision-making apparatus. AIDS patients had demonstrated the power of locally-based patients' groups linked to national and international networks; wouldn't the same approach work for breast cancer patients?

As my discussion of the origins of the movement shows, I was far from unique in this desire for a knowledgeable community with a voice. And unquestionably, we succeeded in creating a community: today, no breast cancer patient in Canada needs to feel isolated. When it comes to treatments and related decision-making, however, I began to doubt that breast cancer groups had succeeded in becoming sites of knowledge to which patients could turn. I also questioned whether the organizations we developed are able to contribute a perspective on treatment policies that is truly representative of patients' needs and concerns. The financial dependence on the pharmaceutical industry may not be the only reason for this failure, but it was the focus I chose for my research.

I designed this study of breast cancer advocacy groups in Canada to understand the evolution of their alliances with the pharmaceutical industry, and the effect of these alliances on their claims about pharmaceutical drugs and drug policies. Chapters 3 to 5 present my results in the form of, first, biographical profiles of three groups with contrasting positions on pharma funding; second, three policy landscapes against which breast cancer groups in Canada have evolved; and third, a detailed narrative describing the evolution of Canada's breast cancer movement and the internal struggles as the groups within it positioned themselves with respect to pharma funding, drug policies, and new breast cancer drugs. In this chapter, I return to my initial questions (pages 5-6) and examine them in the light of my research findings. I then consider the adequacy of theoretical concepts (including the typologies of groups) from my literature review in Chapter 1 to explain my findings. I evaluate the methodological strengths and shortcomings of my research and, finally, I propose recommendations based on my findings and relevant policy discussions in the health literature.

## **6.2 THE RESEARCH QUESTIONS**

My central question was, *how did patient advocacy groups that engage in knowledge claims about pharmaceutical drugs come to form alliances with the pharmaceutical industry?* My research shows that the alliance came about through a combination of internal contestation within and among groups, overtures from the pharmaceutical industry based on a growing awareness of the potential usefulness to the industry of forming such alliances, and government policies that rewrote the rulebook for the civil society sector. As breast cancer patients' groups gained profile and influence, the

pharmaceutical industry recognized them as potentially useful allies in bringing new drugs to market quickly and to reimbursement by public and private sector insurers. At the same time, policies that severely limited grants to non-profit groups and tightened the eligibility for tax-exempt charitable status for groups engaging in advocacy nudged the groups into corporate partnerships by systematically shutting off alternative sources of funds. Within Canadian policy circles, the dominant, critical perspective of the pharmaceutical industry that had prevailed was replaced by a discourse that (as women's health activist *Francine* put it), "working with industry is an important part of making this whole machine [of drug policy] work."

Guided by my additional questions, my research explores the politics of these alliances and their policy implications. I summarize these findings below.

### 6.2.1 Discursive Struggles within the Groups

Within the groups studied, I identified three central discursive struggles. The first was over the ethics of developing relationships with the pharmaceutical industry, an actor whom some groups viewed as untrustworthy and others were willing to trust; the second hinged on the perspective groups had of new cancer drugs, drug regulation and financing, and the remedy/poison duality of drug treatments; and the third was whether taking money from the industry was likely to affect the substance of the group's internal programming and external advocacy.

Underlying the division over these struggles were differences in the views of society, social justice, and the character of drugs. Groups mistrustful of pharma held a collectivist view. Based on the industry's past misdeeds, they argued for solidarity with

women who had been harmed by drugs in the past. Groups in this camp claimed that these past harms should serve as a warning to the public of drugs' inherent duality and the propensity of profit-seeking companies to misrepresent their creations to the public as entirely beneficial. They depict drugs as seductive in their power but having the potential of a Frankenstein's monster, flawed creations that inadvertently maimed or killed innocent people and needed to be closely watched. Society (through the government) had an obligation to protect those who might suffer injury. Unless carefully regulated, the industry had shown it would make fraudulent claims about its creations to the detriment of public health. In questioning the hype around drugs with minor or unproven benefits, their high prices, and government policies for rapid approvals, the groups advocated solidarity with patients who were making treatment decisions in the present and those who would need the resources of a viable health care system in the future. They claimed that taking money from pharma would inevitably affect groups' advocacy, if only by silencing criticism of drugs and their makers when it was needed.

This view was collectivist and rooted in feminist social justice discourses of the 1970s and 1980s. Their position was also framed to protect others from harm in the future, to maintain the social safety net, and to encourage members of civil society groups to speak out in the face of problems or wrongdoing.

The perspective of groups that had few reservations about forming pharma alliances invoked a different type of solidarity. Their leaders favoured partnerships with the pharmaceutical industry and saw these collaborations as examples of diverse actors working towards a common goal, that is, to speed the federal government's approvals of new drugs and to ensure they were placed on provincial formularies on the grounds that

patients should have the choice of trying new treatments that had been shown in clinical trials to have anti-cancer effects. Leaders of these groups reported positive experiences with companies as evidence that such alliances could work and argued that any problems could be worked out privately between the parties involved. Far from seeing drugs as Frankenstein's creations, pharma-funded groups constructed them as potentially curative to patients and thus worthy citizens who deserved to be welcomed into society, not subjected to endless bureaucratic barriers. They felt that cancer patients had nothing to lose and everything to gain in taking new, promising treatments.

Groups like *All-Cancer Advocacy* presented a new advocacy group model which is ideal for a neoliberal era. Like *New Drugs Now!* it was a pharma-funded group devoted entirely to political advocacy and led by high-profile patients. In exchange, the groups forego donations from the public and the tax benefits of charitable status; they also define direct work with the patient community as outside their mandate. The focus of their advocacy is consistent with the neoliberal values of small government, of less regulation of industry, and of individual choice for patients. This perspective was grounded in individual rights and fits comfortably with neo-liberal challenges to the collectivist values that underpin the welfare state. These views are at odds with the basic tenet of a publicly funded health care system based on need over want. They are consistent with the shift towards privately funded clinics in Canada for those who want and can afford faster attention from specialists and access to the latest technologies. Their discourse delegitimizes as advocacy actors civil society groups that work closely with the communities they represent on two grounds. First, these groups usually have charitable tax status (which they need to raise funds from the community); second, they often

receive short-term government contracts as a source of funding, funding which is framed as a conflict of interest compromising their ability to critique or confront government policies.

### 6.2.2 Shifting Alliances and the Question of Co-optation

Once groups began to enter into alliances with drug companies, they fell along a continuum from active rejection of alliances at one end to multiple and ongoing alliances at the other, with contingent alliances (usually short-term and involving relatively small amounts of money) falling at various points in between. Some groups that were open to alliances in general reserved certain types of activities, such as those that involved conveying information to patients about treatments-- as off-limits from pharma funding.

The nature of the alliances also shifted over time. Based on ruptures in the nature of relationships between the groups and the pharma industry, and between the groups and government, the periodization analysis identified three distinctive periods in the relationships between breast cancer groups and the pharmaceutical industry. I identified these as *Grass Roots*, *Contestation*, and *Partnership*. Over time, alliances with industry become more common, more lucrative, more institutionalized, and more accepted. At the same time, funding alliances with government agencies became tied to service provision, diminished in importance and (where they still exist) are viewed within groups as a source of irritation.

These changes can be understood as one example of a political transformation of the country's health care system in which government and private sector actors have gradually moved from a welfare state structure to a neoliberal one, a transformation that

Pat Armstrong argues substitutes dubious, exploitative forms of social cohesion for structures based on a commitment to community and an active, democratic welfare state (Armstrong 2010). The mechanisms of change that she identifies resonate with the shift over time that I found within patients' organizations; for example the transfer of responsibility for care to communities, especially women, who are not given "the means to take up these responsibilities in ways that promote equity" (Armstrong 2010: 90). She also cites the use of fear tactics such as "panic about wait times" (Armstrong 2010:99) when in fact wait times in our health care system have not increased. Armstrong's evocation of the wait-times theme as a fear tactic recalls some of the pharma-funded projects found in the breast cancer patient-group narratives. The wait-times study which *The Hub* undertook, and the Patients' Rights project of the *Patients' Know Your Rights* working group, are both ostensibly concerned with making the system more just. They both, however, tap into patients' fears that the system will fail them and engage circulating discourses that are used to promote private alternatives to Canada's welfare state health care system.

The *Grass Roots Period* supported a welfare state collective model of care, in which the state collaborates with groups of patients who want to increase their autonomy through self-help groups. Over time this model has moved towards one which incorporates the norms of neoliberalism, as outlined by Armstrong (ibid: 100-101): privatization (groups form alliances with industry, the terms of which are not public but which are often designed to encourage rapid drug approvals at the federal level and the addition of new drugs to the provincial formularies); volunteer work used to downsize government services and reduce labour costs; managerial values requiring groups to



assure “accountability” by demonstrating measurable outcomes; and advocacy that supports marketization (in this case, new drugs are a particular focus).

Based on the narrative of Chapter 5, I argue that pharma industry cooptation is a fair description of what happened to the breast cancer movement in Canada as a whole, although the evidence of resistance and ambivalence that remains within the breast cancer community is important to recognize. The “movement” is now better described as several movements and the issue of pharma funding is one important line of cleavage. The original scattering of small, grass roots organizations evolved into a well-structured network of groups and coalitions in which the most powerful are funded by the pharmaceutical industry. These groups enjoy a position of influence in the construction of knowledge about breast cancer treatment drugs which few of the others, if any, can match.

### 6.2.3 Ethical Codes Governing Pharma Partnerships

As seen in the narratives that comprise Chapters 3 and 5, all the groups developed internal codes to govern their relationships with the pharmaceutical industry. These came out of extensive internal discussions at the board level of each group. The initiatives of several organizations to set a standard for the community were unsuccessful with the result that the codes vary from group to group, from an outright prohibition to a willingness of some groups to accept industry as their sole funder. In between are variations on an ambivalent “it depends” policy of case-by-case discussion and decision-making. The variability across the spectrum reflects differences in groups’ cultures of action, particularly their perspectives on whether the industry’s interests coincide with those of breast cancer patients.

I outlined the contrasting discursive themes that suggest the differences in groups' ethical codes in Table 5. These themes illustrate that the speakers on the "Favourable to Pharma Funding" side hold values that are closely aligned with neo-liberal thinking: they welcome industry innovation and are comfortable with capitalism; they support the move to small, non-interventionist government and see partnerships with industry as a positive sign of working together to further a good cause. They see little difference in the vested interests of industry and patients' organizations where drugs are concerned; they cite their businesslike approach as badges of credibility, and champion the savvy, independent patient who wants only the best treatment.

Group members that oppose pharma funding or feel uneasy with it hold a collectivist societal view that rejects most of the tenets of neo-liberalism. They are skeptical of industry claims about drugs and oppose industry partnerships. They argue that patients and industry have very different, often incompatible, interests and that groups cannot serve two masters. Patients' groups therefore have to maintain their independence so they can play a watchdog role, which requires them to discern and publicize one-sided or misleading claims about drugs by both the pharmaceutical industry and government policy-makers. The preferred model for health care for those opposed to, or ambivalent about drug industry funding of groups is a publicly funded system; they deplore government initiatives that they see as weakening the social safety net.

The ethical perspective in-between the above is one of pragmatism. Group members don't necessarily accept a neo-liberal view but they recognize it as the political reality in Canada today. Nor do they necessarily believe they can take pharma money without being influenced but they see few alternatives if they are going to run a viable

organization that provides needed services and information to breast cancer patients. They thus attempt to build firewalls around their contacts with Big Pharma in order to minimize the possibility and/or extent of influence and accept that, in an imperfect world, compromise is necessary. While I judged these attempts to be largely ineffective,<sup>286</sup> they represent a form of resistance.

#### 6.2.4 Group Advocacy, Drug Policy and the Public Interest

From a public interest perspective, the situation depicted in my research is far from ideal. The number and variety of groups is bewildering to the public and their varied relationships to the industry are not part of the public discourse. Within and among the groups, the discourse has broken down entirely. As a collective entity, however, Canada's breast cancer patients' groups certainly influences policy, public opinion and the decision-making of individual patients in the important policy arena of cancer drugs. They could play a legitimate and useful role if the groups were sites in which patients' knowledge of drugs came from sharing their lived experience, augmented by a better understanding of the drug policy process. Most activists lack the latter and, as one acknowledged, mastering the intricacies of drug policy is not easy. Furthermore, nuanced critique and discussions of drugs that expand on both the benefits and side-effects that patients experience are missing from the discussion. Instead, the groups are too often unreserved cheerleaders or unwitting partners in a larger corporate agenda designed to gain approval for new products.

Aware of pressure from the media and groups in the pharma critic camp, groups that accept pharma funds have increasingly moved to the practice of declaring their industry

fundors on their web pages and acknowledging them on projects with phrases like “Funded through an unrestricted educational grant by Company XYZ.” These acknowledgements are not always easy to find, however, and they tell the public little about the nature of the relationship the group has with the company. Furthermore, the declaration of funding from a particular company rarely reveals the amount of the funding, although sometimes donors are grouped by category, such as Silver, Gold, Platinum, with ballpark amounts for each designation. As seen in the narrative describing the *Patients Know Your Rights! Working Group*, the split of the board at *The Hub* over the funding from OrthoBiotech, and the tension between the staff members and the board of *Helping Hand*, these relationships can be very complex and unclear even to members of the groups involved.

A recurring theme throughout my narratives is the Trojan horse nature of alliances in which a group agrees to collaborate in good faith and after much deliberation, only to discover after the fact that the gift presents complications they did not (and in some cases, could not) anticipate. The two public speaking projects for which *Down-Home Peer Support* obtained pharma funding illustrate the point. Although board members took precautions intended to ensure that neither company was directly promoting its product, the sessions allowed for public discussion of a category of novel, expensive drugs for which the science was still uncertain and highly controversial in the oncology community. As presented in Chapter 3 (pages 128 to 138), the group collaborated in well-attended public information sessions, each sponsored by a different company which was in the process of bringing an aromatase inhibitor to market (AstraZeneca, the maker of Arimidex® and Pfizer, the maker of Aromasin®)<sup>287</sup>

The two drug company alliances had the appearance of being attractive gifts with no downside for the group, hence the Trojan horse<sup>288</sup> designation.<sup>289</sup> My research strongly suggests, however, that the group's trust in the terminology of the "Unconditional Educational Grant" is misplaced. The companies or their agents (public relations companies hired to handle advertising and other logistics) do not disclose to the groups the company's vested interest; indeed the companies imply (for example, by using the "Unrestricted Educational Grant" label and a corporate willingness to forego explicit product endorsement) that they have no vested interest other than creating goodwill. While group members suspect the company must have *something* to gain (e.g., a positive image with their shareholders), those that I interviewed were perplexed as to exactly what that might be.

The best explanation in my view is that the events were part of a broad strategy calculated to raise awareness and hope among patients, oncologists and the public about a novel, costly treatment whose worth is still unclear. Although the group was satisfied that the oncologists who spoke did not promote the company's own products in their presentations, in my judgment a less obvious form of promotion was at play. Because the companies in question were launching aromatase inhibitors – new products whose potential value to patients was causing excitement in the oncology community but was as-yet limited by scientific research -- the two "educational events" (and others rolled out across the country) focused on adjuvant treatment for breast cancer were likely to create a buzz within the patient community and a dubious sense of empowering patients with an awareness about a new generation of treatments. For the companies, the "empowered patients" were potential advocates who, when the time came, might well be expected to

support a public clamour to have their drugs approved quickly and added to the provincial formularies.

Aspects of the Trojan horse metaphor that I find particularly applicable in the context of patient groups and the pharmaceutical industry are the duplicitous nature of the gift (like the horse, a new drug remedy and an unexpected gift of money are at once wondrous and dangerous); the war-weariness of the residents of Troy, who (like patients with cancer, and cash-strapped groups) are eager to suspend judgment and believe that the “gift” is safe and will bring them good fortune in a difficult time; the reassurances of the Greek soldier Sinon (like the drug company representative, public relations firm, or physician/researcher who receives payment from the pharmaceutical firm, his assurances that the “gift” is safe and will bring good luck have questionable credibility); and finally, the unwelcome warnings of Laocoön and Cassandra, two members of the community with unnatural insight but whom the Trojans ignore (they are reminiscent of the more cautious segment of the scientific community and the feminist pharma critics, whose warnings sick patients and struggling organizations prefer not to hear).

#### 6.2.5 Analytic Concepts

My analysis builds on a number of concepts from the literature. I have relied on Emily Martin’s depiction of the remedy/poison duality of drugs throughout. A second useful concept from the medical anthropology literature is of pharmaceutical company gifts as a practice that is widespread within the medical community (Oldani 2004, Mather 2005). As I discussed in Chapter 1 (pages 23-26) existing analyses draw from Marcel Mauss’s explorations of the ways gifts subtly set up expectations of reciprocity. Based on

his research of pharmaceutical gift-giving practices to physicians, Oldani observes that such giving needs to be looked at “convergently,” that is, as an ongoing practice that begins in medical school and extends through a physician’s entire professional life, molding his or her acceptance of drugs and drug company funding as central to every facet of the profession. My research suggests that gifting practices to patients’ groups have evolved in a similar way, with small, relatively innocuous gifts, such as the purchase of a table at a fundraising dinner, expanding to public educational events, requests to link the group’s website to the company’s and to large-scale advocacy projects like the YouTube video, the patients’ rights charter and the sponsorship of entire organizations like *All-cancer Advocacy*. Furthermore, the gifts to groups were sometimes linked to gifts to physicians (the drug company provided speaker’s honoraria to oncologists at *Down-Home*’s educational events; a physician appeared on *The Hub*’s YouTube video; and a physician served as an advisor on the *Patients’ Know Your Rights!* document). A complete understanding of the role of gifts in the launch of a particular drug would map the company’s funding to a range of actors, and show the links between them.

My analytic framework also draws from the Science and Technology Studies literature on knowledge as a social construction, in particular lay knowledge and the important perspective of users of technologies. In the last chapter I discussed the concept of *boundary objects* as a way of understanding how some groups bridge the cultural gap between the goals of a grass roots organization and a multinational corporation. My research draws attention to an area of study with an emerging literature that complements the study of knowledge construction, the social construction of ignorance, or *agnotology*

(Procter 1995; Procter and Schiebinger 2004; Tuana 2004; Frickel et al 2010). The type of knowledge that the group *Down-home Peer Support and Education* had about drugs and pharmaceutical companies is instructive. As members of a community in which the drugs were already in use (for advanced disease), their members had a tacit understanding of the potential side-effects of breast cancer drugs, which they shared among themselves on the *Chat Space* and at events the group organized. Critical discussion of pharmaceutical companies was clearly a popular topic of conversation within the group. Equally significant, however, is the knowledge that the group did *not* have. In particular, with respect to drug *policy*, several members of this group told me in interviews that the board considered pharmaceutical policy as outside the group's expertise and its chosen advocacy mandate. For this reason, and based on interviews, I judged *Down-home's* members to be less aware of the intricacies of drug policy than members of *Critical Advocacy*, who had engaged in numerous advocacy and public education projects designed to influence drug policy. More importantly, on the two occasions when *Down-home Peer Support and Education* engaged in a collaborative educational project with a pharmaceutical company, the company did not apprise the group of relevant policy controversies about the drugs under discussion. Equally striking were the gaps in knowledge that members of the *Patients' Know Your Rights Working Group* acknowledged, which began with the recruitment workshop and extended to the company's representative making critical decisions in their absence. Such information-sharing lacuna in alliances between patients' groups and pharmaceutical companies is a form of agnotology, or socially constructed ignorance, and is highly significant in characterizing the relationships and their relationship to power/knowledge.



The collaboration illustrates gaps in power/knowledge between grass roots organizations and pharmaceutical companies in pharmaceutical policy that disrupts the social justice model on which the inclusion of patients in decision-making is built. The belief that including patients in policy deliberations is advantageous rests on the assumption that all parties will share their different knowledge bases, leading to a richer understanding for all; in the cases discussed above, however, the patients' group members were kept unaware by the company, leading to a potentially exploitative relationship.

#### 6.2.6 Typologies of Groups and Partnerships

As discussed in Chapter One, a goal of my research is to develop a typology of groups. The main axis of my typology is the groups' relationships with the pharmaceutical industry as they evolves over time.

Of the typologies in the literature, O'Donovan's (2007) provides the closest match to my findings, although it lacks some important components -- in particular, the dimension of time and change. O'Donovan categorizes groups along a continuum of Corporatist (accepts funding from pharma), Cautious Cooperation (with pharma) and Confrontational (rejects pharma money as an option) and these designations fit most of the groups -- although the term Refuser describes the groups that eschewed pharma funding in my research more accurately than Confrontational. I would add a fourth category, that of Internal Turmoil, in which (unlike Cautious Cooperation) the group is unable to amicably address the tension among different viewpoints without restructuring in some way. Based on the foregoing discussion, the groups could also be identified

according to their relationship to Canada's shifting political climate as Individualistic, Pragmatically Adaptive, and Collectivist.

O'Donovan (see page 39) posits four axes of logic that underlie and legitimate the divergent cultures of action with respect to pharma and I revisit these dimensions with my data in mind. The underlying axes are the group's *social construction of the health cause*, the *identity banners* it adopts, the *modes of political action* used to redress problems, and the way the group *positions itself in relation to other actors*. Held against the groups in my research, these are robust categories. Groups allied with pharma, for example, construct breast cancer as curable with the "right" medication; groups most antagonistic to accepting pharma funds construct the disease as preventable; and the groups that adopted a stance of Cautious Cooperation/Pragmatic Adaptation (*Down-Home and Patients, Know your Rights!*) constructed the disease as one for which patients need a broad range of community supports.

I suggest adding two other axes to those O'Donovan proposes: the group's *social construction of pharma* and the modes of action that the group adopts to *cope with the risks of forming (or rejecting) a pharma alliance*. Both these axes of logic were prominent in the groups' discourses and contributed to their decision-making. Corporatist groups, for example, saw pharma companies as the patient's only hope for producing cures, but considered them hamstrung by bureaucratic roadblocks and "bean-counters." While these groups' leaders acknowledged the reality of pharma's self-interest and the resulting record of malfeasance and pharmaceutical health disasters, they responded to their own positive experiences in which drug company representatives had been fair and easy to deal with. Cautious Cooperators were willing to take a chance under the right

circumstances, especially if other options were limited, but felt they had to remain alert and put safeguards in place to protect their reputations. Refuser groups had little doubt that pharmaceutical companies would use every occasion to push for advantage and that they needed fierce watchdogs, in government and civil society, to keep them from abusing the public trust. The modes of action to be used in dealing with a pharmaceutical company followed from these constructions. Corporatist groups adopted strategies aimed primarily at defending them from the accusations of others who were unduly critical of pharma (e.g., disclosure, having more than donor company for a project, pointing to conflicts of interest inherent in government funding); Cautious Cooperators relied on an Unrestricted Educational Grant designation, rules against endorsing a product, and case-by-case decision-making. Refuser groups declared pharma funding off-limits for themselves and also advocated systemic changes to discourage pharma funding of other actors and to prevent groups with pharma funding from presenting themselves as representing the public interest.

My final addition to O'Donovan's typology incorporates changes over time in which a group moves from a *Refuser* to a *Cautious Cooperator* or *Corporatist*, or shifts in the other direction; in either case the group may go through a stage of *Inner Turmoil*. The underlying axes for changing in either direction are 1) *Changed Reality*, e.g., the group grows, or loses government funding; or conversely finds a funding "Angel" who fills the gap in funding for which pharma money was sought, 2) *Changed Knowledge*, e.g., the group learns that pharmaceutical money is available, and without strings; or conversely, that people look on the group less favourably, or members learn something negative about the industry that they didn't previously know; or 3) *Changed Identity*, e.g.,

new board members have industry ties and see no reason not to tap them, or the group wants to increase its advocacy presence and feels pharma money is the best source to fund that activity; conversely, the group becomes heavily involved in peer support and worries that its service will be viewed as untrustworthy if it has an industry sponsor.

### 6.2.7 Transformations within the Policy Landscape

I have already discussed ways in which the dominant groups in the breast cancer movement as it exists today are closely aligned with neo-liberal values. The acceptance of pharma money as a source of funding for these breast cancer groups are a part of this reality. Given the way the groups began, this state of affairs might well have been very different if the movement had arisen in the welfare state era. The change in the federal government's policies towards providing core funding to civil society groups except for service provision undermined the advocacy ambitions that many groups started out with, particularly groups that saw critique as part of their mandate. One such group (*A Voice for Patients*) died for lack of funds while another (*Critical Advocacy to Prevent Cancer*) decided to focus exclusively on environmental issues. No breast cancer organization in Canada, to my knowledge, today sees the critical assessment of treatments from a patients' perspective as a significant part of its role. Advocacy to raise awareness of new drug treatments, or to have new drugs added to provincial formularies, by contrast, are common, particularly by groups with pharma funding.

Another byproduct of the neoliberal era was the tightening of advocacy rules for groups with charitable tax status. The fear of losing their charitable tax number created a second barrier against advocacy for groups whose budgets depended heavily on money

raised from donations from individuals, foundations, and small businesses. These donors typically expect a tax receipt in exchange for their donations so the threat of losing charitable status is a potent disincentive for groups who have obtained this designation to risk losing it. Funding from the pharmaceutical industry avoids this dilemma, however, since pharmaceutical companies don't require tax receipts for unrestricted educational grants. Thus the board members of *The Hub*, in the group's relationship with OrthoBiotech, welcomed the company's offer of generous funding because the money was entirely earmarked for advocacy. By a similar logic, pharma-funded groups like *All-cancer Advocacy* boast that they can focus entirely on advocacy because they don't have, or seek, charitable tax status. The structure of the pharma-funded groups that are entirely advocacy-focused is unsettling, however. They have no membership and provide no services to the community; on what basis can they be said to represent or speak for cancer patients?

A third significant contrast between Canada's welfare state and its neoliberal sequel is the federal government's perspective on the health care system, the pharmaceutical industry, pharmaceuticals and drug pricing. While the Federal governments of the 1960s and 1970s (guided in large part by the civil service) were willing to battle the industry to enforce safety standards and to lower drug prices, governing parties since the mid-1980s have developed a closer relationship with the industry. With respect to safety, the drive to "modernize" Canada's drug approval process by harmonizing safety standards with other countries has meant "harmonizing down" to lower safety standards in the interests of profits (Graham 2001, Lexchin 2011). With the compulsory licensing system done away with and drug patents extended as a condition

for Free Trade Agreements with the United States, the provincial governments are left to cope with the rising cost of new cancer drugs with the inevitable result of regional disparities. Lower safety standards and rising prices (a barrier to access) are natural concerns of the patient community, yet breast cancer groups with pharma funding have advocated for faster drug approvals, while provincial governments are easy targets for advocacy pressures from patients' groups. Advocacy by breast cancer groups has fostered the perception that formulary decisions are made to save costs rather than in the public interest.

Drug policy issues are neither simple nor straightforward and it is not surprising some members of patients' groups would agree with an individualistic, neo-liberal perspective on cancer drugs. Many do not, however, and others may be uncertain where they stand on such complex questions. What is disturbing is that breast cancer advocacy in relation to drugs is so one-sided and lacking in the nuance one would expect to come from vigorous debate among members of a community who are passionately, corporeally engaged with cancer drugs, experiencing both their remedy and their poison. Here I return to O'Donovan's (2005) argument, which I introduced in Chapter One, that social movements enliven public dialogue when they resist the forces of commodification and government bureaucratization. If the potential of patients' groups was to provide new sites of knowledge and arenas of public debate for people whose lives are in crisis, my research shows the virtual elimination of that potential over time among the breast cancer groups. The funding of patients' groups by the pharmaceutical industry contributes in no small part to this loss.

### **6.3 POLICY CONSIDERATIONS**

My study of the breast cancer movement in Canada supports the argument that pharmaceutical funding of patient and health-related advocacy groups has changed the landscape -- for patients, for the groups that are supposed to represent them, for pharmaceutical policy, and for the public. My findings thus echo, and add an ethnographic window to, the findings of researchers in Australia, Europe and the United States. In identifying areas of policy which I believe merit reconsideration, I draw from my own findings as well as the analyses of others; notably, Agnes Vitry and Hans Lofgren (2011), Geissler (2011) Pehudoff and Alves (2010), Rothman (2011) and Delaney (2005). I also revisit the concluding section of a paper I wrote for Women and Health Protection (Batt 2005), early in my fieldwork.

*Alternative Sources of Funding* If patients and health consumer groups are to be freed from pharmaceutical industry funding, alternative sources of funding must be made available, ideally from an arms-length agency set up for this purpose (e.g., Batt 2005). In Germany, such a fund has been in place since 2000, financed by health insurers who pay a small percentage per year per individual insured to support the self-help, information and lobbying of health consumer groups (Geissler 2011). Organizations that meet agreed-upon criteria, including independence from industry, apply annually for funding. This model might work in Canada, given that health insurers (including provincial governments) could be expected to benefit from well-informed, independent patients' organizations.

*Building Capacity for Expert and Impartial Knowledge Agents to Advise Patients about Drugs and to Promote the Use of Patients' Embodied Knowledge* Patients' groups

should not be free to disseminate whatever information they please about treatments, regardless of accuracy (Rothman, 2011). My research provides several instances of groups publishing material that was highly questionable or refuted by evidence. This does not mean that patients' organizations must always echo the conclusions of credentialed experts. On the contrary, patients' groups have the potential to be important sites of lay knowledge about drugs and reasonable questioning of dominant biomedical views that may run counter to patients' experiences should be encouraged. The potential for such inquiry is diminished, however, by misconceptions and lack of knowledge that cause patients to overestimate the potential benefits and underestimate the harms drug treatments can cause. Some misconceptions derive from the intricacies of drug research and the changing nature of pharmaceutical policies and some from the reasonable desire of patients (and their physicians<sup>290</sup>) to be hopeful about their disease outcome, even in the face of long odds for remission. Pharma partnerships may exacerbate both these sources of bias by exposing patients to information that supports benefits over harms, or exaggerates a drug's effectiveness (Graham 2008). Debate about treatments within the breast cancer movement is further impoverished because patient and health advocacy groups with a critical perspective of pharmaceuticals have all but disappeared. Providing funds for the latter groups and ongoing opportunities for members of the full spectrum of patient and health advocacy groups to improve their literacy in drug evaluation and pharmaceutical policy matters could improve patients' ability to assess information and to engage fully in public debates over drug policies.

Decision aids have been developed to assist patients making individual treatment decisions; they improve knowledge (for example, about the relative likelihood of benefits



or harms), reduce decisional conflict and increase patient's participation in decision-making (e.g., O'Connor, Rostom, Fiset, et al 1999; Elwyn, O'Connor, Stacey et al 2006). These aids could provide models for materials to be used within advocacy groups. Examples of topics for literacy workshops could include are the difference between absolute versus relative risk, the experimental nature of new drugs, the drug approval process, and familiarity with current debates in the policy literature, such as the rising cost of cancer drugs and the use of surrogate endpoints. An existing resource which could be used to build capacity is the Cochrane Collaboration, an international network of "over 28,000 contributors dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide" (Cochrane Collaboration website 2012). The Cochrane Collaboration has a Consumer Network (CCNET) that offers opportunities for patients and consumers to learn about evidence as well as to ensure that a patients' perspective is included in systematic reviews (CCNET website 2012).

Ongoing opportunities for discussion are needed at which patients, researchers, practitioners and other stakeholders could meet and discuss differences in issues of measurement and interpretation among stakeholder groups with respect to breast cancer treatments. OMERACT, an international, collaborative model has been in use for interpreting the meanings of research outcomes for treatments of rheumatoid arthritis since 1992, and might be adapted and applied to breast cancer treatments (e.g., Kirwan, Heiberg, Hewlett, et al 2003, Bingham, Alten and de Wit 2012).

*Promoting Social Cohesion and Democratic Debate* Pharma funding has contributed to a split in the patient and health advocacy community that diminishes the potential for mutual exchange of views and opportunities for democratic debate among

groups whose perspectives differ. A movement that truly represents the interests of women with breast cancer must acknowledge these differences and find ways to exchange knowledge and views. New venues are needed for these debates. On some questions -- such as the importance of recognizing the poison side of new drugs for cancer patients, of investing more funding in research and policy on cancer prevention, and of cost containment to maintain a sustainable health care system -- my research suggests the present divide obscures common concerns.

*Transparency* My research shows that Canadian breast cancer groups have, over time, become more open about their funding from the pharmaceutical industry; furthermore, Canada's Research-Based Pharmaceutical Companies (Rx&D), the industry umbrella organization, now encourages its member companies to disclose their funding to groups. These are important steps, but disclosure of funding is not sufficient. As Vitry and Lofgren point out, disclosure "may make conflicts of interest appear acceptable and may not be an adequate basis for assessments of the risk of bias" (2011:250); indeed, my findings illustrate both these limitations.

Disclosure should not be optional, however. The public has a right to know the amounts and terms of all pharmaceutical company funding to groups involved in health education and advocacy. Industry contributions vary in type (e.g., educational grants, honoraria, travel funds); standardized definitions of what constitutes a contribution are needed (Perehudoff and Alves 2010). Additional ethical principles advocated within the AIDS community in the United States are that the group institute structured communications to ensure that the non-profit agency and not the industry decides how to

communicate with the pharmaceutical and biotech industries, and independence and ownership of all educational materials (Delaney 2005).

### 6.3.1 Directions for Policy Change

- Establish an independent funding agency or mechanism to provide money to patients' and health advocacy groups that wish to be independent of the pharmaceutical industry and other commercial interests. These funds could support such activities as treatment advocacy and related research (e.g., literature searches and dissemination of information on treatments relevant to their disease to their members). Assess the applicability to Canada of models used elsewhere, including the German system which takes a fixed percentage from health insurance policies and requires that eligible groups be independent of the pharmaceutical industry.
- Make funding available to groups with differing perspectives whose members wish to come together to exchange and debate views on treatments, treatment policies, and/or other health-related matters on which opinions are divided.
- Make training modules available to educate patients' and consumer groups about the nuances of clinical trials and drug policy, such as post-marketing surveillance, pharmacovigilance, the use of surrogate end-points, and the use of Quality-Adjusted Life-Years (QALY) as a measurement to assess drugs for formulae placement (McMahon, Morgan and Mitten 2006). Agencies that might contribute to preparing the modules include Health Canada (e.g., through the Office of Consumer and Public Involvement) and non-governmental agencies, such as the

Therapeutics Initiative, the Canadian Health Services Research Foundation, the Pharmaceutical Policy Research Collaboration, and the Cochrane Collaboration.

- Examine mechanisms to maintain the accuracy of informational meetings and educational materials produced by patients' groups, health consumer organizations, and other stakeholder organizations (including organizations of professionals), particularly materials that veer towards direct to consumer advertising, and/or are dismissive of health care costs. Evaluate outcome measures approaches from other existing organizations that could provide viable models.
- Establish criteria to define what counts as a financial contribution from the pharmaceutical industry to a health-related or patients' civil society group and establish disclosure requirements for these contributions on the part of both companies and health-related and patient groups.
- Establish standards of funding transparency as a prerequisite for groups that participate in drug policy consultations as representatives of the public interest.

#### **6.4 CONCLUSION**

Patients' organizations have the potential to be important sites of knowledge and advocacy for the public interest but they need stable sources of funding to fulfil these functions competently. In turning to the pharmaceutical industry for funds as an alternative to increasingly scarce public funding, patients' groups have followed a long list of actors in the health sector, including medical schools (Hebert et al 2008), physicians (Oldani 2004), publishers of medical journals (Smith 2003), medical

researchers (Graham, 2008), government regulators (Abraham 2004), and international agencies such as the World Health Organization (Horton 2002). The dilemmas and debates documented in this dissertation thus find echoes throughout the health field. In providing a detailed account of how industry partnerships have evolved in this particular sub-sector, I have sought to move the debate on pharma funding forward, particularly with respect to patients' groups, but for the health policy community as a whole. Many people engaged in health issues have strong reactions for or against such partnerships, but documentation as to why groups undertake them, the way such collaborations work, and their potential to affect discourses that shape both knowledge and public policies has been limited.

Miriam Smith (2005) analyses how Canada's transformation from a welfare state to a neoliberal globalized state affected group politics. She argues that neoliberal restructuring of Canadian institutions has reshaped group politics in ways that "depoliticizes collective action and undermines democratic participation" (Smith 2005: 186). The cuts in funding to grass roots advocacy and the offloading of service delivery to local community organizations are only one aspect of these far-reaching changes, she contends. Her analysis draws attention to the organized political activity of business elites in convincing the Canadian public to accept neoliberal values, in order to "undermine the political culture of social solidarity and to vaunt the culture of consumerism." Party leaders no longer base their policies on advice from specific departments (the traditional route through which interest groups made their views known to the government); rather they look to "a new class of professional consultants," (ibid: 188) including pollsters, professional lobbyists, and public relations firms who sell their services, and represent "a

commodification of political access in the neoliberal age, acting as a buffer between social groups and the state” (ibid 188). Another feature of neoliberalism is the reorganization of the public sector following the principles New Public Management, a business model of management that used “citizen engagement” as a key concept. New Public Management conceptualizes “citizens” as individual rather than collective actors, however, and seeks their “engagement” via focus groups and questionnaires, rather than participation in organizations.

In this new world order, alliances between patients’ organizations and pharmaceutical companies, with public relations firms as acting as intermediaries, are a structural configuration that provides groups with more than financial viability. The partnerships allow patients’ organizations to participate in this consumerist model of advocacy which eschews contestation. Using an unrestricted educational grant from the industry, a group may contract a public relations firm to poll its members on whether they are “aware” of their risk of recurrence. An organization that has no dues-paying members may launch a media campaign urging governments at the federal and provincial levels to speed patients’ access to costly products for which risks and benefits are still preliminary. The groups’ claim to legitimacy derives, not from popular support, but from a managerial language of efficiency and accountability; the latter reinforces the anti-government sentiment of the corporate collaborators.

Patients’ groups are not alone among civil society organizations in facing the dilemmas of the corporate partnership culture that neoliberalism privileges. A well documented Canadian example from the environmental sector involves the Toronto-based environmental group Pollution Probe which, in 1989, entered into an agreement

with the grocery chain Loblaws. In exchange for endorsing seven products selected from the corporation's new environmentally-friendly line, the group received a one per cent royalty on each of the products sold, and \$1.00 for each sale of a "green" T-shirt. The agreement, which Pollution Probe signed hastily and in secret (to satisfy the company), had serious consequences for the organization's internal cohesion and its public reputation. Although Pollution Probe gained about \$150,000, staff members resigned over the secret negotiations, a national consumer rights' organization subsequently questioned Loblaws' advertising claims for the products, and the Director of Pollution Probe resigned in the furor (Covey and Brown 2001).

Canada's public institutions have likewise turned to the private sector to maintain their services. A study of the downtown central libraries in both Toronto and Vancouver found that, contrary to popular perception, the widespread use of electronic media has not diminished the importance of these institutions as public spaces (Leckie and Hopkins 2001). Rather, the authors concluded, the real threat to contemporary libraries is the ideological shift that has made libraries sites of commodification and branding.

The library is becoming increasingly coopted to multiple private interests (the in-house automated banking machines; food and drink vending machines, cafes, card boutiques, gift shops, company-sponsored events, rooms and facilities) and the corporate model of a cost-cutting, profit-making (or at least self-sustaining) business enterprise. (Leckie and Hopkins 2001:358).

In response to underfunding by the government, these authors observe, the Vancouver library became the first to put corporate logos on its library cards and, in another effort to remain in the black, even rented its premises as a movie set to private filmmakers, closing its doors to the public for the interim.

A parallel transformation of Canada's university campuses began in the 1990s and has manifested in the material processes of branding (corporate logos on teaching materials, the naming of buildings, programs and endowed chairs, and research projects that will yield marketable products under patent with the industry partner) and in the adoption of an internal managerial culture that frames knowledge as a profitable commodity, emphasizing productivity and cost-efficiencies (Newson 1998). Newson argues, however, that the university is more than a passive responder to external pressures; it has facilitated aspects of the corporatization process and can, therefore, challenge these same pressures.

In supporting Miriam Smith's analysis of group politics in Canada's neo-liberal era, my research reinforces what she calls her "pessimistic message about the possibilities for democracy within the Canadian nation-state" (ibid: 191). Like Smith and Newson, I view this challenge to contemporary democracy as contestable, particularly if neo-liberalism's international dimensions are recognized and understood. Case studies are a form of biography; they bring universal features of the human struggle to life at a particular place and time by making them concrete. If my account of Canada's breast cancer movement does no more than tell an untold story of how groups of women have responded to momentous changes in Canadian society, it will serve a valuable purpose; if it renders understandable an incongruous type of collaboration which is emblematic of our age, even better. Its most ambitious purpose is to contribute to the momentum for global collective action aimed at restoring some of the ballast that neo-liberalism has stolen from democracy; success in this goal would be the sweetest of all.



## ENDNOTES

<sup>1</sup> Funding from the pharmaceutical industry as a phenomenon in the breast cancer movement is not entirely unexplored territory and has been discussed in some detail by Brenner (2000), Zones (2000), Lerner (2007) and Anglin (2009). None of these authors, however, examines how the movement made the transition over time from financial independence to one of ongoing alliances with the industry.

<sup>2</sup> In the case of most research participants who were interviewed, I have used pseudonyms. I made a few exceptions to this rule, which I explain in Chapter 2 (Methodology).

<sup>3</sup> Men do develop breast cancer and breast cancer groups do not necessarily exclude male members, whether they are patients/ex-patients, partners of patients, friends, or family members. Men make up less than one percent of the cases of breast cancer however and all of the groups I have encountered, as a researcher or an activist, have had an overwhelmingly female membership.

<sup>4</sup> For centuries, breast cancer had been considered a local disease that spread gradually from the breast to eventually affect distant organs; life-saving treatments did not exist. The introduction of anesthesia and antisepsis in the 19<sup>th</sup> century made surgery a realistic option and in the late 19<sup>th</sup> century the mastectomy became the mainstay treatment for breast cancer patients (Aronowitz 2007). As Barron Lerner recounts in his history of breast cancer in America, various forms of radiation treatments were added to surgery throughout the last century as a second local treatment and an adjunct to less extensive surgery. Chemotherapy was introduced as a treatment in the 1960s but because the disease was considered local in its early stages the value of chemotherapy was doubtful except for palliation in advanced cancers. In any case the existing chemotherapy treatments were considered too toxic to administer on a widespread basis. By the 1980s, however, rather than being viewed as a local disease -- the dominant view to that point in the 20<sup>th</sup> century-- breast cancer had become accepted as systemic from the beginning; that is, some tumour cells were thought to be in the blood stream from the time of diagnosis. Thus, rather than radical breast surgery to remove as much of the disease as possible from the local area, minimal surgery became a medically preferred option and the treatment emphasis shifted to experimentation with chemotherapeutic or other (e.g., biologic) systemic approaches designed to reduce the body's tumour burden to the point where the patient's immune system could cope with it (Lerner 2001).

<sup>5</sup> This paragraph is reproduced from a chapter I wrote on the pharmaceutical company funding of patient groups for the book *The push to prescribe: Women and drug regulation in Canada* (Rochon Ford and Saibil 2009).

<sup>6</sup> Klawiter theorizes that health advocacy groups have distinct cultures which are manifested in a group's modes of behavior, values, tacit knowledge, and the way the organization frames the

issues around which it mobilizes. Cultures of action are fluid and are shaped by external forces as well as internal bargaining.

<sup>7</sup> Jon Church, a cancer researcher at Memorial University in St. John's, Newfoundland, created the Breast Cancer Discussion List for patients following a national breast cancer conference in November 1993. In 1996, a Nova Scotia-based patients' group, Breast Cancer Action Nova Scotia, established a web-based discussion forum for breast cancer patients.

<sup>8</sup> I thank Victoria Seaville-Klein for alerting me to this resource and its potential usefulness in my research.

<sup>9</sup> This text is abbreviated and adapted from my comprehensive exam on ethics, titled , "No Easy Flow": Social Sciences, Philosophy and Bioethics – Epistemic Divides, Political Dilemmas," Batt, 2005.

<sup>10</sup> The women all volunteered their time and their numbers fluctuated over the life of the project.

<sup>11</sup> From *Critical Advocacy to Prevent Cancer's* website.

<sup>12</sup> Robert Bazell (Bazell, 1998) describes the dispute between Genentech and Breast Cancer Action over compassionate access in his book *Her2*, Chapter 8, pp 109-132.

<sup>13</sup> *Critical Advocacy to Prevent Cancer*, Minutes, June 4, 1996.

<sup>14</sup> Dr. Bailar is a (now retired) American M.D and epidemiologist who spent much of his career arguing that, based on the statistical evidence, the "war on cancer" had been lost and cancer policy should focus on preventing cancer rather than looking for treatments and cures (Bailar 1979, Bailar and Smith 1986, Bailar and Gornick1997). He is a Professor Emeritus of the University of Chicago.

<sup>15</sup> In 1991, Brady published *I in 3: Women with cancer confront an epidemic* an edited collection of writing by women with cancer about industrial pollution and its contribution to the disease; and in 1994, she co-founded the Toxic Links Coalition, a collection of Bay-area activists who organized events like the Cancer Industry Awareness Tour of the city's financial district to raise awareness of the links between corporate profits, pollution and local health problems (Ley 2009: 40-41).

<sup>16</sup> By contrast, a group in Ontario, *Helping Hand*, was established with an infrastructure for the specific purpose of providing information and support. I refer to Helping Hand later in this chapter and discuss the group in more detail in Chapter 5).

<sup>17</sup> S.B. was a member of *The Hub's* founding board of directors.

<sup>18</sup> Interview with *Deirdre*, 2007.

<sup>19</sup> From *Critical Advocacy to Prevent Cancer* website, June 27, 2007

<sup>20</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Dec 5, 2001.

<sup>21</sup> *Critical Advocacy to Prevent Cancer* Protests Eli Lilly Funding of Chair in Women's Health, *Critical Advocacy to Prevent Cancer, Bulletin*, 8(2), Summer, 2000. Retrieved online August 3, 2010: <http://www.bcarn.gc.ca/html/bulletin/8-2/lily.html>

<sup>22</sup> The Bulletin was published by the regional "information exchange" project funded by the Canadian Breast Cancer Initiative set up following the National Forum on Breast Cancer. Seed money to set up five regional projects was provided by Health Canada on a five-year basis. The Initiative was renewed in 1998 for another five years; however, just as the breast cancer groups that received start-up funds from the Initiative were advised their funding could be cut back or cease, the Information Exchange projects were expected to become self-sufficient over time.

<sup>23</sup> *Critical Advocacy to Prevent Cancer*, Minutes, August 1, 2001.

<sup>24</sup> *Critical Advocacy to Prevent Cancer*, Minutes, October 3, 2001.

<sup>25</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Feb 6, 2002.

<sup>26</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Feb 6, 2002

<sup>27</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Feb 6, 2002

<sup>28</sup> Letter of resignation from to the President of *The Hub* from the former President, February 11, 2002

<sup>29</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Sept 3, 2002

<sup>30</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Dec 3, 2002

<sup>31</sup> *Critical Advocacy to Prevent Cancer*, Minutes, Dec 11, 2002

<sup>32</sup> *Critical Advocacy to Prevent Cancer*, Minutes, January 2003.

<sup>33</sup> The work of Prevention First is described in Barbara Ley's book, *From Pink to Green: Disease Prevention and the Environmental Breast Cancer Movement*, (2009) New Brunswick, New Jersey: Rutgers University Press: 91-95.

<sup>34</sup> Profits in Pink Report, *Critical Advocacy to Prevent Cancer*, 2004, page 5.

<sup>35</sup> In December 2001 *Critical Advocacy to Prevent Cancer* placed a Coalition- designed ad "Will Prevention ever come in a Pill?" in two local weeklies and on its website. The ad challenged the clinical trial to test tamoxifen and raloxifene for prevention. In an initiative that reflected the Coalition's concern about the inadequacy of the Canadian and U.S. drug regulatory systems to track adverse drug reactions (ADRs) once drugs are approved for market (*Critical Advocacy to Prevent Cancer*, minutes, Feb 6, 2002);

Linda organized screenings for community groups of a Canadian documentary, *Drug Deals: the Brave New World of Prescription Drugs*. The film links the influence of the pharmaceutical industry within universities, hospitals, prescribing doctors, and health protection agencies to the

failure of the drug regulatory system to adequately track and regulate drugs that have serious side-effects. The film was made in 2001 by the National Film Board of Canada and had aired on David Suzuki's television program, *The Nature of Things*. It highlighted the case of Vanessa Young, an Ontario teenager who died of heart failure on March 19, 2000 while taking Prepulsid (cisapride), a drug for gastro-intestinal problems prescribed by her physician and made by Janssen-Ortho. The FDA withdrew Prepulsid (cisapride) from the market the following week; Health Canada sent a warning letter to physicians on May 30, 2000, but did not withdraw the drug until August 7, 2000 (See Health Canada safety advisory, [http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/\\_2000/prepulsid\\_hpc-cps-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2000/prepulsid_hpc-cps-eng.php)).

In 2003, Linda took the lead in organizing the group's annual public event, a panel discussion with the title, "Pills, Profits and Women's Health;" the two featured panelists talked about pressure by the pharmaceutical industry to reverse the Canadian ban on direct-to-consumer-advertising of prescription drugs and about the links between inflated drug costs and the promotional strategies that both brand name and generic companies use. Putting Pills in Perspective, *Critical Advocacy to Prevent Cancer, Bulletin*, 11(2) Spring 2003.

<sup>36</sup> Tamoxifen gets a "Black Box" rating, *Critical Advocacy to Prevent Cancer, Bulletin*, 10(3) Fall 2002.

<sup>37</sup> *Critical Advocacy to Prevent Cancer*, minutes, Feb 6, 2002; A challenge to tamoxifen, *Critical Advocacy to Prevent Cancer, Bulletin*, 10(1) Spring 2002.

<sup>38</sup> The World Conference on Breast Cancer is an initiative developed in 1995 by a local women's organization in Kingston Ontario. The first meeting in Kingston in 1997 and subsequent conferences were held in Ottawa in 1999, in Victoria in 2002, in Halifax in 2005, and in Winnipeg in 2008.

<sup>39</sup> The Precautionary Principle, *Critical Advocacy to Prevent Cancer, Bulletin*, 11(1) Winter 2003.

<sup>40</sup> "Prevention is the Cure" is a green breast cancer organization in Huntington, New York. Founded in 1992 as the Huntington Breast Cancer Action Coalition, the group began holding *Prevention is the Cure* marches and encouraged like-minded organizations in other communities to do the same.

<sup>41</sup> Articles published in the Bulletin that discuss drug company funding of activist groups include, Breast Cancer Advocacy: The reality check, *Critical Advocacy to Prevent Cancer Bulletin* 7(4) Fall 1999; Breast Cancer Advocates and Pharmaceutical Industry Funds, *Critical Advocacy to Prevent Cancer Bulletin* 10(3) Fall 2002; The Dangers of "Pharma Partnering," *Critical Advocacy to Prevent Cancer, Bulletin*, 12(2) Spring 2004; All is not as it Seems – Cancer Group has Big Pharma Roots, *Critical Advocacy to Prevent Cancer, Bulletin*, 12(2) Spring 2004; Cancer war tells only half the story, *Critical Advocacy to Prevent Cancer Bulletin* 13(2) 2005; Why doesn't *Critical Advocacy to Prevent Cancer*, accept contributions from pharmaceutical companies? *Critical Advocacy to Prevent Cancer Bulletin* 15(1) 2007.

Articles about pharmaceuticals and pharmaceutical policy include: Benefits of hormone replacement therapy questioned, *Critical Advocacy to Prevent Cancer Bulletin*, 8(2), 2000; A challenge to tamoxifen? *Critical Advocacy to Prevent Cancer Bulletin*, 10(1); Tamoxifen gets a ‘black box’ rating, *Critical Advocacy to Prevent Cancer, Bulletin*, 10(3) 2002; Book reviews of *Prescription Games* and *Dr. Susan Love’s Hormone Book*; Pharmed and Dangerous, *Critical Advocacy to Prevent Cancer Bulletin*, 12(1), Winter 2004; The Fuss over Femara®, *Critical Advocacy to Prevent Cancer Bulletin*, 12(1), Winter 2004; Update on Hormones, *Critical Advocacy to Prevent Cancer Bulletin*, 12(2), Spring 2004; Good News for Women (comment on Opening the Medicine Cabinet, a report of the Parliamentary Standing Committee on Health) *Critical Advocacy to Prevent Cancer Bulletin*, 12(2), Spring 2004; Public Health versus Chemoprevention, *Critical Advocacy to Prevent Cancer Bulletin*, 12(2), Spring 2004

<sup>42</sup> The San Francisco group Breast Cancer Action launched Think before You Pink in 2002 in response to the growing trend for companies to use breast cancer as a marketing hook for products from yogurt, to blue jeans to cars. The project examined particular “pink” campaigns and asked probing questions about each one, such as how the money was being raised, how much of the consumer’s purchase would actually go to supporting a breast cancer cause, what type of organization would benefit, and whether the company in question was using the campaign to mask its own cancer-causing practices. See, <http://thinkbeforeyoupink.org/>

<sup>43</sup> *Critical Advocacy to Prevent Cancer Minutes*, Oct 15, 2002; Nov 6 2002.

<sup>44</sup> Profits in Pink, *Critical Advocacy to Prevent Cancer Bulletin* 13(2), Spring 2005.

<sup>45</sup> Profits in Pink, *Critical Advocacy to Prevent Cancer Bulletin* 13(2) Spring 2005.

<sup>46</sup> Examples include an account of the Canadian Environmental Protection Act, CEPA 1999 (*Critical Advocacy to Prevent Cancer Bulletin* 14(3), Fall 2006), a federal plan to lower Canada’s standards for allowable pesticides on fruits and vegetables to harmonize with standards in the US and Mexico (*Critical Advocacy to Prevent Cancer Bulletin* 15(3), Fall 2007), an overview of Canadian regulations for plastic products containing Bisphenol-A (*Critical Advocacy to Prevent Cancer Bulletin* 16 (2), Spring 2008), and an interview with an academic researcher about Canada’s low standards governing electro-magnetic fields (*Critical Advocacy to Prevent Cancer Bulletin* 18(1), Winter 2010).

<sup>47</sup> Examples include a report on a workshop titled “Chemicals out of Control” about toxic chemicals and the green chemistry movement (*Critical Advocacy to Prevent Cancer Bulletin* 14(3), Fall 2006); a report on a *Critical Advocacy to Prevent Cancer*-sponsored lecture about the Breast Cancer Fund in California and the Fund’s regular *State of the Evidence* reports on environmental contaminants and breast cancer (*Critical Advocacy to Prevent Cancer Bulletin* 15(2) Spring 2007); a report on *Critical Advocacy to Prevent Cancer*’s annual “Prevention is the Cure” march (*Critical Advocacy to Prevent Cancer Bulletin* 16(3) Fall 2008); and an overview of the achievements of *Critical Advocacy to Prevent Cancer*’s flagship health and the environment project, *FemmeToxique*, designed to raise awareness about and protest the prevalence of toxic

chemicals in everyday products (*Critical Advocacy to Prevent Cancer Bulletin* 18(2) Spring 2010).

<sup>48</sup> Examples include a review of *Toxic Trespass*, a Canadian film about how environmental toxins affect children (*Critical Advocacy to Prevent Cancer Bulletin* 15(3) Fall 2007); a book review of *Cancer: 101 Solutions to a Preventable Epidemic* (16(1) Winter 2008); a review of *The Secret history of the War on Cancer*, by American epidemiologist Devra Lee Davis (*Critical Advocacy to Prevent Cancer Bulletin* 16(2) Spring 2008); and a review of the book *Slow Death By Rubber Duck: How the Toxic Chemistry of Everyday Life Affects Our Health* (*Critical Advocacy to Prevent Cancer* 17(3) Fall 2009).

<sup>49</sup> Examples of interviewees include Montreal cancer epidemiologist Dr. Jack Siemiatycki (*Critical Advocacy to Prevent Cancer Bulletin* 17(3), Fall 2009), French cancer epidemiologist Dr. Annie J. Sasco (*Critical Advocacy to Prevent Cancer Bulletin* 18(1), Winter 2010), and Dr. Irena Buka, director of the Pediatric Environmental Health Specialty Unit (PEHSU) in Edmonton (18(2), Spring 2010).

<sup>50</sup> Examples include research on the drugs tamoxifen and Raloxifine for preventing breast cancer breast cancer *Critical Advocacy to Prevent Cancer Bulletin* 14(3), Fall 2006) and hormone therapy (*Critical Advocacy to Prevent Cancer Bulletin* 15(2) Spring 2007) and the promotion of the vaccine Gardasil as a preventative for cervical cancer (*Critical Advocacy to Prevent Cancer Bulletin* 16(2), Spring 2008, *Critical Advocacy to Prevent Cancer Bulletin* 16(2), Fall 2008).

<sup>51</sup> *Critical Advocacy to Prevent Cancer Bulletin* 15(1) Winter 2007.

<sup>52</sup> At the Fifth World Conference on Breast Cancer in Winnipeg, in 2008, *Critical Advocacy to Prevent Cancer* presented workshop titled, “The Beast of Beauty: Toxic Chemicals in Cosmetics.” Not only was the workshop attended by over 100 people, in contrast to the controversial presentation on cause marketing at the previous World Conference, the entire audience was receptive to the message -- including, as an article the next newsletter pointed out with satisfaction – women who had attended Look Good, Feel Better make-up sessions for women with cancer. “Rather than challenging our point-of-view, they supported it, saying that they felt better with make-up and thought it unacceptable to have potentially harmful chemical ingredients permitted in cosmetics.” (*Critical Advocacy to Prevent Cancer Bulletin* 16(3), Fall 2008).

<sup>53</sup> *Critical Advocacy to Prevent Cancer Website*.

<sup>54</sup> I discuss the reasons the issue came to the fore in the community nationally in the late 1990s in Chapter 5. Two key events were Anne Rochon Ford’s booklet, *A Different Prescription: Considerations for women’s health groups contemplating funding from the pharmaceutical industry*, and the experience of the national umbrella breast cancer organization, which in 2000 formed a partnership with the company Ortho-Biotech, an alliance some board members of that organization ultimately found compromising.

<sup>55</sup> . The year 2000 was a time of public sector cutbacks and she had just lost her job as a teacher.

<sup>56</sup> Funded Projects for 2003-4: [http://www.phac-aspc.gc.ca/publicat/bc\\_projects-cs\\_projects/app\\_03-04-eng.php#proj4](http://www.phac-aspc.gc.ca/publicat/bc_projects-cs_projects/app_03-04-eng.php#proj4) . Funded projects up to 2012: <http://www.phac-aspc.gc.ca/cd-mc/funding-cbci-iccs-eng.php>

<sup>57</sup> In 2006, the Public Health Agency of Canada (PHAC) was established and the Canadian Breast Cancer Initiative moved from Health Canada to PHAC. After that, any federal money that was available to breast cancer groups came from PHAC, and not Health Canada. Several activists told me they felt the move had undermined the Initiative, in part because the Agency was preoccupied with preventing a repeat of an infectious disease like the Severe Acute Respiratory Syndrome (SARS) outbreak that hit Canada In 2002, killing forty-four people. They considered the Agency underfunded compared to Health Canada and, additionally, felt that a reclassification of cancer from an acute disease to a chronic disease that took place about the same time relegated the disease to a lower priority.

<sup>58</sup> In 2006, the Public Health Agency of Canada (PHAC) was established and the Canadian Breast Cancer Initiative was moved from Health Canada to PHAC. After that, any federal money that was available to breast cancer groups came from PHAC, not Health Canada.

<sup>59</sup>The book, titled, *How We Told Our Children*, was an example of patients sharing lay knowledge related to their disease.

<sup>60</sup> Members of the group were frankly perplexed about the industry's motives for making funds the group. *Meredith*, for example, commented during our interview, "It would be nice if we knew exactly what pharma wanted from us." When I asked *Ruth* why she thought drug companies wanted to support their events, she responded: "... I guess it looks good on their bottom line to say, 'we gave money to *Down-home Peer Support and Education*.' So presumably they are getting some good PR out of it with their stockholders -- or maybe, or whatever." (Interviews with *Meredith*, 2007 and *Ruth*, 2007)

<sup>61</sup> Stephen Cannistra (2004) cites the Goss et al (2003) study of letrozol and tamoxifen as an example of a study in which early stopping may have led to a misleading conclusion, noting:

A statistically significant difference in the 4-year DFS [disease-free survival] rate was observed in favor of the letrozole group compared with placebo (93% v 87% respectively;  $P < .001$ ) .... Based on these data, the DSMB [Data-Safety Monitoring Board] recommended study termination and disclosure of the results to patients in the placebo arm, thereby permitting cross-over. However, there was no statistically significant difference in OS [overall survival], and the letrozole group experienced a greater frequency of osteoporosis, fractures, hot flashes, and myalgias. In addition, no patient received letrozole for more than 3 years, precluding any meaningful assessment of long-term toxicity or optimal duration of therapy. Although a QOL [quality of life] analysis was performed as part of this study, the results were not available at the time of the initial study publication." (Cannistra, 2004:1543)

<sup>62</sup> In the newspaper editorial cited, the term "information inhibitor" is used with respect to the suppression of clinical trial results on the grounds that the information constituted "trade secrets". In this case, the clinical trials in question were used to study selective serotonin reuptake



inhibitors (SSRIs) and the fact that the pharmaceutical industry – with the collaboration of the government agency – withheld the fact that the drugs were potentially lethal to young people on the grounds that the information was “confidential business information” (Editorial 2011).

<sup>63</sup> In this article Joel Lexchin assesses the adequacy of PAAB as a monitoring agency, and compares it to similar agencies in Australia and the U.K., and to the Canadian pharmaceutical industry’s own monitoring code. He judges the PAAB to be effective in its enforcement and pre-clearance but argues that the quantity and quality of the information in the agency’s annual reports (which publicize breaches to the code), and the distribution of these reports, could be improved (Lexchin 1997).

<sup>64</sup> One could argue that the guidelines Chepesiuk discusses are therefore not applicable to the event in question, since it was not an event for physicians. It is difficult to see, however, why guidelines for public information sessions would be less stringent than those for physicians. More likely, Chepesiuk did not discuss public information session for patients in his articles because these are a relatively new phenomenon for which guidelines had not yet been developed. In recent years, guidelines have appeared to restrict the types of statements that companies can make about drug products on websites and other information venues available to patients.

<sup>65</sup> *Jenny*, for example, described attending a conference of hospital-based cancer patient educators in 2007 at which a delegate presented a paper about a website that a large Canadian hospital had established for its patients. A key feature of the website was that it would be monitored to ensure that patients could trust the information posted. She reflected, “I thought it was interesting that, here’s this PhD going to run this website, with all these helpers, and basically do what we did ten years ago!” (Interview with *Jenny*, 2007).

<sup>66</sup> Astra Zeneca markets tamoxifen under the brand name Nolvadex®. The company introduced the drug as a breast cancer treatment in the 1978 and it became a standard treatment for certain breast cancers (those classified as “estrogen-positive) in the 1980s. See Chapter 4 for more about this drug as an actor in the breast cancer arena.

<sup>67</sup> The two women who attended the invitational workshop both represented provincial breast cancer organizations. One was a paid employee of the provincial cancer care centre and had not had breast cancer; she thought the document was a good idea, but that it should be developed by women who were part of the community of breast cancer survivors. She therefore asked Wendy, a member of a patients’ support and advocacy organization, if she would agree to take her place. The woman who asked *Martha* to replace her was personally unenthusiastic about the project because she didn’t believe the proposed document would have any teeth; she knew *Martha*, however, and thought, however, that she might be a willing advocate for a patients’ rights document. She was correct in this assumption – *Martha* eventually became the group’s chairperson and a passionate advocate for the document.

<sup>68</sup> Differences in the way the same condition is treated -- from region to region, or from one specialist to another -- is not always the result of inequalities but can simply reflect confusion in the field because no one approach has been shown to be superior to others, despite masses of data. Ranjana Srivastava (2011) argues that physicians should be more willing to admit



uncertainty when they don't know the answers to a patient's questions, recognizing that the science guiding their decisions is often murky and trusting the patient's ability to deal with this uncertainty.

<sup>69</sup> I was a founding member of the organization although no longer active beyond receiving the newsletter and e-mail announcements.

<sup>70</sup> I discuss the political history of drug regulation in Canada, including patent laws, in the next chapter. At this point I simply note that this citation refers to amendments to the Patent Act under the 1987 Bill C-22, which took effect in 1989 and changed the term of a patent from 17 years from the date a patent was issued to 20 years from the date when the patent application was filed (Smith 2000). Also worth noting is that the claim in this citation that links extended patent protection to high drug prices in Canada is a contested one. The Report of the Commission on the Future of Health Care in Canada states that "there is no empirical evidence to suggest that Canada's patent protection laws are responsible for increasing drug prices" (Romanow, 2002: 209). Lexchin (2005), by contrast, argues that use of the International Patent Rights system (the impetus for changing Canada's Patent Act) has resulted in "higher drug spending, more reliance on imports, [and] a divergence of the R&D budget away from basic research" (ibid: 250). Lexchin further argues that the patent system "warps the pharmaceutical marketplace" (ibid: 250) and leads companies to engage in wasteful competitive strategies, such as spending vast sums of money on promotional costs.

<sup>71</sup> See, Kyriakides, S. Curriculum Vitae: [http://www.ecco-org.eu/binarydata.aspx?type=doc/Stella\\_Kyriakides.pdf](http://www.ecco-org.eu/binarydata.aspx?type=doc/Stella_Kyriakides.pdf)

<sup>72</sup> Europa Donna, Press Release, Brussels (October 18 2005), "Record Number of MESs Attend 'Breast Cancer in the EU-25' Reception and Exhibition: New Edition of European Guidelines for Quality Assurance of Breast Cancer Screening and Diagnosis Presented."

<sup>73</sup> This was the same meeting where Stella Kyriakides appeared. The annual American Society of Clinical Oncologists (ASCO) meetings in San Antonio are a key venue for clinical oncologists to present and discuss new developments in breast cancer treatments (a larger ASCO meeting, encompassing all cancers, is held every spring).

Although intended very much for medical researchers and practitioners, members of advocacy organizations have been a presence at ASCO meetings since the mid-1990s. Patient-group advocates are not guaranteed easy access to ASCO and similar professional meetings, however; the entrance fees are prohibitive for many patients' groups, which thus look to the sponsoring organization to grant fee waivers. In 2001 the American advocacy organization *Breast Cancer Truth-Tellers* ran an article in its newsletter describing the difficulties its members encountered trying to gain free entrance to a spring ASCO meeting, either by applying for a press pass, or by participating at a special booth that ASCO provided for select patients' organizations. Members of *Breast Cancer Truth-Tellers* felt that the group's public criticisms of ASCO in 1999, when the oncologists' organization delayed announcing research results showing that high-dose

chemotherapy was no more effective than conventional treatment, had resulted in *Breast Cancer Truth-Tellers* being effectively blacklisted from the advocacy groups whose \$500/person entrance fees were waived at the 2001 meeting.

<sup>74</sup> Interview with *Jenny*, 2007.

<sup>75</sup> Interview with *Ruth*, 2007.

<sup>76</sup> The federal government's contribution to health spending can be calculated in a number of ways and not all analysts agree on the 15 per cent figure.

<sup>77</sup> The slight restoration of funding which began in 2001-2 was a response to public pressure as the government began posting large annual surpluses. In 2004 the government committed \$41 billion over ten years to the transfer payments which brought the federal government's direct share of federal/provincial health spending up to 25 per cent, half what it was when the single-payer system was instituted (Armstrong and Armstrong 2008: 23).

<sup>78</sup> The first Conservative Party of Canada was formed in 1867. The party adopted the name Progressive Conservative in 1942 and in 2003 the Progressive Conservative Party merged with Canadian Alliance and revived the banner the Conservative Party.

<sup>79</sup> These figures are based on the annual federal cash contribution to Provincial-territorial expenditures on hospital and physician services. The debate over federal health transfers is a confusing one because several methods of assessing the federal contribution are used. *The Commission on the Future of Health Care in Canada* (Romanow 2002) explains the systems of calculation and the way different parties use them to present their case. "The original 'medicare bargain' involved the federal government sharing with the provinces all eligible hospital and physician expenditures on a 50:50 basis. Historically, the principle of cost-sharing only covered what would become known as Canada Health Act Services. Over time, however, the public, along with governments increasingly debated cost-sharing in the context of total provincial health expenditures" (Romanow 2002:66) In addition, the report points out, in 1977-78 the government instituted a system of using cash + tax points in lieu of cash transfers only, and this transfer regime bundled transfers for health and post-secondary education; in 1995, social assistance and social services were added to the transfer bundle.

It is the cash transfers for hospital and physician services that fell to a low of 14.6 % in 1998/99. The Romanow Commission Report recommended that Ottawa once again move closer to a 50:50 position in funding health and that the health transfer be exclusively a cash transfer because the latter are more transparent and they allow the federal government the leverage to enforce the Canada Health Act (i.e., by withholding the cash transfer if a province does not comply with the terms of the Act) (ibid:68). This recommendation has not been implemented; I use the figures for cash transfer here, however, because it is a transparent measure and a reflection of the government's power (and will) to enforce the Canada Health Act.

<sup>80</sup> A slight restoration of funding which began in 2001-2 was a response to public pressure as the government began posting large annual surpluses. In 2004 the government committed \$41 billion over ten years to the transfer payments which brought the federal government's direct share of

federal/provincial health spending up to 25 per cent, half what it was when the single-payer system was instituted (Armstrong and Armstrong 2008: 23). The provinces were left to spend this money as they chose, however, so the funds have not always gone to health care and problems were not addressed. Furthermore, by giving the provinces free reign on spending the money the federal government abandoned its main tool for enforcing the *Canada Health Act* (Armstrong and Armstrong 2008).

<sup>81</sup> The discussion that follows is restricted to drug treatments for breast cancer patients, since breast cancer groups are the focus of this dissertation. Many of the general trends, however – an increased reliance on chemotherapy treatments, an expansion of the pharmaceutical menu, and a rise in chemotherapy costs – apply to other cancers as well.

<sup>82</sup> The inconvenience and cost of travel for patients living in rural and remote areas were an issue, as was regional variation in breast cancer surgery. Neither problem was the result of a single-payer system, but rather reflected the structural tendency for specialized medical care to concentrate in major centres – a phenomenon just as prevalent in the American privately-funded system [REFS].

<sup>83</sup> The debate about whether breast cancer was local or systemic had been going on for at least a century but the proponents of the systemic theory remained a small minority, especially in the United States. Surgeons, especially, who had been the mainstays of breast cancer care, were slow to accept evidence that cancer cells were disseminated throughout the body almost from the outset (Lerner 2001)

<sup>84</sup> In the first (1990) edition of her popular and comprehensive guide for lay readers, American breast surgeon Dr. Susan Love lists eleven cytotoxic drugs used for breast cancer and says the list is “not meant to be exhaustive” (Love with Lindsey 1990:388-390); a 1994 medical oncology reference book gives a list of ten cytotoxic drugs as the “most commonly used” cytotoxic agents found to be effective in the treatment of breast cancer (Harris et al, 1993, cited in DeGregorio and Wiebe 1999: 18-24). The two lists are identical save for the inclusion of cisplatin in the book by Love and Lindsey.

<sup>85</sup> Love with Lindsey, 1990:390.

<sup>86</sup> This procedure is sometimes referred to as high-dose chemotherapy with autologous bone-marrow transplant.

<sup>87</sup> The first pharmacopoeia is attributed to the Greek physician Pedanius Dioscorides who lived in the first century A.D. His book *De material medica* (On Medicine) was based on his collected knowledge of remedies of the period, in particular his description of more than 600 plants with notes on their habitat and instructions on how to prepare them to use the drugs they contain for medicinal purposes. The *De material medica* also describes animal derivatives and minerals used therapeutically. The book was reproduced, translated and used for centuries afterwards. Additional important pharmacopoeia were produced in the Renaissance, including the “Nuovo

Receptario of Florence (1499), the Dispensatorium (1546) and the London Pharmacopoeia of 1618. (Huguet-Termes 2008)

<sup>88</sup> The law followed a three-strikes-and-you're-out formula: a baker caught selling a "faulty loaf" for the first time was to be dragged through the streets with the offending item tied around his neck. Punishment for a second offense escalated to include an hour in the town pillory, while a third was cause for pulling down the merchant's oven and a lifetime ban from ever again doing business in the city.

<sup>89</sup> Letheby was the former Medical Officer of Health to the City of London and one of three London physicians who crusaded for the first health protection laws in mid-18<sup>th</sup>-century England (see page XX). His essay on adulteration appears in the 9<sup>th</sup> Edition of the *Encyclopaedia Britannica*, published in 1890.

<sup>90</sup> The title of Accum's book *Treatise on Adulterations of Food, and Culinary Poisons Exhibiting the Fraudulent Sophistications of Bread, Beer, Wine, Spirituous Liquors, Tea, Coffee, Cream, Confectionary, Vinegar, Mustard, Pepper, Cheese, Olive oil, Pickles, and Other Articles Employed in Domestic Economy, and Methods of Detecting Them* hints at the broad scope and the crusading flavour of his work (cited in Letherby 1890).

<sup>91</sup> Hassell published his findings as a book, with recommendations, in 1855. Apparently his name did not appear as the author of the articles in *The Lancet* because he and Wakley anticipated law suits from angry merchants (which Wakley was prepared to finance, if need be). Instead, the articles appeared as Reports of the Analytical Sanitary Commission. No law suits materialized, however, and the book appeared under Hassell's name (website of the Royal Society of Chemistry, accessed March 24, 2011).

<sup>92</sup> Known as the Bradford Sweets Poisoning, the incident involved deliberate adulteration as well as an accident. Instead of arsenic, the lozenge-maker had meant to purchase "daft," cheap filler commonly substituted for sugar to save manufacturers money. The number of people poisoned range was estimated at about 400 (Carter 1999: 216).

<sup>93</sup> This was essentially a tax act. The Ministry of Inland Revenue, created in 1867, was the country's first federal tax department and the precursor to the Ministry of National Revenue, established in 1927 (now Revenue Canada).

<sup>94</sup> Like the movement towards regulation that precipitated the Adulteration of Food Act in the UK a half-century earlier, the actors behind the American reforms included physicians, chemists, politicians and journalists. The American reformers included a public-spirited physician and chemist named Harvey Wiley, the progressive politician Theodore Roosevelt, who became President in 1901, the American Medical Association, and a clutch of editors and journalists, among them Upton Sinclair whose book *The Jungle* exposed exploitation of the poor and corruption among the powerful in the meatpacking industry. A series of journalistic exposés in popular American magazines revealed that alcohol, cocaine and opium were among the

substances pedaled to relieve all manner of unrelated symptoms and diseases, from crying infants and “female complaints” to tuberculosis and mumps (Hilts 2003).

<sup>95</sup> Those that did have to be disclosed included opium, morphine and alcohol.

<sup>96</sup> The same acronym, “the FDA”, is used to refer US Food and Drug Act, the US Food and Drug Administration, and the Canadian Food and Drugs Act. To avoid confusion, I avoid using initials and spell each out.

<sup>97</sup> Avorn notes that, in 2011, the term ethical drugs referring to prescription medications, “seems oddly archaic in a time of scandals about deceptive marketing practices and heavily advertised, costly medications that turn out to have major unreported risks.” (Avorn 2011:1187)

<sup>98</sup> These include several Canadian entries, such as Charles E. Frosst & Co., founded in Montreal in 1899, and Frank W. Horner Ltd. also of Montreal. Both were taken over by American interests in the early 1960s (Lang 21, 295).

<sup>99</sup> Public pressure on pharmaceutical companies to respect human rights was seen dramatically in 1998 when the South African pharmaceutical umbrella association, representing 39 drug companies, sued the government of South Africa and then-President Nelson Mandela for passing an Act that would allow the country to acquire low-cost, generic anti-retroviral drugs to treat South Africans suffering from HIV/AIDS. The case sparked international outrage over the industry’s greed and indifference to human suffering; Oxfam, *Médicins sans frontières* and the World Health Organization were among the organizations that denounced the suit. Oral arguments in the case began March 5, 2001; by April 19, the companies had unconditionally withdrawn their legal action (Cahill, 2003).

<sup>100</sup> The submissions at this time went to the Department of Health and Welfare, the Food and Drugs Divisions; later the Health Protection Branch was created to conduct the reviews (Carter 1999:219).

<sup>101</sup> Thalidomide was discovered by Ciba, in 1953, but the company discarded the drug when it concluded the drug had no pharmacological effect on animals (Sherman and Strauss, 1986, cited in Kristina E. Lutz (online): From Tragedy to Triumph: the approval of Thalidomide. <http://leda.law.harvard.edu/leda/data/351/Lutz.pdf>

<sup>102</sup> The thalidomide sold in Canada came from two sources, the U.S. company Merrell and the Canadian company Horner, both of which manufactured the drug under license from the German developer (Report of the Thalidomide Task Force of the War Amputees of Canada, Ottawa: undated; accessed online, April 19, 2011 at: [http://www.waramps.ca/uploadedFiles/English\\_Site/Newsroom/Archives/Thalidomide/Media/PDF/synopsis.pdf](http://www.waramps.ca/uploadedFiles/English_Site/Newsroom/Archives/Thalidomide/Media/PDF/synopsis.pdf)

<sup>103</sup> The task force report by the War Amputees of Canada cites a 1963 report by Health and Welfare Canada stating that 115 children with thalidomide-related congenital malformations were born in Canada, only 74 of whom had survived. The War Amputees task force had identified 109

victims, however, and concludes that Health and Welfare Canada's figures are "not reliable" (Report of the thalidomide task force of the War Amputees of Canada, see Note 23: p 5).

<sup>104</sup> At this writing, an attempt to modernize the Act, has been tabled in the House of Commons in 2008 but has yet to pass.

<sup>105</sup> Regulation of pharmaceuticals in Canada falls to the federal government because it is a "residual subject", that is, an area of concern not specifically named in the Constitution as either provincial or federal, and Canada's legal system grants residual powers to the federal government if a law is deemed necessary for "peace, order and good government" (Carter 1999:221).

<sup>106</sup> Bill C-51, was introduced in the 39<sup>th</sup> Parliament but did not become law when the session ended, in September 2008. <http://laws-lois.justice.gc.ca/eng/acts/f-27/>.

<sup>107</sup> The reviews are still carried out in a similar fashion although changes have been introduced over the years, which I discuss in the subsequent text; structurally, the Department has undergone a major reorganization since the Food and Drugs Act became law in 1953. In 1993 the Department was renamed Health Canada. The Health Products and Food Branch (the HPFB) was subsequently created, as one of the department's nine branches, to review therapeutic product applications for approvals. Within the HPFB are two bodies that review submissions for the approval of human therapeutics: the Therapeutic Products Directorate (TPD), which reviews drug companies' applications for the approval of pharmaceuticals (i.e., therapeutics made from chemicals), and the Biologics and Genetics Therapies Directorate (BGTD) which reviews biologic drugs -- therapies derived from living sources such as blood, vaccines, monoclonal antibodies, and gene and cell therapies.

<sup>108</sup> The Canadian and American review processes are sufficiently similar that Canadian reviewers will accept the same submission as the Food and Drug Administration, although they do not necessarily render the same decision.

<sup>109</sup> *The Politics of Drugs*, Ronald W. Lang's 1974 book comparing the pharmaceutical industry pressure groups in Canada and the UK was based on his doctoral research for the University of London. For purposes of this discussion I omit most of his analysis relating to events in the UK.

<sup>110</sup> Two analysts of the period made the claim, "No other industry approaches the pharmaceutical industry in its degree of attachment to patent protection." (Taylor and Siberston 1973, cited in Vandergrift and Kanavos 1997:245).

<sup>111</sup> Ronald Lang quotes Harry J. Tomlinson of Upjohn's remarking at the 1962 conference of the Pharmaceutical Manufacturers' Association that "the Kefauver hearings had led to government investigations in 17 countries and had left the American pharmaceutical industry under fire in 25 to 30 others" (Lang 1974: 19).

<sup>112</sup> Two initial reports concluded that Canada's drug prices were the highest in the world and that the US patent system was the heart of the problem. The first was the *Green Book*, based on an inquiry undertaken by the Combines Division of the Restrictive Trade Practices Commission

(1958 to 1961); the second was the Royal Commission on Health Services, a public inquiry also known as the Hall Commission, which held hearings across the country and summarized its findings in two reports in 1964. A House of Commons Special Committee on Drug Costs and Prices, known as the Harley Committee, issued a report in 1967 (see Lang 1974: 28, n 10, n 44).

<sup>113</sup> Vandergrift and Kavanos, cited in Cohen 2004, p 5, state that “no other industry approaches the pharmaceutical industry in its degree of attachment to patent protection.”

<sup>114</sup> Compulsory licensing was not unique to Canadian patent law; the Paris Convention of 1883 recognized it as a mechanism by which national governments could prevent abuses that might result from the exercise of exclusive patent rights [ Paris Convention, Article 5A(2)] and as a means to encourage dissemination of technical knowledge.

<sup>115</sup> Kefauver proposed reducing exclusive patent rights on pharmaceuticals in the United States from seventeen years to three, to be followed by fourteen years in which a compulsory licensing system would apply, with the royalty paid to the patent-holder to be capped at eight per cent of sales [p14].

<sup>116</sup> Also relevant, although its focus was not specifically on drugs, was the Royal Commission on Patents, Copyright and Industrial Designs, chaired by James Lorimer Ilsley and established in 1960. The Ilsley Commission issued three reports, in 1957, 1958 and 1959 (Davies, Canadian Encyclopedia).

<sup>117</sup> In 1938, Germany dominated the world market with 39% of sales; the United States (at 13%), Britain (12%) and France (12%) followed a distant second. Switzerland (7%), Holland (5%) and Italy (2%) all had smaller shares of the world market, while Canada and the USSR each had 1%. By 1963, the world market had increased almost ten-fold, from \$130 million to \$1,124 million and the United States had displaced Germany as the world leader in sales with 25% of the market. Germany (15%), Britain (14%) and Switzerland (14%) shared second place, with France (9%), Holland (5%) and Italy (4%) as minor but significant players. Japan, Denmark, Belgium, Poland and Bermuda each had 2% of the market while Canada and the USSR remained at their 1938 levels with 1% of the market each. (Lang, 1974, Appendix B, citing MH Cooper, 1966, Prices and Profits in the Pharmaceutical Industry, Pergamon Press, London 1966, p 249.)

<sup>118</sup> The brand name companies did engage in competition with one another, but they did so by manufacturing “me too” drugs. These are not exact copies of existing drugs, but rather involve slight modifications that allow the “me too” drug to be patented.

<sup>119</sup> The third group, which did not present to the Harley Committee, comprises only five per cent of the market. Its members are known as 'Independents' and their views were known not to be congruent with PMAC's (Lang 53).

<sup>120</sup> This division carries forward today, with the brand name companies lobbying under the umbrella of Canada's Research-based Pharmaceutical Companies (which uses the acronym Rx&D) and the Canadian Generic Pharmaceutical Association (CGPA).

<sup>121</sup> Citation from an interview Ronald Lang conducted with Michael Sheldon, a former PR director for Smith, Kline and French who was on loan to PMAC to prepare its case before the Parliamentary Committee on Drug costs and Prices 1965-67 (quoted in Lang, 1974 p 42)

<sup>122</sup> With support from Conservatives and the Social Credit party members on the 15-person committee, PMAC kept the safety issue in the forefront for the next several years while the Liberals and NDP fought to make prices an explicit part of the committee's mandate. This initiative gained strength in 1963 when the government changed from Conservative to Liberal.

<sup>123</sup> Forty-three of 69 compulsory licenses issued by 1971 were appealed in the courts [Lexchin cited in Carter, 242, n 218.]

<sup>124</sup> In *C.E. Jamieson & Co. Ltd. v. Canada* [1987] 12 F.T.R. 167 the Court examined the Food and Drugs Act in relation to the Canadian Constitution to determine under which area of federal jurisdiction it fell. The Court decided that the Act spanned two subject areas: the regulation of *public safety* and of *trade and commerce*; however, its dominant subject matter (its "pith and substance") was the regulation of public safety (Carter 1999:222).

<sup>125</sup> Nicholas Regush continued to write about drug safety issues until his death in 2004.

<sup>126</sup> Medroxyprogesterone 17-acetate (also known as medroxyprogesterone acetate or MPA) is a progestin, a synthetic variant of the hormone progesterone.

<sup>127</sup> Clearly a drug-lag skeptic, Hilts devotes whole sections of his book and an entire chapter to the issue of what he terms "so-called drug lag" (2003: 191). He notes that structural factors such as staff capacity and training can affect the time it takes to conduct a proper review; for example, in the 1970s, when the FDA was building its professional staff, developing standards – essentially, inventing the process of drug review -- he estimates that some half-dozen to two dozen delays may have indeed had a therapeutic impact (p 368).

<sup>128</sup> The figure for the percentage of 'Me-too' drugs approved will vary from study to study depending on the definition used, the year the figures were compiled and the country where the study is done. A 1981 U.S. FDA report cites the percentage of new drugs approved in that country that have a therapeutic advantage over existing drugs as 15 per cent; a report by the American watchdog organization, Public Citizen's Health Research Group in Washington, D.C., cites only five per cent of the new drugs in development pipeline in the US as having the potential for therapeutic gain (both figures cited in Regush, 1993: 15-16. In a more recent analysis, Joel Lexchin states, "There is no argument against getting breakthrough drugs onto the market faster but these represent less than 1% of all new drugs" (2011:10).

<sup>129</sup> The increase reflected the number of new drug submissions to the HPB as well as requests to review products already on the market (Regush 1993: 15). Silicone breast implants are an example of the latter, i.e., products for which an initial judgment of safety was called into question following consumer complaints and/or new scientific data.



<sup>130</sup> These were the Eastman Commission of Inquiry into the Pharmaceutical Industry (1985), the Ministerial Task Force on Program Review (1985), the Auditor General's Report (1986) and the federal Working Group on Drugs (1987) (Regush 1993: 17-18).

<sup>131</sup> The Health Protection Branch was renamed the Health Products and Food Branch in 1999.

<sup>132</sup> The CBC has an archival account of Dr. Napke's pioneering efforts to develop Canada's system of tracking adverse drug reactions. Dr. Napke filed reports in a system of pigeon holes and used coloured tabs to mark particularly severe reactions. A cluster of coloured tabs in the same or adjacent pigeon holes indicated a potential problem. See: <http://www.cbc.ca/news/adr/> (accessed October 18, 2011).

<sup>133</sup> The Mème was manufactured in the United States, originally by a company called Natural-Y Surgical Specialties, Inc. [YEAR], which sold the product to a New York company, Cooper Surgical. In 1988, Surgitek, a subsidiary of the pharmaceutical giant Bristol-Myers Squibb purchased the Meme production plant (Regush, 1992: 28). The implant was distributed in both Canada and the United States and was the subject of news stories and government investigations in both countries. Several factors contributed to the attention the Mème received in Canada. First, Montreal journalist Nicholas Regush made the Meme a topic of ongoing investigation, writing a series of articles in *The Gazette* (Montreal) and later in the American magazine *Mother Jones* (1992); second, Pierre Blais, an outspoken senior scientific advisor to Health Canada's Product Safety Branch had urged the department to withdraw the product from the market and was fired when he made his concerns about the device public; and third, the product was especially heavily marketed in Quebec, creating a critical mass of affected women (Regush 1992: 28).

<sup>134</sup> Two others who voiced concerns were Quebec City Member of Parliament Suzanne Duplessis, Jacques Papillon, a plastic surgeon in Montreal.

<sup>135</sup> In one well-documented immune response, known as contracture, scar tissue forms around the implant creating a hard shell; and the devices sometimes leached silicone into the body, a suspected cause of chronic, painful inflammation of the joints that some women with implants suffered (Regush 1993:85-6).

<sup>136</sup> The Deputy Minister had requested the meeting because his coverage of the *Mème* story disturbed the Minister of Health.

<sup>137</sup> These three drugs have all been in use for over forty years and are among the oldest in the chemotherapy repertoire. Perhaps for this reason they are commonly known by their generic, not their brand names, and so I have used the generic names in the text. Brand names are Cytoxan® (cyclophosphamide), Rheumatrex® and Trexall™ (methotrexate) and Adrucil® (5-fluorouracil or 5-FU).

<sup>138</sup> Not all analysts agreed that surviving ten or twenty years post-diagnosis meant the woman was effectively cured. Breast cancer can recur twenty or more years after diagnosis. Thus, Williams offers this gloomier assessment regarding women diagnosed as stage 1 or stage 2: chemotherapy was "an investment with uncertain payoff [because] most patients with operable breast cancer relapse and die of the disease" (Williams 1992:248). His point concerning chemotherapy is the

same as Lerner's, however. For any given case, the evidence of benefit measured in life extension was slim and uncertain while the evidence for loss in quality of life was significant and certain.

<sup>139</sup> Dr. Susan Love defines adjuvant chemotherapy as “Anticancer drugs used in combination with surgery and/or radiation as an initial treatment before there is detectable spread, to prevent or delay recurrence.” (Love with Lindsey 1990:433). Adjuvant means “helping” so the chemotherapy is considered a secondary treatment intended to “help” the primary treatment(s) reduce the burden of cancer cells in the body.

<sup>140</sup> The *Journal of Clinical Oncology*, which had published Dr. Bezwoda's bogus findings in 1995, issued a retraction in its June 1, 2001 issue. See retraction, at <http://jco.ascopubs.org/content/19/11/2973> and related editorial at [http://jco.ascopubs.org/content/18/12/2353.full?ijkey=06fbb9b41a4fcd3ec28be2afc3991e9748fac78d&keytype=tf\\_ipsecsha](http://jco.ascopubs.org/content/18/12/2353.full?ijkey=06fbb9b41a4fcd3ec28be2afc3991e9748fac78d&keytype=tf_ipsecsha) (both retrieved October 18, 2011).

<sup>141</sup> The literature on these groups includes rich debates about the theoretical underpinnings of various terms; for example, the term “social movement” may be reserved for groups on the left, and “interest group” may imply a pluralistic theoretical framework in which all groups are assumed to pursue the interests of their members on a level playing field. Miriam Smith argues, however, that common analytic tools can be profitably used to understand groups engaged in collective action outside the formal party system (Smith 2005: see especially 10-13). Smith's approach suits my own analytic purpose, which is to examine patient-identified groups as a subset of organizations undergoing a process of change, differentiation and self-definition. Like Smith, I therefore use a variety of terms from the literature interchangeably.

<sup>142</sup> Feminist activism in this era dates from the late 19<sup>th</sup> century to 1930 and the beginning of the Great Depression. While the struggle centred primarily on gaining the right to vote and for women to be defined in law as persons, the suffrage discourse contested the belief that women were intellectually inferior because of their bodies. The increased professionalization of medicine in the 19<sup>th</sup> and early 20<sup>th</sup> century undermined women's traditional roles as experts in childbirth, sexuality, menopause, and care of the elderly. Disenfranchised, and with women's spheres of knowledge usurped, early feminist reformers in Canada made claims for political representation based on the particular knowledge of family concerns gained through their experience as wives and mothers, including the care of sick family members (Morrow 2007).

<sup>143</sup> The Women's Institute began in Stoney Creek, Ontario in 1897 as an outgrowth of the Farmer's Institute and soon spread around the world. Much of the organization's work involved educational activities and civic involvement, such as setting up libraries and organizing talks, particularly on issues related to food and healthy eating. The group's Canadian founder, Adelaide Hoodless, unknowingly gave contaminated milk to her 18-month-old son, who then died. Feeling that she “should have known better,” she turned to community activism to educate other women as a way to avert future tragedies (Cogswell, No date). The Women's Institute is thus an early example of food and health protection activism.

<sup>144</sup> The Victorian Order of Nurses was established by Lady Ishbel Aberdeen, the wife of Canada's then Governor General, in response to hearing women's "horror stories" about young mothers and children isolated areas who died before their husbands or fathers could reach medical help. At the meeting of the National Council of Women in Halifax in 1897, Lady Aberdeen was asked to found an order of visiting nurses in Canada who would care for sick people in their own homes. She took up the cause with efforts that included a campaign to overcome the resistance of doctors, and the Order admitted its first 12 nurses later the same year. Accessed April 25, 2011 at: <http://www.von.ca/en/about/history.aspx>

<sup>145</sup> Abortion and the dissemination of birth control information had been illegal in Canada since 1869, subject to a penalty of life imprisonment.

<sup>146</sup> In 1969, Canadian abortion laws were liberalized to make therapeutic abortions available pending approval from a hospital committee that agreed the woman's health was in danger. Canadian women won the legal right to birth control information the same year. Pro-choice feminists were not satisfied with the restrictive abortion law, however, which gave hospital committees rather than the woman the power to decide whether she could obtain an abortion.

<sup>147</sup> Governments in Canada have a tradition of encouraging pressure groups and this practice grew during the Trudeau administration in the late 1960s and 1970s (Pross 1992:45). In his historical analysis of pressure groups in Canada, Paul Pross observes that Canadian governments discovered in the interwar years that interest groups were valuable to the policy-formation process in a variety of ways: they clarified the needs of particular communities, they channeled information, and they lent legitimacy to demands as well as to the policy-making agencies themselves (ibid:44). By the late 1960s it was clear that the women's movement expressed concerns that were widespread and the government responded by actively building structures that would help government and the participants in the movement communicate (ibid:96-97). The funding of various types of women's centres was part of this evolution.

<sup>148</sup> DES Action Canada, *Healthsharing* magazine, and the Vancouver Women's Health Collective were among the collaborating groups.

<sup>149</sup> Harriet Simand and her mother Shirley lived in Montreal where they founded DES Action Canada. Shirley Simand had taken DES during pregnancy to prevent miscarriage and when Harriet was 21 they learned she had clear-cell carcinoma, the rare cancer caused by DES (Regush 1987:237).

<sup>150</sup> At the time this would have been the Ministry of National Health and Welfare.

<sup>151</sup> Founded in 1960 as an international union of consumer watchdog organizations dedicated to protecting the rights of consumers, the organization changed its name to Consumers' International in 1995. Accessed April 28, 2011: <http://www.consumersinternational.org/who-we-are/we-are-50/history-of-the-consumer-movement>

<sup>152</sup> Contributors to the book from the Canadian women's health movement were Anne Rochon Ford, Carla Marcelis, Ann Pappert, and Sari Tudiver.

<sup>153</sup> Feminist health groups supported the goal of providing women with birth control options but argued that the methods promoted by governments, industry, and NGOs promoting population control sometimes failed to meet adequate safety standards and were not accompanied by adequate risk/benefit information. One example was the injectable contraceptive, Depo-Provera, which the World Health Organization (WHO) and International Planned Parenthood promoted as a means of controlling population growth in developing countries. In 1978 the FDA refused Upjohn Company's request to approve the drug for use in the United States on the grounds that the scientific evidence of safety was inadequate. Two American consumer health advocacy groups, the National Women's Health Network and the Health Research Group, had argued in favour of this decision. In 1983, when Upjohn Company applied to Health Canada's Health Protection Branch for a license to market Depo-Provera in Canada, some 45 women's groups who were aware of the American controversy formed the Canadian Coalition on Depo-Provera. They argued that the drug's risks had not been adequately demonstrated and demanded a public hearing to air the viewpoints on its risks and benefits (Regush 1987:229-230).

<sup>154</sup> The Epcot Center is a Disneyland-style centre featuring different cultures.

<sup>155</sup> I refer here to the drugs developed by mainstream researchers and companies with the goal of gaining approval for marketing through the medical system. Demands by individual patients for access to "alternative treatments" have a long history among cancer patients (see, for example, Gerson 1958, Reich 1973, and Moss 1992). The term "alternative treatments" is broad but in the case of cancer usually refers to treatments outside the standard trilogy of surgery, chemotherapy and radiotherapy. Often a controversial treatment is one that was developed outside the culture of allopathic medicine and which has not been subjected to the animal tests and clinical trials that drug regulatory agencies require for approval; hence its safety and/or efficacy is considered to be in doubt (Hess 1999).

<sup>156</sup> She began writing about AIDS issues, "as a kind of homage" to her cousin, Brian Silversides, after he died in 1996. As she explains in the preface to her book about Canadian AIDS activist Michael Lynch, she and her cousin had always been close and when he became HIV-positive she met and became friends with many members of the activist community (Silversides 2004: xi).

<sup>157</sup> In 1999, Silversides wrote a series of critical articles about the pharmaceutical industry's involvement in Canadian AIDS groups for *Xtra!* a supplement to the Toronto-based gay publication *Body Politic*, in which she observed that it was unusual to attend an AIDS function where the lunch was not provided by a pharmaceutical company (Silversides, 1999) These articles are discussed in the next chapter.

<sup>158</sup> Two other main reasons were the centrality of the medical profession in the treatment of breast cancer and the cultural meanings of women's breasts (Waserman 1997:4). On the first point, Waserman notes that, even though medical knowledge of breast cancer is wanting and treatments are controversial, "it is difficult not to turn to the medical profession when faced with a life-threatening illness" (ibid: 14); furthermore, until AIDS activism, the treatment of diseases was thought to be "outside the realm of politics" (ibid"68). With respect to culture, the centrality of women's breasts in women's sexuality and motherhood contributed to a taboo against talking

about women's breasts as sites of disease. The emphasis on and idealization of women's breasts as cultural symbols of a woman's worth contributed to women feeling too ashamed or too embarrassed to talk about breast cancer (ibid: 69-70).

<sup>159</sup> The silence about breast cancer in the Canadian women's health movement that Wasserman documents has striking similarities to Maren Klawiter's analysis, ten years later, of the same phenomenon in the San Francisco area (Klawiter 2007: 166-167). Klawiter contrasts the development of the AIDS movement in San Francisco to the absence of a similar movement for breast cancer until 1986, when a group called the Women's Cancer Resource Center (WCRC) was established. The women's health movement in the U.S. had not ignored breast cancer, notes Klawiter, but neither had it launched a movement around women's cancer or breast cancer. "Instead of breast cancer, the women's health movement focused its attention on the politics of reproduction – sexuality, birth control, abortion, pregnancy, childbirth, breast-feeding, unnecessary hysterectomies, forced sterilizations, and the safety of pharmaceutical technologies (for example, the birth control pill, the DES controversy, hormone therapy) – and on violence against women" (ibid: 167). As in Canada, the result was invisibility and a lack of politicization. "Despite the network of feminist rape crisis centres, shelters and Planned Parenthood offices across the US, "ordinary flesh-and-blood women with breast cancer were still invisible to each other and invisible, as embodied speaking subjects, to the public." (ibid: 167)

<sup>160</sup> HIV/AIDS, until the 1990s, was seen as a disease of gay men.

<sup>161</sup> Others were Audre Lorde, the black American poet who wrote the *Cancer Journals* (1980), and Deena Metzger, who wrote the book *Tree* (1978).

<sup>162</sup> This use of surrogate endpoints illustrates Ilana Löwy's (2000) point about in cancer treatment research.

<sup>163</sup> In a chapter titled "Clinical Cancer Alerts: Less than Wise," George Omura begins his critique by stating "The recent advent of the National Cancer Institute "Clinical alerts" and "Updates" is well intentioned but ill advised" (Omura 1992:421). The thrust of his argument is that these press releases bypass the established process of peer review and journal publication (often with accompanying commentary, if the results are controversial) which is essential to putting a scientific report in proper perspective. Media coverage based on an incomplete assessment of findings will typically follow and may exaggerate and/or confuse the importance of the findings by misinterpreting their significance for clinical practice. He notes that the 1988 Alert failed to consider cost-benefit ratios and did not point out the possibility of late toxicities. He also observes that as a publicly-funded entity, the National Cancer Institute (NCI) has a vested interest in publicizing new cancer research findings: "Another consideration ... is the reality that NCI is a publicly funded institution which must compete for funds with innumerable science and non-science activities of the federal government. One hopes that the need for publicity and to be in favor with Congress are not considerations when Clinical Alerts are issued" (Omura 1992:433).

<sup>164</sup> The three women attended a support group meeting at the Cancer Society and found they were the only people there, other than the group leaders. I summarize this account recognizing that the

women at the Cancer Society might well have a different telling; however, the account captures an activist's problematization of the way in which professionalized cancer organizations controlled what knowledge should and shouldn't be imparted to patients, how, and by whom.

<sup>165</sup> In 1988, the annual number of women diagnosed in Canada was about 12,000 (ref - Cancer Society/Statistics Canada).

<sup>166</sup> In the 1970s, Public Interest Research Groups (PIRGs) were established on university campuses in the United States and Canada with the goal of encouraging action for social change. Most Canadian PIRGs are now funded through a small annual levy on members of the student body and funds are made available to campus and community organizations whose work fits the PIRG mission.

<sup>167</sup> As noted, I use my initials, S.B., as a distancing technique to refer to myself as an activist in the movement.

<sup>168</sup> In testimony before a Parliamentary Committee and in media interviews, Tardif said that within four days her incision began to secrete fluids and her breasts and face began to swell (HC 1992, 9:34; Picard 1992). In the months that followed, the symptoms worsened: she suffered extreme tenderness and swelling in her face, arms and torso and infections accompanied by fevers that required hospitalization. X-rays showed her kidneys to be twice their normal size. [HC 1992, 9:43]. During the next sixteen months, specialists treated her for arthritis and gave her pills "just to shut me up" (HC 1992, 9:36). When she complained to the plastic surgeon, who had assured her the prosthesis was "200% safe", (HC 1992, 9:38) he replied that she was an isolated case, that none of his patients had ever rejected the implants, and that her problem was "between her ears." Being diabetic she had lived on insulin all her adult life and she trusted her ability to read her body's cues. She sought a second opinion from a general surgeon who advised her to have the prostheses removed immediately. She did so and within a few weeks the pain and the numbness in her hands were gone.

<sup>169</sup> The Sub-committee was part of the Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women.

<sup>170</sup> Other members were Edna Anderson, also of the Progressive Conservatives, Mary Clancy of the Liberal Party of Canada, Dawn Black of the New Democratic Party, and Pierrette Venne of the Bloc Quebecois.

<sup>171</sup> Some witnesses represented more than one specialty in which case I have categorized them according to the main content of their testimony.

<sup>172</sup> Verbatim transcripts document the social world of breast cancer in Canada at the time and provide a rich record of the discourses on breast cancer issues.

<sup>173</sup> These included basic scientists, clinical trialists, epidemiologists, and public health researchers with clinical trials/treatment research dominating.

<sup>174</sup> The Canadian Cancer Society (CCS), the YWCA and the newer, but rapidly growing, Canadian Breast Cancer Foundation (CBCF) all discussed their services to breast cancer patients at the hearings.

<sup>175</sup> In 1999, PMAC changed its name to Rx&D. Under both names, the organization represents the brand-name pharmaceutical companies; generic companies have their own organization.

<sup>176</sup> This striking disparity between the Committee's perspective and that of the federal Cabinet evokes Lynn Haney's (1966) caution against treating the state as a uniform structure.

<sup>177</sup> By the time the National Forum on Breast Cancer took place, Health and Welfare Canada had been reorganized and rebranded as Health Canada.

<sup>178</sup> S.B. was designated Chair of the SAN Subcommittee and was responsible for the budget; *Eve* was designated Co-chair. The other three groups were called, Prevention and Screening, Treatment, and Research.

<sup>179</sup> This Department was dismantled in 1993 and replaced by Industry Canada, which has an Office of Consumer Affairs within its structure.

<sup>180</sup> One example she gave of PMAC's support for women within the industry was an award made to companies that initiated projects such as an on-site day care.

<sup>181</sup> I have chosen to focus on the network of groups whose central mandates included community education, support and advocacy. Several important breast cancer initiatives unrelated to the government process emerged in Canada in this period, which I excluded from this discussion. Notable among these are the World Breast Cancer Conference, which premiered in Kingston, Ontario in the mid-1997; breast cancer Dragon Boat Teams, and a wide variety of breast cancer fundraising groups.

- *The World Breast Cancer Conference* became a biannual event staged in different parts of the country and attracted participants from around the world. Conference participants have made several bids to move the conference out of Canada, ideally to a developing country. The legal structure is such that this is virtually impossible and the six meetings to date have been held in six different Canadian cities. For each meeting, a core planning group from Canada recruits additional members to the organizing committee from other countries.

- *Breast cancer dragon boat teams* began in 1995 as a collaborative project between University of British Columbia researcher Donald McKenzie and Vancouver women with breast cancer and soon spread across the country and internationally (McKenzie 1998).

- *Fundraising groups* include the *Avon Crusade*, which began in Canada in 1992 and raises money for breast cancer research by selling Avon Products; *Rethink Breast Cancer*, which raises money to educate and conduct research related to young adults concerned about breast cancer; and *Titz 'n Glitz*, which raises money to assist women with breast cancer in financial need.

- Significantly, although breast implant information and advocacy groups for women harmed by implants remained active, they evolved apart from the breast cancer movement, despite the prominence of *Je sais/I know* activists with breast cancer at the Parliamentary hearings. A full exploration of this process is outside the scope of this dissertation. One explanation is that, by the time the breast cancer activists mobilized, breast implants had already been defined as a mainly cosmetic device for women seeking breast enlargement and only 20 per cent of users had had breast cancer surgery. In addition, in the late 1980s, breast cancer patients who had had a mastectomy were offered a more involved form of reconstructive breast surgery which doesn't use an implant. Instead, a flap of skin, muscle and fat from the woman's back, abdomen or buttocks is transplanted to the woman's chest (Love with Lindsey 1990:353-357). Arguably, a different understanding of industry promotional strategies and the risks of medical procedures might have resulted if breast cancer and breast implant groups had been more closely allied. This potential applies particularly with respect to the responsibilities of corporations and regulatory bodies in preventing harms from drugs and devices.

<sup>182</sup> The exhibit included messages from the government leaders in each of the provinces and territories.

<sup>183</sup> S.B. was a co-founder of *Critical Advocacy to Prevent Cancer* and remained actively involved in the group until 1999.

<sup>184</sup> Health Canada hired S.B. and *Eve* on contract for seven months as chair and co-chair respectively. The two roles were virtually identical except that S.B. was responsible for the subcommittee's finances.

<sup>185</sup> An Astroturf group is a fake grassroots citizen's group or coalition that is "primarily conceived, created, and/or funded by corporations, industry trade associations, political interests or public relations firms" (from the Sourcewatch web page on Astroturf, retrieved August 2, 2011 at: <http://www.sourcewatch.org/index.php?title=Astroturf>. For an academic source on Astroturf groups, see Beder, 1998). While early literature on Astroturf groups appearing in the 1990s documented specific campaigns (for example, to defeat the Clinton administration's proposed health care reform legislation, and to oppose restrictions on smoking in public), more recent analyses characterize the creation of the Tea Party Movement in the United States as an Astroturf coup, in which the American billionaire Koch brothers, in concert with the Rupert Murdoch media empire (particularly Fox News), managed to "mobilize the anger of people who found their conditions of life declining, and channeled it into a campaign to make them worse" (Monbiot, 2011). The Tea Party movement is an even more unsettling example of Astroturf as the activists who are its public face are largely unaware that the movement is funded and directed by a handful of billionaires using a complex invisible machinery to promote tax cuts for the rich.

<sup>186</sup> The complete list of potential sources reads, "Health and Welfare – seed money for network development; Status of Women [i.e., a second federal government department]; Provincial Governments; Cancer Society; National Women's Organizations; Breast Cancer Foundation; drug manufacturers; bra/clothing manufacturers; cosmetic industry." (SAN subcommittee 1993, p 11)



<sup>187</sup> Both *Francine* and *Eve* discussed these debates in interviews; the tensions are also reflected in minutes of the *Helping Hand* board in the summer and fall of 1995.

<sup>188</sup> Because a major impetus for breast cancer movement had been the dissatisfaction patients' expressed with existing organizations and programs, the founders of this new breed of groups made efforts to ensure that "survivors" were included in their decision-making structures. The means a group chooses to signal its commitment to a patient-centred process is entirely up to the group. One mechanism was to require a fixed percentage of patients and/or post-patients on their governing boards; thus, *Helping Hand* set a 50% minimum and *Down-home Peer Support and Education* set an 80% minimum. *The Hub*'s board is made up entirely of patients and post-patients, with an additional requirement for regional representation.

<sup>189</sup> In 1999 Rhone-Polenc merged with Hoechst AG of Germany to form Aventis; and in 2004, Aventis merged with Sanofi-Synthelabo to create Sanofi-Aventis, based in Paris.

<sup>190</sup> By this time, *Eve* had left *Helping Hand*.

<sup>191</sup> Alicia Swasy, an American journalist working for the Wall Street Journal, published *Soap Opera: the Inside Story of Procter and Gamble* in 1993 (NY: Touchstone/ Simon & Schuster Inc). Swasy critically examines the company's environmental practices and a series of marketing campaigns of products marketed mainly to women, among them Rely tampons, a brand implicated in the "toxic shock syndrome" deaths in the 1970s.

<sup>192</sup> *Helping Hand* board meeting, Minutes, November 28, 1995

<sup>193</sup> I borrow this term from Kathryn Jones (2008) who researched pharma funding of patients' groups in the UK. See the discussion on typologies in Chapter 1, page 39.

<sup>194</sup> Her initial involvement with breast cancer groups was a response to her mother's death from the disease in 1986. She participated in a Run for the Cure in 1992 then joined *A Voice for Patients* when the group first began the same year. She was diagnosed with breast cancer in 1994 and in 1995 left *A Voice for Patients* because the workload had become very time-consuming. With two young children, she decided to put the demands of her illness and family first.

<sup>195</sup> See Terms and Abbreviations.

<sup>196</sup> Other research areas of note are touched on but are less central to my analysis. These include the discovery of a genetic mutation dubbed BR CA1 which was shown to increase a carrier's chances of developing breast cancer later in life, opening the door to genetic testing for breast cancer (Williams-Jones and Graham 2003); the study of estrogen-mimics (xeno-estrogens) in the environment and their potential to affect breast cancer rates (Ley 2009); the launch of the Women's Health Initiative in the United States which looked at the potential of HRT to increase the risk of breast cancer (Harder 1992, Krieger et al 2005); and research on breast implant safety (Wilson and Brown 1995).

<sup>197</sup> A genetic defect causes a subset of all breast tumours to produce abnormally high amounts of a protein known as HER-2/neu that makes cancer cells grow quickly (15-30%). Herceptin inhibits tumour cell growth by inactivating the protein.

<sup>198</sup> Neupogen® (generic name filgrastim) is made by California-based biotechnology company Amgen and first received FDA approval in June 1989. Epogen® (generic name epoetin alpha), also made by Amgen, first received FDA approval in December 1990 and has a complicated social and legal history. Much of the developmental work was carried out at Columbia University under government grants, and the drug is used in blood doping to enhance athletic performance. Amgen licenced the right to sell erythropoietin as a treatment for chemotherapy-based anemia to Johnson & Johnson. Johnson & Johnson sells the drug through its subsidiary, OrthoBiotech, under the name Procrit® (epoetin alpha) in the US and Eprex® (epoetin alpha) in Canada. Hoffman LaRoche also makes a version of erythropoietin, under the brand name NeoRecormon® (epoetin beta).

<sup>199</sup> An “orphan disease” afflicts so few people that it risks being neglected by the research and treatment community.

<sup>200</sup> Patients with this condition have an abnormally low number of neutrophils, a subset of white blood cells crucial for fighting infections.

<sup>201</sup> The *Genetic Orphan Disease Group* fits the model of a disease group that Nicholas Rose and colleagues (Rose and Novas 2005) characterize as an example of “biological citizenship”; as I argue in Chapter 1, the breast cancer groups that form the core of my research fall outside the key parameters of this model.

<sup>202</sup> The California-based biotechnology company Amgen makes Neupogen®.

<sup>203</sup> Whether insurers would provide reimbursement for a costly preventative treatment was uncertain and this was only one of many questions about using the drug as a prophylactic rather than as a treatment. Indeed, declaring oneself at “high risk” of breast cancer might undermine a woman’s eligibility for insurance generally (health, mortgage, life). Another unanswered question was how long a healthy woman would take tamoxifen. Clinical trials had shown that after five years drug-resistance set in and tamoxifen was no longer an effective treatment; the drug in fact promoted breast cancer if taken beyond five years. Whether the same restriction should be applied to women taking the drug to prevent cancer was another area of uncertainty.

<sup>204</sup> ASCO, the American Society of Clinical Oncologists, has an annual meeting every June where researchers present the latest research findings on treatments for cancer. Sessions that announce promising new therapies typically receive intense media coverage.

<sup>205</sup> Anglin uses this pseudonym for the group in question, which was based in Northern California.

<sup>206</sup> Provide the U.S. approval dates for Taxol for ovarian and breast cancer.

<sup>207</sup> Andre Picard is a health columnist at the *Globe and Mail* and author of *The Gift of Death*, a book on the tainted blood scandal in Canada.

<sup>208</sup> The reference to the Krever Inquiry invokes the Royal Commission Inquiry by Justice Horace Krever into Canada's tainted blood scandal of the 1980s. The blood supply used for blood transfusions became contaminated with HIV and Hepatitis C. Thousands of patients undergoing transfusions were infected and many died; Canada's hemophiliac population was particularly affected and many patients unknowingly contaminated partners. At the time, the blood supply was managed by the Red Cross. The Krever Inquiry began in 1993 and its final report, issued on September 20<sup>th</sup>, 1996, included a series of recommendations designed to prevent a health safety disaster from happening in Canada again. A subsequent RCMP investigation found that the Red Cross, a U.S.-based pharmaceutical company, and several doctors, failed to properly screen blood donors, failed to properly test blood, and failed to warn the public about the risks of blood products.

<sup>209</sup> In 1993, Justice Horace Krever was named head of a Royal commission into the contamination during the 1980s of Canada's blood supply by the human immunodeficiency virus (HIV) and with the hepatitis C virus. Many died, not only in Canada but in every country affected by the HIV virus before its transmission was understood. Volume IV of Justice Krever's report examines in detail the response of seven countries: Australia, France, Germany, Japan, the Netherlands, the United Kingdom, and the United States (Krever 1997:721). Canada's Red Cross, in collaboration with Health Canada and the privately owned Connaught Laboratories, were each responsible at the time for managing various aspects of the donated blood used for transfusions and other medical purposes (Krever 1997; Picard, 1996). In Canada's "tainted blood scandal," the triumvirate of Canadian agencies responsible for guaranteeing the safety of the blood supply was slower than similar agencies elsewhere, particularly in the United States, to take action, as scientific evidence about blood-borne transmission of HIV and methods of screening donations gradually accrued (Picard 1995: 64-65; Krever 1997 Vol 2). Estimated costs of the screening, which varied widely (e.g., between \$5 and \$8 million per year, by one estimate, and \$19.9 million for the first year by another) (Krever 1997, Vol. 2: 657), was the main reason the Canadian agencies delayed these procedures; but the estimates did not take into account the medical, economic or societal benefits of testing (Krever 1997, vol. 2:658): hence *Eve's* reference to discovering that "we couldn't afford not to screen" the blood supply for the two viruses.

<sup>210</sup> Blood products are a subset of biologic drugs and are regulated within Health Canada's Bureau of Biologics and Genetic Therapies Directorate, which is within the Health Products and Safety Branch. The breast cancer drug Herceptin was the first biologic developed for cancer treatment. Most pharmaceuticals used in cancer treatment are derived from chemical manufacturing, however, and are not biologics. They are regulated in an almost identical fashion by the parallel Therapeutics Products Directorate of the Health Products and Safety Branch.

<sup>211</sup> In Fugh Berman's analogy, "You wouldn't normally jump off the roof of your house, but if your house is on fire, you might" (Fugh Berman 1993).

<sup>212</sup> Another difference between the two meetings was that *Together to an End* was billed in the subtitle as a “Canada-US Advocacy Conference.” Two national breast cancer organizations, the New York-based *American Breast Cancer Network* and the Chicago-based *Here for You* participated. Both these organizations were members of “*Breast Cancer’s National Voice*”, the official umbrella advocacy organization in the U.S. but the latter group declined to participate on the grounds that it alone had responsibility for setting the advocacy agenda for American breast cancer groups.

<sup>213</sup> The other funders of the National Forum on Breast Cancer were the Medical Research Council of Canada, the National Cancer Institute of Canada, the Canadian Cancer Society, and the Canadian Breast Cancer Foundation (see Appendix 5.1).

<sup>214</sup> Each of the lead sponsors had a major breast cancer drug either on the market or in the pipeline, as follows: BristolMyers Squibb (Taxol), Zeneca pharma (Nolvadex [tamoxifen] and Arimidex), Eli Lilly (Raloxifene), and Rhone-Polenc Rorer (Taxotere®). Of the other sponsors, Amgen Canada markets Neupogen®, Eprex® and Aranesp®; the Edmonton-based Biomira Inc. had a breast cancer vaccine in the pipeline (see Anonymous 2003); Glaxo Wellcome makes the anti-nausea drug Zofran® (ondanestron) which is used to alleviate chemotherapy-induced nausea and vomiting; and Pharmacia & Upjohn makes Aromasin® (used to treat advanced breast cancer in patients whose disease has progressed after treatment with tamoxifen) and Ellence®, a drug in the same class as Adriamycin®, used as a component in adjuvant therapy.

<sup>215</sup> The sessions were titled “Issue #13: Addressing the conflict about a national (advocacy) organization” and “Issue # 14: Empowerment for common action: A national advocacy group??”

<sup>216</sup> In 2003, the federal government modified the ten-per cent rule to take into account the annual budget of the organization. Thus, according to Circular CPS-022, the percentage of a registered charity’s income that can be devoted to advocacy depends on the organization’s annual resources, according to the following graduated scale: less than \$50,000 (20%), \$50,000 to \$100,000 (15%); \$100,000-\$200,000 (12%); over \$200,000 (10%). (Elson 2009)

<sup>217</sup> The website of the Therapeutics Initiative describes the Initiative as follows: “The Therapeutics Initiative (TI) was established in 1994 by the Department of Pharmacology and Therapeutics in cooperation with the Department of Family Practice at The University of British Columbia with its mission to provide physicians and pharmacists with up-to-date, evidence-based, practical information on prescription drug therapy. To reduce bias as much as possible the TI is an independent organization, separate from government, pharmaceutical industry and other vested interest groups. We strongly believe in the need for independent assessments of evidence on drug therapy to balance the drug industry sponsored information sources.” Accessed November 2, 2011 at: <http://www.ti.ubc.ca/>

<sup>218</sup> The *Through the Looking Glass* nature of this analogy is evident from a brief review of Ralph Nader’s work as a consumer protection crusader. Nader published *Unsafe at any Speed: The Designed-in Dangers of the American Automobile*, in 1965. Subsequent to the book’s publication, General Motors, the company that bore the brunt of Nader’s critique, hired private detectives in

an unsuccessful effort to discredit him. Nader, a Harvard-educated lawyer, successfully sued the company for invasion of privacy and won both an apology and a financial award. He used the money to hire young activists (known as “Nader’s Raiders”) to expand his consumer rights investigations into the ways government corruption served the interests of big business at the expense of ordinary citizens. Nader founded the organization Public Citizen in 1971 to investigate corporate and government corruption in environmental, health, and consumer product safety. Public Citizen’s Health Research Group, which Nader co-founded in 1971 with physician Sidney Wolfe, “promotes research-based, system-wide changes in health-care policy and drug safety” (from the Public Citizen Health Research Group website, accessed August 5, 2011). Public Citizen describes itself as “the countervailing force to corporate power” and states that it has “successfully challenged the abusive practices of the pharmaceutical, nuclear and automobile industries” (*About Us* page of the *Public Citizen* website, accessed August 5, 2011). Further, the *Donate Now* page of the same Public Citizen website states that, to maintain its independence, the organization accepts no corporate or government funding and depends on donations from the public.

Public Citizen Home Page: <http://www.citizen.org/Page.aspx?pid=524>

Health Research Group: <http://www.citizen.org/hrgpublications>

About Us: <http://www.citizen.org/Page.aspx?pid=2306>

Donate Now:

[https://secure.citizen.org/p/salsa/donation/common/public/?donate\\_page\\_KEY=6096](https://secure.citizen.org/p/salsa/donation/common/public/?donate_page_KEY=6096)

<sup>219</sup> NAFTA came into force on January 1, 1994.

<sup>220</sup> A brand name company had only to argue that its patent had been infringed and an injunction of up to two years was granted; the onus was on the generic company to prove that it had not violated patent law (Cohen p 10).

<sup>221</sup> The industry’s spending in Canada did increase but remained low by international standards. By 2000, the industry was investing \$945 million in Canada, the lowest rate of spending among the comparator countries the PMPMB used to determine Canadian price controls (Cohen, p 10).

<sup>222</sup> Pharmaceutical companies have challenged these powers in court but without success (Smith 1995; Carter 246-7)

<sup>223</sup> Public health principles are largely preventative and are aimed at improving the health of populations through broad, health-promoting measures, such as the provision of clean water, adequate nutrition, shelter, and a clean, safe environment (REF).

<sup>224</sup> A parallel regulatory reform effort undertaken in the US the same year, called the “Reinventing Government Initiative,” made the FDA a “priority target” for reforms. David Kessler, the Commissioner of the FDA, had already told Congress on his appointment in 1991 that he would “teach the elephant to dance.” A 1995 report, *Reinventing Drug & Medical Device*

Regulations, identified “areas of the regulatory process that could be reduced or eliminated without lowering health or safety standards” (Carter 249). The Food and Drug Modernization Act was passed in 1997.

<sup>225</sup> The US had adopted user fees to expedite drug reviews and approvals in 1992 with the Prescription Drug User Fee Act (PDUFA), using the money to computerize the FDA’s system and to hire 600 new reviewers (Carter p 251); (Carter 251). Targets of 6 months for priority applications and 12 months for standard ones were set for approval times (the first goal fell short in 1997, achieving only 8.9 months; the second goal was met). The administration said this expedited approval would not affect review quality (Carter 251, citing Clinton & Gore 1995). In the US, smaller companies pay only half the fee of larger ones and the FDA can waive user fees altogether for small business or if innovation is thought to be at risk (Carter 252).

<sup>226</sup> In the British publication *Marketletter*, 1997, July 21 (cited in Carter 1999).

<sup>227</sup> In 2004, Mr. Bryden crossed the floor to join the Conservative party. In the next election, he failed to gain the nomination for his Hamilton-area riding and he is no longer an MP.

<sup>228</sup> In 1994, for example, Mr. Bryden argued introduced a private member’s bill that would require charities and non-profit groups to disclose the salaries of their senior executives. The bill did not become law.

<sup>229</sup> One of Mr. Bryden’s concerns was that governments were now “offload[ing] to charities the social services they traditionally supplied” (ibid: introduction, n.p.) but that these groups had no oversight to ensure they met adequate any performance standards. The implication is that volunteers should be under surveillance to ensure that they met externally-determined standards.

<sup>230</sup> Importantly, in new labour parlance, the derogatory term “special interests” is reserved for groups that promote social democratic ideals; lobbying by business elites is not defined as advancing special interests. Sociologist Bob Russell, in an extended discussion of the discourse in Canada about “special interests”, comments:

Ironically, a special interest is practically any collective that supports popular government programs, other than the most powerful elites, who on most issues, support a shrinking of the state. Indeed, it is both quite telling and surprisingly wrong-headed to concentrate on the power exerted by senior citizens, the unemployed, students, visible minorities and public-sector workers, while ignoring the influence of groups such as the Business Council of Canada and the interests which they represent. In this analysis, interest groups are arrayed against faceless markets, but the latter are not perceived as being represented by interests, let alone social classes. There is something disingenuous in this exercise and its willful ignoring the most consequential power relationships in society. (Russell, 2000: 46).

<sup>231</sup> In a longitudinal study of Canadian public interest groups, Paul Pross and Kernaghan Webb interviewed leading officials in more than twenty national groups, in the early 1990s and again in 2000-2001. Most of the groups were working in either health or social justice and in these fields,

“and in these sectors the elimination or reduction of core funding had severely constrained the ability of groups to do what they set out to do” (cited in Pross, 2006:10).

<sup>232</sup> Children and education were the other two priority areas singled out for SIS spending.

<sup>233</sup> From an interview with *Gordon*, a research scientist hired by Health Canada in [1999?] to coordinated the plan (interview conducted in 2008).

<sup>234</sup> Implicit in the group’s choice is the fact that government programs were *not* supporting these needs, or certainly not adequately. The group’s dilemma thus illustrates the two-step process by which the neoliberal and new labour policies sweeping through governments were redefining the role of civil society. First, the social safety net was retooled to be much more loosely knit, and second, those most in need of assistance – in this case people suffering from a stigmatizing fatal disease – were called on to either provide the support services they needed on a volunteer basis, or find funding for them.

<sup>235</sup> Recalling that the women’s movement discourse on pharmaceuticals (Chapter 4, pages 236-241) had been develop primarily from the perspective of healthy women, Darien Taylor’s participation on the panel could also be seen as a step towards including the voices of critically ill women in the feminist analysis of drug policies.

<sup>236</sup> Where discourses are concerned, the Canada-US border is porous and debates within the breast cancer movement reflect this.

<sup>237</sup> In 1998, the federal government launched an initiative called “Legislative Renewal” which it argued was needed to update Canada’s 50-year old Food and Drug Act (REF); the following year the government re-branded the Health Protection Branch, calling it the Health Products and Foods Branch. Women’s health groups, including DES Action were among the pharmaceutical policy watchdog groups to ask whether the government’s wish to change the Food and Drug Act was driven by trade motives rather than a desire to better protect the public’s health. A number of organizations, academics and health activists concerned about the apparent shift in pharmaceutical policies--away from safety and health and towards a culture that emphasized trade, profits and product promotion -- joined forces to form Women and Health Protection. The coalition included the women’s health groups DES Action, the Canadian Women’s Health Network and BCA/U and it received federal government funding from a women’s health office within the Health Products and Foods Branch to monitor policy changes related to the Legislative Renewal project. From the outset the coalition raised alarms about the expansion of pharmaceutical funding within the health and drug policy arena, including industry funding of the drug review process and pharma funding of patient and health-related community-based organizations (Rochon Ford and Saibil 2009).

<sup>238</sup> The Breast Cancer Prevention Trial was halted in April 1998, before the expected end date, because results at that point indicated that the drug was clearly reducing the risk that a tumour would appear. According to the Trial’s “stopping rules” the trial had to be halted because denying women who were in the control group the opportunity to take the drug would have been

unethical. Although the practice of stopping a trial early when the results are deemed to be conclusive is an accepted practice, it is controversial, because long-term effects of the drug – including some adverse effects -- will never be known. Furthermore, drugs often seem to have a marked in the short term but over the long-term the effect may attenuate or reverse. These were only a few concerns raised by those who were unconvinced that the Breast Cancer Prevention Trial, demonstrated the benefits of tamoxifen for healthy women at higher-than-average risk of developing breast cancer (Goel 1998).

<sup>239</sup> See websites for PricewaterhouseCoopers Canada at: <http://www.pwc.com/ca/en/index.jhtml> and The Canadian Institute at: <http://www.canadianinstitute.com/> (both websites accessed June 28, 2011).

<sup>240</sup> An article by Donna Nebenzahl in the *Montreal Gazette* (Nebenzahl 2003) cited a \$100,000 grant to the Canadian Breast Cancer Network in 2000. An article about pharmaceutical company funding of patients' groups, published in the *Globe and Mail* January 4, 2001, quotes representatives of several groups who disclosed the amount or proportion of their group's annual budget that came from the pharmaceutical industry. None of the organizations mentioned in this article were breast cancer groups; however, as I state in the next chapter, the phenomenon of partnerships between patients groups and the pharmaceutical industry was observed in disease-specific organizations representing a wide range of conditions. Thus, the president of the Colorectal Cancer Society of Canada said that 70 per cent of that organization's \$500,000 budget in 2000 came from pharma funding and the CEO of the Arthritis Society of Canada declared a \$30 million budget the same year, with \$1.8 million coming from the pharmaceutical industry.

<sup>241</sup> AstraZeneca makes the breast cancer treatments Novladex® - D (tamoxifen citrate) and Arimidex.

<sup>242</sup> I understand her to mean they are less likely to question information that comes from a non-medical source, especially from a "peer" who understands from her own experience what they are going through and can therefore be trusted.

<sup>243</sup> The other EPAs on the market are Procrit®, Epogen® and Aranesp® (Khuri, 2007).

<sup>244</sup> Topics highlighted in other articles included the lack of adequate data, staff shortages, delays in treatment, and how to be an advocate.

<sup>245</sup> The article summarized a few key points developed in a much longer article, "The ethics and law of access to new cancer treatments" in the academic journal, *Current Oncology*, 6(3); 1999, p 161-74.

<sup>246</sup> The article, titled, "Winning strategies for cancer care: A look at BC's integrated approach" quotes Dr. Critchley as saying, "We have developed a system of care that includes early detection and diagnosis, treatment, support services and rehabilitation. Our goal is to ensure that patients move smoothly through each phase of their care." (Shapiro, 2000:20). Dr. Critchley further explained that the province tried to ensure the same standard of care, no matter where the patient lived, using standardized guidelines which it updated as new results were published. Other



provinces, by contrast, were said to have a disjointed system of regional sites. BC also boasted a range of counseling, support and education services, including nutrition counseling and school-based programs to teach children about healthy lifestyles.

<sup>247</sup> The media is an important actor in co-producing discourses about drugs and drug policy; in Canada, Lisa Priest is one of a small number of high profile journalists who report regularly on drug issues. At the time she wrote the book *Operating in the Dark*, Priest was a reporter for the *Toronto Star*. She subsequently moved to the *Globe and Mail* where she continued to specialize in medical stories, including stories on new drug treatments for breast cancer. In 2005, she was awarded a Michener award for a series of articles critical of the restrictions on access to Herceptin in Ontario. The articles were credited with fast-tracking approval of the drug as an adjuvant treatment and expanding the use of the drug ([www.michenerawards.ca/english/winAward/winaaward2005.htm](http://www.michenerawards.ca/english/winAward/winaaward2005.htm)). In 2011, another front page feature by Lisa Priest challenged the Ontario government's criteria for funding Herceptin, in this case a guideline that excluded women whose tumours on diagnosis were less than one centimeter in size. A public outcry ensued and the province changed the funding criteria (Priest, 2011).

<sup>248</sup> Helen Bramswell, writing for the Canadian Press, said that the figures didn't take province-by-province cancer *incidence* rates into account and without these statistics the mortality rates were meaningless; furthermore, she quoted Dr. Richard Schabas, head of preventive oncology at Cancer Care Ontario, who said he had looked at the registry data and the Canadian provinces were in fact scattered throughout the rankings, not piled at the bottom (Bramswell 2000). Steve Buist in the *Hamilton Spectator* (who also quoted Dr. Schabas) asserted flatly that the claims the group was making in its report about the inferiority of Canadian survival rates were "not true". He also stated that "There is no accurate way of measuring the success of cancer treatments on overall mortality rates" and "your chances of dying from cancer have little to do with the treatment you receive and almost everything to do with the fact that you have cancer in the first place" [i.e., incidence rates are critical] (Buist 2000:A1). Susan Murray in the *Winnipeg Free Press* quoted Erich Kliewer, the director of epidemiology at CancerCare Manitoba, saying that he had obtained a copy of the original report and after doing his own math concluded the Canada-US comparison showed the opposite of the coalition's claim; and another cancer epidemiologist quoted in the same article, said that the CACC's report had cherry picked the data and focused on cancer types such as colorectal where Canada's mortality rates were slightly higher than those in the U.S. (Murray 2000).

<sup>249</sup> In a statement attributed to *Eve*, for example, Brad Evenson in the *National Post* wrote that, "Provincial cancer agencies are often silenced by the governments that fund them, so they fail to push for important new therapies" (Evenson 2000: A4); the same article gives *Eve*'s account of the incentive for forming the CACC as follows: "... the new organization was formed in January after Canadian breast cancer patients found they were being denied drug therapies available in the United States. Soon, they found their problems were not exclusive to breast cancer. 'People with lung, prostate and other cancers had the same complaints,' she said" (Evenson 2000: A4). Helen Branswell wrote, "The group called on politicians in all parts of the country to make improving cancer care a high priority, suggesting things like increasing the number of training spots for

oncology doctors, speeding up the approval process for new cancer drugs and treatments and channelling some of the new federal monies for health care into cancer care” (Branswell 2000:A4). Steve Buist in the *Hamilton Spectator* wrote, “[T]he explicit message put forth by the advocacy group [was that] more money equals better cancer care equals better outcomes for patients. The implicit message, however, was that Canadians are being shortchanged when it comes to cancer treatment. But there’s also a problem with the implicit message. There is no accurate way of measuring the success of cancer treatments on overall mortality rates, either here or in the U.S.” (Buist 2000:A1).

<sup>250</sup> Robert Bazell’s book, *Her2: the making of Herceptin, a revolutionary treatment for breast cancer*. NY: Random House, 1998.

<sup>251</sup> In time, tumour cells become resistant to a particular drug. Thus, once a patient has been treated with a specific drug like tamoxifen or Adriamycin, they will usually be treated with a different drug if the cancer recurs (Gottesman 2002)

<sup>252</sup> I refer here to Sylvia Morrison’s plea before the Parliamentary subcommittee that the experimental use of high-dose chemotherapy and accompanying costly drugs anti-anemia drugs Eprex and Neupogen®, the Taxol® lobby led by *A Voice for Patients*, and the *Genetic Orphan Disease Group*’s advocacy for Neupogen®.

<sup>253</sup> The exact number could vary from month to month as the number of eligible groups in the country shifts, and as new boards change their group’s previous board’s decision about whether or not to be a member.

<sup>254</sup> I was part of “The Coalition to Prevent Cancer without Drugs” that launched a complaint with the FDA over the ads AstraZeneca used to promote the use of tamoxifen as a preventative. The FDA agreed with our complaint that the company had overstated the evidence for benefits and understated the evidence for harm. The FDA wrote the company a letter requiring AstraZeneca to withdraw the ads.

<sup>255</sup> This article is excerpted from a book about the development of Gleevec titled *The Magic Cancer Bullet* and is co-authored by the Chairman and CEO of the Swiss pharmaceutical company Novartis and the CEO of the New York public relations firm Ruder Finn.

<sup>256</sup> The cost of this particular book, although prohibitive by academic standards, is in keeping with the cost of other books in the company’s series. I made ongoing efforts to obtain a copy through the university’s library services, without success. Although the U.S. Library of Congress listed a copy in its holdings, the book had gone missing when I visited the library in 2005 and was still unavailable three years later when I attempted to borrow it through interlibrary loan.

<sup>257</sup> The advertisement lists ten companies profiled: Abbott Laboratories, AstraZeneca, Bristol-Meyers Squibb, Eli Lilly, GlaxoSmithKline, Merck, Novartis, Pfizer, Roche, and Wyeth.

<sup>258</sup> \$190,000 in 2002, according to Kelly (ibid:5).

<sup>259</sup> In a section titled “The Sponsor’s Problem” (pp 6-8), Ms. Kelly outlines “*All Cancer Advocacy’s*” need to raise funds and at the same time maintain its credibility and integrity. The section describes the critical attention that the organization drew because of its funding from the pharmaceutical industry, with particular attention to the segment on the CBC television show Marketplace. Ms. Kelly cites “*All Cancer Advocacy’s*” sponsorship of the research again in her summary of Chapter 1: “the research question posed in this study was relevant to the integrity and credibility of the sponsor. Exploring significant ethical issues was an urgent issue for “*All Cancer Advocacy*” to resolve in order to ensure ongoing fundraising and sustainability.” (p 14).

<sup>260</sup> Other sources of data for the thesis were interviews with two government bureaucrats who had experience with both sectors, an interview with an academic who opposes pharma funding of groups, and websites and texts written by leaders in groups that did not take pharma funding.

<sup>261</sup> See *The Argument Culture: Moving from Debate to Dialogue*, by Deborah Tannen, 1998, NY: Random House.

<sup>262</sup> As previously noted, in 2003 the “10-percent rule” limiting the amount that registered charities can devote to political activities was modified to take the size of charities into account; small charities (with incomes up to \$50,000) can now spend up to 20 per cent of their annual income on advocacy. (Elson, 2007:59-60).

<sup>263</sup> In my interview with *Eve*, I asked her to elaborate on the distinction she saw between an Astroturf group and one that received funding from the pharmaceutical industry but was not Astroturf. She replied:

“Who starts the group? I think that’s, that’s probably fundamental to it. It’s, ‘Where did this come from?’ Was it a marketing objective, or a marketing strategy to promote a product? Or did it come because there was a gap in service? Or is it because there was a desire to have policy change that you couldn’t change from an individual organizational point of view? Or because the existing organizations involved in that structure are providers?”

“I think one of the biggest challenges is that the cancer agencies or the professional organizations of nurses and radiation oncologists and therapists, who in the [United] States are really influential, they’re employees of government here. So their hands are tied. As individuals, they can they can lobby candidates during an election. But they can’t lobby government directly because that’s what their organizations [do] -- their senior government officials meet with senior officials from the cancer agencies. And some cancer agencies, if not all, have restrictions on communications, so they can’t really change the system from within. And they’re really reliant on external grass-roots advocacy efforts, particularly as I think patients now are a pretty powerful voice, a compelling voice for change. So that’s the difference.”

<sup>264</sup> PMAC changed its name to Rx&D in 1999, a rebranding that more clearly distinguished it from the generic wing of the industry as an organization of “research-based” companies. The name change also implied a maturing of the Canadian wing of the industry beyond the American branch-plant status that was so obvious in the 1970s’ battle over compulsory licensing (Lang,

1974). Meanwhile, the American lobby group had changed its name from the Pharmaceutical Manufacturers' Association (PMA) to the Pharmaceutical Research and Manufacturers of America, or PhRMA).

<sup>265</sup> Academics were excluded because guidelines for this group already existed.

<sup>266</sup> Arguably, the Liberals had political as well as economic motives for weakening the civil society sector, however, they were not overtly acknowledged. Many Liberal Party members and voters who supported the Liberal party opposed aspects of the free trade agreements that the government signed onto in the 1990s; concerns about losing control of Canada's social programs, including the health care system, were one reason for the opposition (Smith 2005).

<sup>267</sup> According to Flanagan, in the lead-up to the federal election on January 23, 2006, the "Liberal outsider organizations ... came at us in human waves, claiming that [Prime Minister Steven] Harper would roll back abortion rights, use the notwithstanding clause to quash gay marriage, and repudiate the Kelowna Agreement and the Kyoto Accord. ... If the Conservatives can stay in power for any length of time, it should be a high priority to de-fund the support groups that the Liberals have cultivated so long with grants, subsidies, and access to the government." (Flanagan 2007:264). I would agree with Flanagan's assessment that groups on the left of the political spectrum see little common ground with the Conservative party as it is presently defined. This has not always been the case, however. In its earlier guise as the Progressive Conservatives, the party was more broadly based and included an influential contingent of members known as Red Tories, who combined fiscal conservatism with a socially progressive agenda. Red Tories supported feminism, gay rights, aboriginal rights, environmental rights and other causes from which the party as currently defined has distanced itself (Wesley 2006). Indeed, in his analysis of the struggle over pharmaceutical pricing in the 1970s, Robert Lang concludes that the industry in the U.S. played its hand badly because it did not understand that, in the Canadian politics of that period, the Progressive Conservative Party and the New Democratic Party were closer ideologically to one another than either was to the Liberal Party (Lang 1974).

<sup>268</sup> While I have not traced all manifestations of this shift, the re-classification of cancer as a chronic disease is evident in documents at the World Health Organization and the United States. The move did encounter some critical pushback from cancer activists I interviewed as well as from activists in other countries. Some saw it as a manoeuvre to shift from cancer funding to other diseases (e.g., viruses like H1N1); others noted that the shift was accompanied by rhetoric to the effect that cancer medications had improved to the point that cancer was now a disease people could "live with," like diabetes, by making lifestyle changes and taking medications, and thus supported the general pro-pharma discourse within neoliberal governments. The late American activist Rita Arditti argued that cancer was more accurately characterized as "recurrent" because neither lifestyle changes nor medications offer any real certainty of controlling the disease. See Barbara Brenner's article in the *Breast Cancer Action* newsletter, March 21, 2009, "Treating breast cancer as a recurrent – not chronic – disease": <http://bcaction.org/2009/03/21/treating-breast-cancer-as-a-recurrent%E2%80%94not-chronic%E2%80%94disease/> (accessed November 7, 2011).

<sup>269</sup> Early results of four clinical trials released in 1999 found the complex procedure to which Sylvia Morrison and several million American women with advanced cancer had submitted to be no more effective than less toxic, less complicated and less expensive chemotherapeutic regimens. Results of the fifth trial were found, in 2001, to be fraudulent. To my knowledge, however, Eprex was never viewed as the reason this procedure did not live up to the promise of its proponents. The extreme levels of the toxic chemotherapy drugs used – from two to twenty times higher than used in normal practice (Lerner 2001), would be an equally compelling explanation for the (sometimes fatal) toxicity of high-dose chemo with autologous bone marrow rescue.

<sup>270</sup> The black box is the FDA’s highest level of warning about a drug, and usually refers to possible fatal outcomes. Canada does not use black boxes but rather issues safety alerts, advisories and warnings.

<sup>271</sup> These adverse effects may have been related to the high levels of hemoglobin the studies were attempting to achieve (i.e., it is possible that the drug might be used safely at lower doses); however, a member of the FDA’s review committee observed that studies with a lower target hemoglobin level might now be impossible to carry out because of the negative publicity generated by these trial results (Medscape 2007; *NEJM* 2007; 356: 2445-8, 2448-51?).

<sup>272</sup> In Canada, because tamoxifen dates to the era when compulsory licensing was in effect, many generic versions of tamoxifen were available long before the Nolvadex patent expiry date of 2002.

<sup>273</sup> Evista™ (raloxifene hydrochloride), made by Eli Lilly, is approved for the treatment of osteoporosis but not breast cancer; a clinical trial to compare raloxifene to tamoxifen as a breast cancer preventative was begun in 1998, however. Evista™ appeared from early clinical trial results to have benefits equivalent to tamoxifen and fewer serious side-effects.

<sup>274</sup> A conditional approval refers to a “Notice of Compliance with Conditions” or NOC/c, that is, the company can market the drug for the given indication but must continue to monitor results and submit them to the regulatory agency.

<sup>275</sup> The anti-inflammatory drugs Vioxx (made by Merck) and Celebrex (made by Pfizer) were aggressively promoted to treat pain from arthritis. In 2004 and 2005 the two drugs were withdrawn from the market amid accusations that they had caused thousands of strokes and sudden fatal heart attacks and that the companies had covered up clinical trial results showing the dangers of the drugs.

<sup>276</sup> The three questions were:

- For women still on treatment: “What is my risk?”
- For women who have completed treatment: “What are the next steps and what are my options?”
- And for those who have been off treatment (no matter how long): “What has changed since my therapy was completed? What are my options?”

<sup>277</sup> Aromatase converts certain hormones including testosterone into estrogen. In postmenopausal women, whose ovaries no longer produce estrogen, this converted estrogen is the body's main source of estrogen. Thus a drug that blocks or inhibits aromatase acts to reduce estrogen in postmenopausal women (who produce these precursors of estrogen in the ovaries and the adrenal glands) and might be expected to reduce their chance of a breast cancer recurrence (Love with Lindsey, 2010: 356-357)

<sup>278</sup> The United States and New Zealand are the sole exceptions among industrialized countries (Mintzes, Morgan and Wright, 2009).

<sup>279</sup> In April 1, 2005, Femara® was approved as a follow-up therapy for women who had already taken tamoxifen for five years (i.e., the normal period of treatment for tamoxifen) (Health Canada, 2005)

<sup>280</sup> One criticism the report makes is that cancer drugs are typically approved in the U.S. and Britain before they are approved in Canada; the authors don't mention that drug companies typically apply for approval first in the U.S. because the market in the U.S. is so large and approval by the U.S. Food and Drug Administration (FDA) is a critical hurdle in getting a drug to market.

<sup>281</sup> The Fraser Institute, founded in 1974, is Canada's premier conservative policy think tank. In its publications, it describes its vision as "a free and prosperous world where individuals benefit from greater choice, competitive markets, and personal responsibility" (Rovere and Skinner, 2011:45). Both authors of *Access Delayed, Access Denied* are employed by the Institute. Brett Skinner is President of the Fraser Institute and its Director of Health Policy and Insurance Policy research. Mark Revere is the Associate Director of the Institute's Health Policy Research Centre. For the past six years, the Institute has published updated versions of the same report. The 2011 version of *Access Delayed, Access Denied* includes a disclosure statement in which it states that "less than 5%" of the Fraser Institute's budget" comes from research-based pharmaceutical companies (ibid: 42) (The most recent annual returns according to the Fraser Institute's Revenue Canada filing is in 2007 and revenues that year were stated as 13.7 million.) The Fraser institute also publishes an annual report on wait times in Canada's healthcare system, titled *Waiting Your Turn*. Mark Rovere, and Brett J. Skinner were also co-authors of the 2010 Wait Times report, 20<sup>th</sup> edition, along with first author Bacchus Barua.

<sup>282</sup> Turner & Associates Inc. Consultants to Healthcare. Toronto, Ontario. Website accessed August 10, 2010 at: [http://www.turnerassociates.ca/?page\\_id=29](http://www.turnerassociates.ca/?page_id=29)

<sup>283</sup> Lerner cites a personal communication with Freya Schnabel, Associate Professor of Surgery at Columbia University, as the source of this insight and term to describe the improvements in treating breast cancer (Lerner, 2001:255).

<sup>284</sup> Tanya, the executive director of the American group *Breast Cancer Truth-Tellers*, observed that her group has also had to confront the issue of focus. As one of the few disease-identified cancer advocacy groups in the U.S. with a policy to refuse pharma funding, she felt *Breast*

*Cancer Truth-Tellers* had to give priority to speaking out on pharmaceutical issues. To address environmental justice issues, *Breast Cancer Truth-Tellers* works in alliance with environmental justice groups which they feel are covering those issues well but does not itself take the lead.

<sup>285</sup> The campaign was ostensibly run by “a coalition of doctors, nurses and patients” called Cancer United and it linked disparities in cancer patient survival in various regions of Europe to the amount local governments spent on drugs (Boseley 2006).

<sup>286</sup> Examples of protective strategies that, in my judgment, failed to ensure independence include *Down-home*'s reliance on the Unrestricted Educational Grant for the small grants received to participate in community education events; the *Patients' Know Your Rights! Working Group*'s attempt to maintain its independence by insisting on control of the content of the document, at the same time that the sponsoring company made administrative decisions that limited the group's control over the process; *All-Cancer Advocacy*'s strategy of never being dependent on a single company, which ignores that fact that companies share the goals of faster approval times and formulary inclusion. I also argue that the lack of public discussion on the part of the groups about the toxicity of drugs such as Eprex, and of the implications for the sustainability of the health care system of the cost of new cancer drugs in general, is evidence of a silencing effect.

<sup>287</sup> Both Arimidex and Aromasin® had the *potential* of providing benefits to patients similar to tamoxifen and each was quite possibly superior to that drug -- but with the added theoretical likelihood that side effects would be more severe than tamoxifen's. Clinical trial results were preliminary and trials of the drugs had been stopped prematurely on the basis of promising but inconclusive early results leaving in the balance questions about whether the drugs, in the long term, might have no greater benefit than tamoxifen, the real possibility that they would be more toxic than tamoxifen, and the virtual certainty that they would be many times more expensive than tamoxifen.

<sup>288</sup> The idea of a Trojan horse is a common metaphor for a gift used to deceive its recipients and comes from the story of the Trojan horse in Greek mythology. The event is a turning point in the nine-years war between the Greeks and the Trojans (residents of the city Troy), which began around 1200 B.C. Paris, the Prince of Troy, abducted Helen of Sparta, known for her beauty, and Helen's husband Menelaus vowed to get her back. After a prolonged war in which the Greeks won many battles, the walls of Troy remained impervious and the Greeks devised the idea of building a large wooden horse that was hollow so that soldiers could hide inside it. One Greek soldier, Sinon, who remained outside the horse, presented it to the Trojans while pretending to be angry at the Greeks for deserting him. When the Trojans came outside their walls to marvel at the enormous creation, Sinon claimed the horse was safe and would bring the Trojans good luck. Only Laocoön, a priest, and Cassandra, a princess of Troy who had the gift of divining the future, suspected a ruse, but their warnings were ignored. The Trojans dragged the horse inside the city walls and celebrated their victory over the Greeks. At night, the soldiers crawled out of the horse and slaughtered the Trojans. (This account of the myth is summarized from a Stanford University version, accessed November 29, 2011 and presented online at: <http://www.stanford.edu/~plomio/history.html>)

<sup>289</sup> To recall the terms of these two agreements, discussed in detail in Chapter 3: in exchange for office work, which the group was equipped to do, *Down-home* received some money (about \$1,000 in each case), augmented its mailing list, enjoyed the prestige and profile of being associated with a successful event, and appeared to have control over its end of the bargain (its demands for “no signage” and no promotion of the specific drugs were honoured and the money was awarded as an Unconditional Educational Grant, which the group took to mean it had no strings attached).

<sup>290</sup> Oncologists may communicate unwarranted faith in drug treatment to their patients as three Toronto researchers demonstrated. They provided oncologists with two clinical scenarios for breast cancer patients and asked them to estimate the percentage of improvement in survival they could expect from chemotherapy. The physicians overestimated the likely therapeutic gain by threefold overall (Rajagopal, Goodman and Tannock 1994).



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**Table 1 Summary of Research Goals and Methods Used**

<b>Goals</b>	<b>Methods Used</b>
<b>A. Holistic analysis of actual groups</b>	<b>Ethnographic methods</b>
Objective: to present holistic picture of actual groups and ensure diversity of perspectives on pharma funding.	Create ethnographies of PAGs that are “critical” and “representative” regarding pharma funding based on: <ul style="list-style-type: none"> <li>• Interviews with group leaders;</li> <li>• Site visits to active groups situated along a discursive continuum;</li> <li>• Document analysis of group activities;</li> <li>• Auto-ethnography based on my movement experience</li> </ul>
Objective: to fill gaps in historical narrative of pharma funding within the movement.	Process of data collection: <ul style="list-style-type: none"> <li>• Snowball sampling to identify and interview movement leaders from different points in time and with different roles and perspectives.</li> <li>• Document analysis;</li> <li>• Autoethnography.</li> </ul>
Objective: to provide the perspective of other actors within the breast cancer arena on the pharma-funding of PAGS.	Selective data collection: <ul style="list-style-type: none"> <li>• Interviews with selected leaders from other actor-networks within the breast cancer arena (e.g., pharma, government);</li> <li>• Review of documents from other actor-networks within the breast cancer arena (e.g., pharma, government).</li> </ul>
Objective: to achieve strong objectivity.	Narrative techniques: <ul style="list-style-type: none"> <li>• Develop narrative with polyphonic voices;</li> <li>• Allot equal space in narrative to actors with differing perspectives from my own;</li> <li>• Respect all perspectives;</li> <li>• Engage in self-reflexivity.</li> </ul>
Objective: to analyse data to identify and present in context themes related to pharma funding discourses.	Thematic analysis of discourses related to pharma funding to create: <ul style="list-style-type: none"> <li>• Narrative life stories of groups;</li> <li>• Narrative biography of the movement;</li> <li>• Visual representation using “mindmaps” of actors and their interrelationships.</li> </ul>
Objective: analyse PAG activities that engage in constructing the meanings of breast cancer drugs.	<ul style="list-style-type: none"> <li>• Identify drugs that are a target of PAG advocacy;</li> <li>• Describe advocacy activities for these actors in biographies of PAGs and narrative of the breast cancer movement;</li> <li>• Develop profile of selected drugs showing the perspectives of key actors and summarize results in a breast cancer pharmacopoeia.</li> </ul>

<b>B. Identify changes over time</b>	<b>Actor-network analysis, Discourse Analysis</b>
Goal: Describe and analyse processes by which PAGS influence the meanings of breast cancer treatments.	<ul style="list-style-type: none"> <li>• Recognize PAGs as active, potentially powerful and diverse actors in the scientific process of meaning-making re: drugs</li> <li>• Identify and describe PAG actors and their networks</li> <li>• Follow the PAGs and identify turning points in which the actor-network is realigned via <i>translation</i>.</li> </ul>
Objective: Analyse daily practices and struggles over truths within breast cancer PAGs	Discourse analysis, archaeology and genealogy: <ul style="list-style-type: none"> <li>• Ask, ‘How did this practice come to be?’</li> <li>• Locate archive of appropriate materials</li> <li>• Gather programmatic texts</li> <li>• Uncover the beginnings of the practice via secondary research and interviews.</li> </ul>
Objective: Identify shifts and breaks in discourses	Periodization: <ul style="list-style-type: none"> <li>• Systematically track PAGs through distinct phases of their evolution.</li> <li>• Use narrative to highlight periods and the processes that underlie them.</li> </ul>
<b>C. Macro-Influences</b>	<b>A Political Economy Approach using Critical Discourse Analysis</b>
Objective: Analyse meaning of PAG/Pharma alliances for ideals of justice and democracy	<ul style="list-style-type: none"> <li>• Highlight influences of Canada’s changing political economy on local events and relationships.</li> </ul>
Objective: Avoid ascribing agency to abstract entities.	<ul style="list-style-type: none"> <li>• Recognize macro entities as networks of diverse, meso-level institutions;</li> <li>• Collect data and analyse macro-level actors at the local level;</li> <li>• Recognize the capacity of PAGs to exercise power <i>vis à vis</i> macro-level actors.</li> </ul>

**Table 2 Members of Groups A, B and C Mentioned in Text and their Views on Pharma Funding**

<b>Group A Critical Advocacy to Prevent Cancer</b>		
<b>ID</b>	<b>Period(s) of involvement and status</b>	<b>History and views on pharma funding</b>
<i>Sara</i>	Board member since 1993 and former president.	Long-time political activist (anti-war, abortion rights, etc) Strict opponent of pharma funding;
<i>Georgina</i>	Member since 1993, board regular with intermittent breaks (“I keep coming back”)	‘Purist’ on corporate funding issues; with <i>Sara</i> and <i>Diane</i> ; assumes watchdog role so that group does not ‘slip’ on principles. Former hippie, political perspective acquired through activism in group.
<i>Dierdre</i>	Former president, board member since 1999; women’s health activist in 1980s.	Strong support of policy based on history of activism promoting lay women’s expertise on menopause prior to cancer diagnosis and joining group; critical views on drug industry derive from long experience.
<i>Diane</i>	Board member since 1997	Self-described ‘hard line’ board member on pharma issues.
<i>Brenda</i>	President in 2007	Opposes pharma funding but strident opposition could lose potential converts to group’s cancer prevention cause focused on carcinogens in cosmetics – a ‘motherhood’ issue that resonates with young women.
<i>Zoë</i>	Board member since 2001	Supports policy but self-identifies as a relatively conservative member; married to a medical researcher who receives money from pharma and works in hospital setting herself.
<i>Marilyn</i>	Board member since 2000.	Policy means group “can hold its head high.” Drugs pollute so are an environmental issue.” Sees parallel to presence of drug companies and their gifts to doctors at a hospital where she does volunteer work.
<i>Martha</i>	Board member since 2000.	Supports policy but “sees both sides” – as a social worker, has worked on pharma funded research projects which she believes contributed to patients’ quality of life; but policy sets group apart – not tainted, generates respect.
<i>Cora</i>	Paid administrator since 2000. No voting status but has indirect influence through reports to board meetings.	Supports no pharma funding policy but her extensive contact with public and potential donors can challenge group’s perspective.
<i>Liz</i>	Part-time paid fundraiser since 2002.	Agrees pharma funding should be off-limits but considers policy application extreme at times – suggests an “anti-money culture” that limits fundraising opportunities. Seeks middle ground so the group can grow, do its work.
<i>Celine</i>	University student in women’s studies, hired for research projects.	Completed projects

<i>Linda</i>	Hired from 2001 to 2003 as group's liaison with <i>the Coalition to Prevent Cancer without Drugs</i> . Volunteered for several years on board.	Completed Master's in Public Health while working with Coalition. Undertook many pharmaceutical projects for the group, linking no-pharma policy to her work with group.
SB	Co-founder, executive director from 1995-1999. Left group to move to a university position in another city. Continues in an advisory capacity.	Supports policy but left group before its formulation and adoption.
<b>Group B Down-home Peer Support and Education</b>		
<b>ID</b>	<b>Period(s) of involvement and status</b>	<b>History and views on pharma funding</b>
<i>Meredith</i>	Board member	More critical of pharma funding than most other members of group; would prefer group took no pharma funds & considers some recent funding to go against policy of board discussion.
<i>Thora</i>	Former board member; currently paid staff member. Also a member of Group C.	Pharma funding ok if given as 'unrestricted educational grant'; advocates a mix of all funding sources (donations, corporate, government).
<i>Cindy</i>	President	Expresses discomfort with pharma funding but sees few alternatives.
<i>Fiona</i>	Initiated <i>Chat Site</i> as a volunteer in 1996; later hired as webmistress to run it; let go when funding was cut.	Strongly opposed to pharma funding, especially for <i>Chat Site</i> which she believes must remain independent of industry to ensure integrity of information given to women
<i>Jenny</i>	A founder, former paid staff, currently on board.	Critical of pharma funding in some instances (attended initial meeting of Group C and objected to "hidden agenda", lack of genuine consultation); does not believe it necessarily silences critique and believes it may be necessary to provide services.
<i>Ruth</i>	Board member	Views all corporations with suspicion but comfortable with unconditional educational grants from pharma, for some purposes.
<i>Keith</i>	Fundraiser hired on government grant for six months; paid by group for several months afterwards.	Doesn't understand group's reservations about pharma funding. Secures numerous small Unrestricted Educational Grants from pharmaceutical companies.

<b>Group C Patients, Know Your Rights! Working Group</b>		
<b>ID</b>	<b>Period(s) of involvement and status</b>	<b>History and views on pharma funding</b>
<i>Martha</i>	Retired social worker, now a career cancer activist (since 1993). Chair of Working Group; active in many other cancer patient committees and groups.	Resigned from <i>The Hub</i> over a decision to take pharma money with strings. Considers this project different -- company didn't dictate content. Like other members of this Working Group, she characterized AstraZeneca's representative as "too hands-on" but insisted he did not influence the project's content.
<i>Thora</i>	Member of <i>Working Group</i> since beginning; also a member of group	Comfortable with pharma funding if given as unrestricted educational grant; advocates a mix



	B	of all sources (donations, corporate, government).
<i>Wendy</i>	Member of Working Group; also active in several groups and projects in her province (Prairies).	Wary of corporate efforts to ‘use’ group’s good works to burnish reputation; distinguishes between pharma funding with interference and ‘hands off content’ relationship (this project); negative experiences with government make pharma funding palatable by comparison.
<i>Jenny</i>	Attended the initial workshop then withdrew.	Did not object to the pharma funding but was uneasy about the process. Felt the workshop had a hidden agenda and that the project was being imposed.
<i>Samantha</i>	Attended initial workshop on behalf of <i>The Hub</i> , then withdrew.	Withdrew because she felt the workshop outcome was predetermined and the project was a waste of time and money.
<i>Sue</i>	Attended the workshop , then withdrew.	Withdrew from the project because she thought the document would have no teeth; asked <i>Martha</i> to represent her region.
<i>Leona</i>	Attended initial workshop, then withdrew.	Supported the project but withdrew because she did not have breast cancer. Asked Wendy to replace her as the representative for their region.
<i>James</i>	Worked for Astra Zeneca	<i>James</i> was assigned to the project 6 months before it ended. Members of the working group referred to him as “hands on”, which they thought was inappropriate. He did not try to dictate the substance of the document, however.
SB	A former advocate who received notices about breast cancer meetings and events.	Was unaware of the workshop but responded to a request for comments on a draft document circulated by <i>The Hub</i> . The letter caused considerable consternation within the Working Group.
Stella Kyriakides	A European breast cancer activist invited to speak to the group about work in Europe.	Members of the Working Group responded positively to Stella Kyriakides’ talk and regained some of the motivation they had lost following critical response to the project from SB and others.
Courtney-Rainey Group	A Toronto-based Public Relations firm hired by Astra Zeneca to provide logistical support for the project.	Acted as a liaison between the Working Group and the project for the first two years, creating a buffer which the activists appreciated. The Astra Zeneca representative replaced the PR company six months before the launch.

**Table 3 Communities Testifying at the Parliamentary Sub-Committee Hearings on Breast Cancer and the Môme Implant 1991-1992**

<b>Actor Category</b>	<b>Number of Witnesses</b>
Clinicians	2
Researchers	
Basic science	1
Epidemiology	
○ Government	2
○ University	1
Clinical trials/ treatment	
○ Government	1
○ University, hospital	9
Public health/prevention/screening	
○ Government	2
○ University	3
Policy, evaluation	
○ Government	2
○ University	2
Quality of life	4
Alternative treatments	2
Pharmaceutical Industry	2
Traditional Charities/ Foundations	6
Patients and representatives of patients' organizations	8
U.S. patients' information and advocacy organization	1
<b>TOTAL</b>	<b>48</b>

**Table 4 Breast Cancer and Health-related Groups Cited in Text**

<b>Group Pseudonym</b>	<b>Culture of Action</b>	<b>Members Mentioned in Text</b>	<b>Geographical region</b>	<b>Life Span</b>	<b>Pharma funding policy</b>
<b>Breast Cancer Groups</b>					
<i>Peer Support and More</i>	Peer Support and self-help for women with breast cancer	<i>Eve</i>	Local	1988 to present	Accepts pharma funding
<i>Citizen Action &amp; Education Group</i>	Public interest education on cancer and the environment	--	Local	1991 to present	No pharma or other corporate funding
<i>Down-home Peer Support and Education</i>	Peer support, education, provincial network, advocacy	<i>Jenny Thora Fiona</i>	Provincial	1994 to present	Board discusses pharma funding case-by-case
<i>Critical Advocacy to Prevent Cancer</i>	Critical advocacy and education with environmental focus; local information line	<i>SB Cora Celine Liz</i>	Local (Urban)	1991 to present	“No pharma funding” policy adopted in 2001
<i>Patients, Know your Rights! Working Group</i>	Project to develop a charter of rights for breast cancer patients	<i>Martha Thora Wendy Jenny Leona James (pharma)</i>	National	2005? to 2007	A limited-term project, funded entirely by AstraZeneca Canada
<i>The Hub</i>	National coordinating and advocacy group for groups across Canada	<i>Helen Hanna Hazel</i>	National	1994 to present	Has accepted pharma funding since 1998; corporate policy introduced in 2001.
<i>Helping Hand</i>	Peer support service via toll-free line	<i>Eve Francine Virginia</i>	Provincial, evolved to national	1993 To present	A “no-pharma funding” policy adopted in 1995, dropped in 2000.
<i>A Voice for Patients</i>	Advocacy mandate; also support, via professionally-led meetings	<i>Eve Virginia Vera</i>	Local (Urban)	1992 to 1999	A “no pharma funding” policy; folded for lack of funds
<i>Protect the Environment, Prevent Cancer</i>	Education	<i>Helen</i>	Provincial	2000 to present	An unwritten “no pharma funding” policy
<i>The Pink Foundation</i>	Raises funds for breast cancer research and support	--	National with regional offices	1986 to present	Accepts pharma funding

<b>Group Pseudonym</b>	<b>Culture of Action</b>	<b>Mentioned in Text</b>	<b>Geographical region</b>	<b>Life Span</b>	<b>Pharma funding policy</b>
<b>U.S. Breast Cancer Groups</b>					
<i>Here for You</i>	Peer support service via toll-free line	--	American - national	1979 to present	Accepts pharma funding
<i>Breast Cancer's National Voice</i>	Policy advocacy at national level-umbrella group with an evidence-based philosophy	<i>Sherri</i>	American – national with state chapters	1991 to present	Accepts pharma funding.
<i>Breast Cancer Truth-Tellers</i>	Advocacy and education – outspoken with feminist perspective	<i>Tanya</i>	American- local with national reach	1990 to present	“No pharma funding” policy adopted in 1998

<b>Groups Representing all Cancers</b>					
<i>All-Cancer Advocacy</i>	Advocacy to reduce cancer rates in Canada	<i>Eve Jillian</i>	National	2000 to present	Almost entirely pharma funded
<i>Canada's Cancer Plan</i>	A large collaborative group that promotes a comprehensive plan to reduce cancer incidence and mortality in Canada	<i>Eve Paula Gordon</i> (government)	National	1998 to present	Pharma funding accepted for some purposes since 2001
<i>Advocate 4 the Cancer Plan</i>	Advocacy to raise awareness of and gain support for Canada's Cancer Plan	<i>Eve</i>	National	2001 to present	Almost entirely pharma funded
<i>Patients for the Cancer Plan</i>	A subgroup within the Cancer Plan that represents patients	<i>Paula</i>	National	2001 to present	“No pharma funding” policy
<i>The Coalition to Prevent Cancer without Drugs</i>	A U.S.-Canada coalition of feminist health groups, breast cancer groups, and consumer protection health groups that formed in response to the clinical trial to test tamoxifen as a breast cancer prevention drug.	<i>Tanya Christina S.B.</i>	U.S. - Canada	2000-2002	A “no pharma funding” policy

<b>Health-related Groups with a Feminist Groups and/or Consumer Protection Mandate</b>					
<i>Implant Action Now</i>	A national network of women Advocating for safe breast implants	--	National		
<i>Learn from Drug Tragedy</i>	A national network of women who have suffered harm from the drug DES	<i>Francine</i>	National		A “No pharma funding” policy
<i>Feminist Health Service for Women</i>			Local (Urban)		
<i>Pharma Policy to Protect Women’s Health</i>	A national coalition of activists, academics and women’s health organizations that monitors the federal government’s pharmaceutical policy	<i>Francine SB</i>	National	1998 to 2011	Critical of pharma funding; entirely funded by Health Canada until 2011.
<i>Buyer Beware</i>	A national organization established to protect consumer rights	Wendy Armstrong	National with regional branches	1950s to present	Government funded until the 1990s
<i>Genetic Orphan Disease Group</i>	A network of families in which children have a rare inherited form of anemia	<i>Gloria</i>	Started local, grew to international	1989 to present	Initial funding from pharma companies for newsletter; a “no pharma funding” policy since 1991 or 1992.

**Table 5 Pharma Funding Discourses (by Theme) within Breast Cancer Groups**

Discursive theme	Favourable to Pharma Funding	Against Pharma Funding
Utilitarian	<ul style="list-style-type: none"> <li>- Pharma funds enable group to do good work;</li> <li>- Alternative sources are limited in era of slow economic growth and government cutbacks;</li> <li>- Government funding programs, when they exist, are bureaucratic, short-term, and have more strings attached than industry funding;</li> <li>- Governments won't provide long-term or core funding, just project funding;</li> <li>- government won't fund advocacy (10% rule on charitable status and advocacy);</li> <li>- Enormous pressures on group to do more.</li> </ul>	<ul style="list-style-type: none"> <li>- Pharma funds enable some useful projects but ultimately skews groups' work towards (potentially harmful) policies and drug use;</li> <li>- governments are pushing groups to do unpaid service work as a cost-cutting measure;</li> <li>- Government policies that limit advocacy, and government funding of groups' core activities need to change;</li> <li>- Groups should resist pressures and live within means.</li> </ul>
Capitalism and profit motive	<ul style="list-style-type: none"> <li>- "Why not?" All money is tainted and drug companies are no different from banks, other big businesses;</li> <li>- Capitalism not a problem, profits help companies develop new, better drugs;</li> <li>- Big business uses charity to 'give back' to communities – human face of Capitalism &amp; beneficial to their image;</li> <li>- Big pharma benefits from our use of their products, they owe it to patients to give money for our groups.</li> </ul>	<ul style="list-style-type: none"> <li>- Drug companies <i>are</i> different: they have a vested interest in health and drug policy;</li> <li>- Profit motive drives companies to over-promote their drugs, ultimate effect is health harms;</li> <li>- Big business uses charitable giving as a cover for exploitative behavior;</li> <li>- Money is never strings-free and balance of power is in companies' favour.</li> </ul>
Silencing Effect	<ul style="list-style-type: none"> <li>- Pharma has never tried to control our messages or work;</li> <li>- Money is given as an Unrestricted Educational Grant – protects group from interference;</li> <li>- Collaboration and cooperation are positive values; critique is divisive.</li> </ul>	<ul style="list-style-type: none"> <li>- Pharma money silences criticism;</li> <li>- "Unrestricted Educational Grant" is illusory; groups that critique pharma will have grants cut;</li> <li>- Debate and critique are important to democracy; differences should be aired and made visible.</li> </ul>
Truth claims, fraud and information that patients need about drugs	<ul style="list-style-type: none"> <li>- Companies have changed their ways and past corporate malfeasance is not indicative of present behavior;</li> <li>- new cancer drugs are based on better science, have potential to be curative without toxic effects;</li> <li>- Patients need hope;</li> <li>- Modern patients are savvy and want/need as much information from as many sources as possible.</li> </ul>	<ul style="list-style-type: none"> <li>- Past examples (DES, psycho-tropics) show companies are fraud-prone, self-interested and unreliable sources of information about their products;</li> <li>- new drugs have side-effects just as old drugs do; newer is not necessarily better;</li> <li>- Patients need truthful information;</li> <li>- Information-seeking patients are particularly vulnerable to false claims and need independent information about risks of drugs and other treatments.</li> </ul>

<p>Patients need/use drugs &amp; they keep some group members alive</p>	<ul style="list-style-type: none"> <li>- Critique of pharma not relevant to sick people and is based on harms to people who don't need drugs to stay alive;</li> <li>- Drug companies are necessary to our members' health and are natural allies of patients' groups.</li> </ul>	<ul style="list-style-type: none"> <li>- Benefits of drugs to patients not relevant to group's need to maintain integrity;</li> <li>- Drugs can harm and hasten the deaths of cancer patients;</li> <li>- Drugs potential benefits of will only be realized with regulatory restraints on companies and public vigilance ("Drugs good, companies bad").</li> </ul>
<p>Appearances and group's credibility</p>	<ul style="list-style-type: none"> <li>- Perception is in eye of beholder – we know our group is doing good work and not influenced by pharma money;</li> <li>- Our experience with people who work for drug companies shows they are humane, compassionate people;</li> <li>- Collaboration with industry a good thing; negative perceptions reflect "old thinking" of adversarial relationships between sectors;</li> <li>- Critics have selfish motives for tainting the image of pharma-funded groups' – they want government funding for themselves.</li> </ul>	<ul style="list-style-type: none"> <li>- Alliances with drug companies taint public image, reduce organization's credibility;</li> <li>- Drug companies hire "gosh-darn nice" people to work with public as a strategic move;</li> <li>- Industry is more powerful than ever, more in need of watchdog agencies, organizations and individuals;</li> <li>- Groups critical of industry are the ones losing funding, not vice-versa.</li> </ul>
<p>Many drug companies also make cancer-causing products, such as pesticides. Some have been fined for dumping toxic chemicals into the environment.</p>	<p>Environmental problems are a broader political problem -- they are not really our issue.</p>	<ul style="list-style-type: none"> <li>- The environment is very much our issue because we need to stop cancer before it starts.</li> <li>- Pharmaceutical companies that make pesticides and other cancer-causing products are making money at both ends – they cause cancer then sell drugs to treat it.</li> </ul>
<p>Conflicts-of-interest undermine policies for public good and should be reduced or eliminated</p>	<ul style="list-style-type: none"> <li>- All groups have conflicts of interest—government funding is as conflicted as corporate funding;</li> <li>- onus is on critics of pharma funding to demonstrate wrongdoing or harm.</li> <li>- Our group is vigilant and careful about which companies we deal with; if company is not working for patients or in good faith we won't take their money.</li> </ul>	<ul style="list-style-type: none"> <li>- Government funding is less problematic because government is supposed to work for public good &amp; is responsible to public; companies only responsible to shareholders.</li> <li>- research shows that COI has an effect; companies wouldn't spend money this way unless it helped their bottom line;</li> <li>- Effect of money is subtle and unconscious; being vigilant and open doesn't solve the problem.</li> </ul>

**Table 6 Prescriptive Texts, Contestation Period (1997-2001)**

<b>Author, Year</b>	<b>Title</b>	<b>Sector</b>	<b>Country of origin/scope</b>	<b>Position</b>
R. Baraldi, 1997	Drug Company Money: To Accept or not to Accept?	Women's Health/Patient Group (iatrogenic)	Canada	Debate (predominantly critical)
A. Rochon Ford, 1998	A Different Prescription	Women's Health	Canada	Debate (predominantly critical)
B. Mintzes, 1999	Blurring the Boundaries	Consumer	Europe/Canada	Critical
<i>Breast Cancer Truth-Tellers</i> , 1999	Corporate donations policy	Breast Cancer Group	USA	Critical
<i>Critical Advocacy to Prevent Cancer</i> 2001	Corporate donations policy	Breast Cancer Group	Canada	Critical
Rule and Chapman, 1999	Strategic alliances between disease-specific non-profit organizations and private sector pharmaceutical companies	Industry	Canada	Favourable
Breitstein, 2000	Patient Advocacy: for the Love of the Game	Industry	USA	Favourable
F. Mills, 2000	Patient Groups and the Global Pharmaceutical Industry	Industry	UK/global (industrialized countries)	Favourable
K. Miller, 2000	Patient Advocacy	Industry	USA/global	Favourable
Whamond and Wong-Rieger, 2000	NGO and industry partnerships: Lessons learned	Breast Cancer Group + Consultant	Canada	Favourable



**Table 7 A Different Prescription: Discourses and Counter-Discourses about Funding from the Pharmaceutical Industry**

(Arguments in each heading are paraphrased from the original text)

Discourses in Favour	Counter-discourse
It's a win-win situation: the company looks good and we have money to keep our service running.	<ul style="list-style-type: none"> <li>• The 'win' is mostly by big pharma; most donations come from the marketing budget and are linked to a product line of the company's.</li> <li>• The company gains goodwill that enhances the value of its products, raises awareness of its new product in a captive, target audience, and detracts attention from disease prevention and from competitors' products.</li> <li>• Corporate funding dulls criticism of overmedicalization and acts against education about non-medical ways of staying healthy and recovering from illnesses.</li> </ul>
We need the money for our service. We can't afford to be purists.	<ul style="list-style-type: none"> <li>• Money from the pharmaceutical industry is often attractive because it comes with relatively little effort; thus, groups are tempted to see it as their only option.</li> <li>• Considering other companies that have a connection to your group may suggest alternatives that are less likely to compromise your basic purpose.</li> </ul>
All money is dirty money, pharma money is no different.	<ul style="list-style-type: none"> <li>• Some -- but not all -- other companies engage in unethical activities, including activities that can undermine health (e.g., tobacco companies).</li> <li>• A more nuanced understanding of what types of corporate behaviours are at odds with the group's purpose and values will allow the group to draw lines that the group can defend.</li> </ul>
Most women just want help; they don't care where the money comes from. If we say 'no' to pharma money we are turning our backs on the women who need help from our services.	<ul style="list-style-type: none"> <li>• This may be true for some women and organizations, especially when women face a life-threatening disease.</li> <li>• This time of decision-making also presents an opportunity to raise their members' consciousness about the role the pharmaceutical industry plays in our lives and about government drug regulation.</li> <li>• Canvassing your members will provide a reading of how members feel about the group taking industry funds.</li> </ul>
The company is giving the money with no strings attached. Why should we doubt them?	<ul style="list-style-type: none"> <li>• The assurance of 'no strings' can't be taken at face value; a company's donations are targeted to groups whose purpose is related to their product lines so the group can expect to be promoting sales in some way.</li> <li>• Although the company's concern is with profit, the individuals who contact the group from the company may well have sincere motives and want to help the organization.</li> <li>• Unfortunately this doesn't preclude the company later making demands on the group either to provide more recognition to the company, or to silence criticism.</li> <li>• Communicating with organizations that have worked with the same company may help the group assess the risks.</li> </ul>
Discourses against	Nuanced version of the argument
This is just 'free publicity' for the company.	<ul style="list-style-type: none"> <li>• The publicity may be more subtle than the group realizes; because direct-to-consumer advertising of prescription drugs is illegal in Canada, the group may be inadvertently aiding the company in bypassing the law and could unwittingly be a conduit for information to potential users of the company's product.</li> <li>• The group also needs to be aware of distinctions between products, such as</li> </ul>

	<p>'copy-cat' drugs which add little or nothing to the repertoire of existing drugs; drugs which are not needed; and drugs for which evidence of benefit is still preliminary.</p> <ul style="list-style-type: none"> <li>• A written contract or agreement with the company, ideally one prepared with legal advice, can provide minimal protection for the group if the company attempts to influence the group's advice to members or to target them with its products.</li> </ul>
<p>The company makes pesticides which contribute to the disease; taking money from them endorses their role in causing breast cancer.</p>	<ul style="list-style-type: none"> <li>• The fact that some pharmaceutical companies that sell cancer treatments also produce pesticides that may contribute to cancer is one of several reasons a group might want to do a background check of the company's record on ethical dimensions.</li> <li>• Other potential ethical problem areas include employment practices and product marketing in Third world countries.</li> </ul>
<p>We have an obligation to refuse pharma money to show solidarity to the women who were harmed more than helped by pharma drugs.</p>	<ul style="list-style-type: none"> <li>• The historical context which has led many women's groups to oppose funding from the pharmaceutical industry merits attention. In addition to the benefits that drugs have for many people worldwide, drugs have caused harm to many women, often because they were improperly tested.</li> <li>• The synthetic hormone DES (diethylstilbestrol) is an example of a drug which caused serious harm to the women and men who took it;</li> <li>• The companies that made the drug denied negligence and did nothing to notify women who may not have been aware that the drug they took during pregnancy might cause cancer in their daughters and other serious problems to both sons and daughters.</li> </ul>

**Table 8 Prescriptive Texts, Partnership Period (2002-Present)**

Author, Year	Title	Sector	Country of origin/scope	Position
Teri P. Cox 2002	Forging Alliances	Industry	US	Win/win if done right
Joanna Breitstein 2002	Partnerships and Perspectives	Industry	US	PR companies improve partnerships
Patricia Kelly 2002	Begging Your Pardon: Exploring the Impacts of Pharmaceutical Industry Funding on Non-Profit Groups	Non-profit Organization	Canada	Partnerships as practiced are ethical but Best Practices would increase public support
Daniel Vasella and Kathy Bloomgarden, 2003	Courage Under Fire	Industry	US	Partnerships are necessary to successfully launch a drug
Best Practices LLC, 2004	Patient Advocacy & Professional Organizations: Building Effective Relationships	Industry	US	Successful relationships require a strategic approach
Cohn & Wolfe, 2004	Partnership Report	Public Relations	Canada	Successful relationships require a strategic approach (based on a Canadian survey)
Health Products and Food Branch 2004, 2008	Voluntary Statement of Information Form for Public Involvement	Government	Canada	Health Canada supports transparency but respects privacy rights
Rx&D, 2009	Rx&D Guidelines for Transparency in Stakeholder Funding: Principles and Guidelines	Industry	Canada	Partnerships should be transparent and avoid real or perceived COI
Sharon, 2004	Marching to Different Drummers	Non-profit organization	Canada	Pharma-funded groups and women's health groups have contrasting views.
BreWendy Armstrong, 2007	The Consumer Interest, Experience, Issues and Advocacy Groups (powerpoint)	Non-profit organization	Canada	Trade-driven policies have undermined the concept of public participation in policy process
Barbara Mintzes, 2007	Should patient groups accept funding from drug companies? No.	University, Non-profit organization	Canada, Europe	The consumer interest, experience, issues and advocacy groups
Sharon, 2009	Who Pays the Piper?	University, Non-profit organization	Canada	Partnerships perpetuate myths about drugs.

S. Katrina Pehudoff and Teresa Leonardo Alves, 2010	Patient and consumer organizations at the European Medicines Agency: Financial Disclosure and Transparency	Non-profit organization	Europe	Disclosure guidelines do not ensure disclosure of pharma funding; monitoring is necessary, as are alternative funding sources
S. Katrina Pehudoff and Teresa Leonardo Alves, 2011	The patient & consumer voice and pharmaceutical industry sponsorship	Non-profit organization	Europe	Pharma funding of NGO health organizations may influence policy positions and undermines multi-stakeholder format of public consultations

**Figure 1 Using Epstein's Typologies to Map Typologies of Groups**

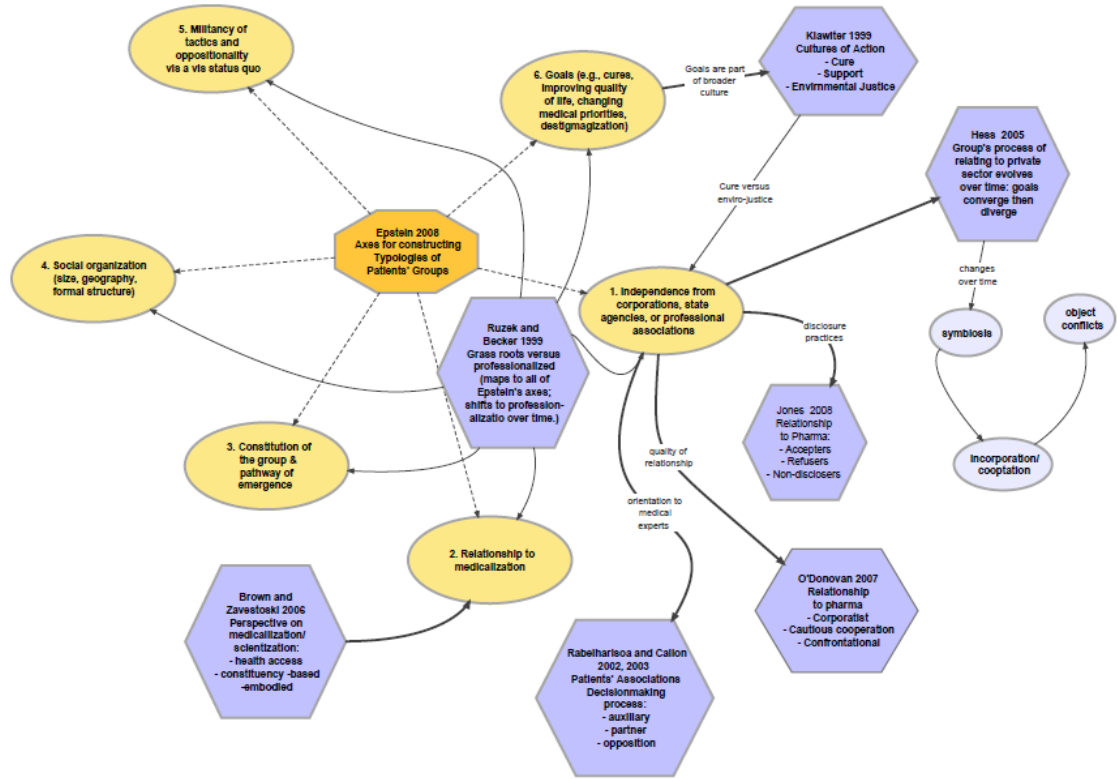


Figure 1.2 Typologies of groups in the health movement literature in relation to Epstein's typology of patients' group typologies

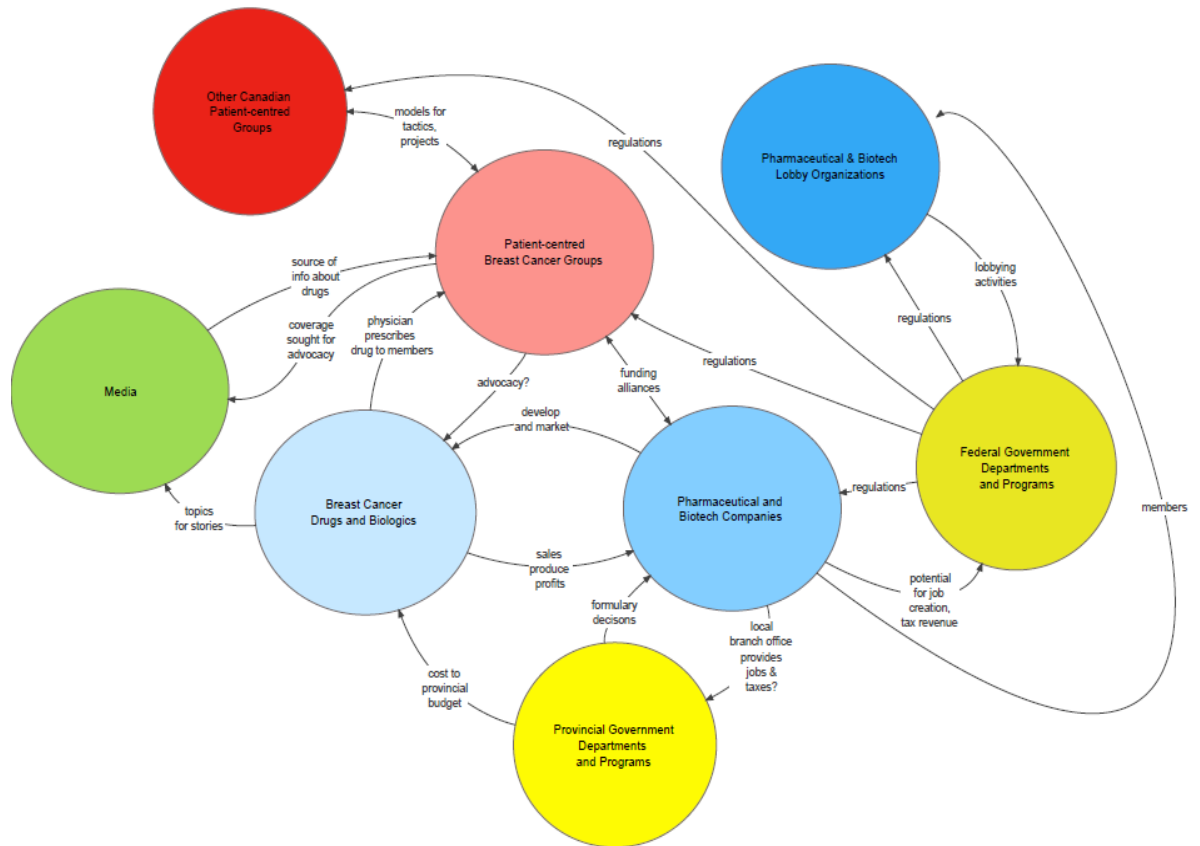
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**Figure 2 Hypothetical Advocacy Opportunities in the Life Cycle of Medications**



Figure 1: Pressure points in the life cycle of medications

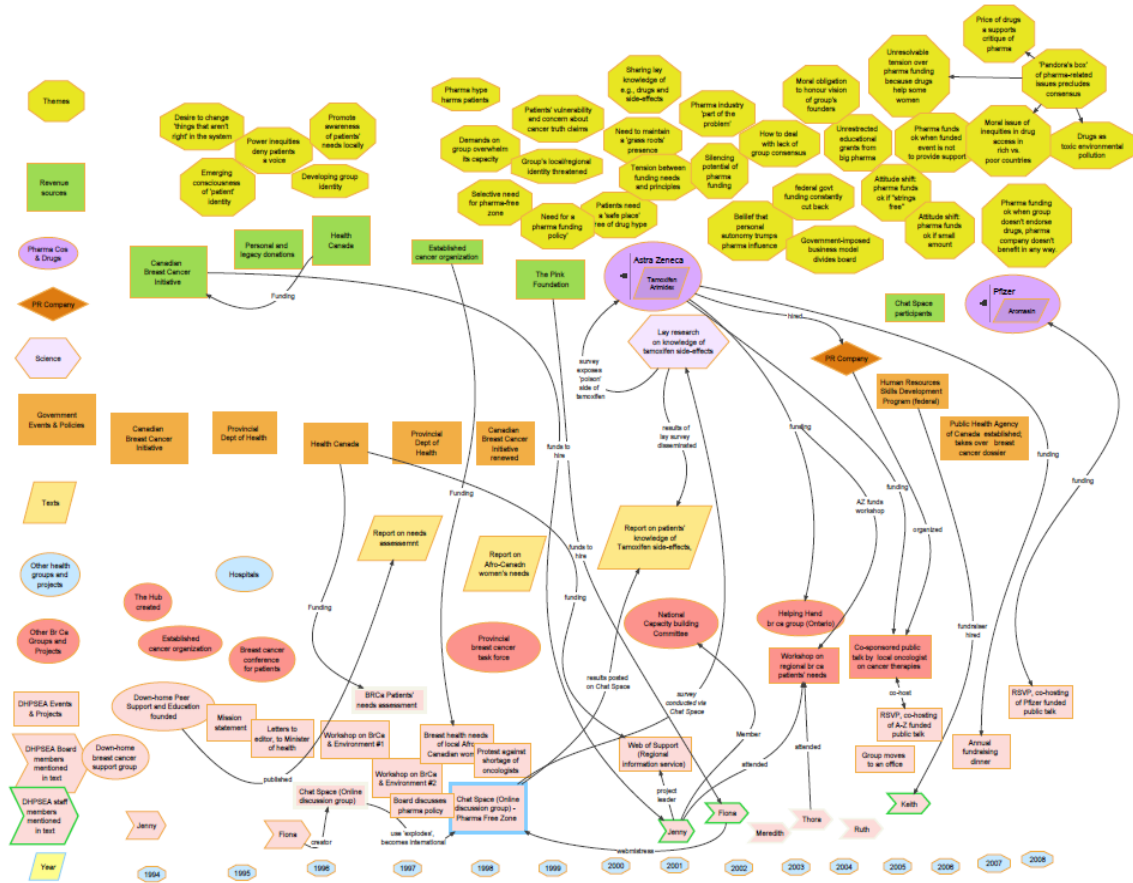
**Figure 3 A Hypothetical Actor-Network Map of a Breast Cancer Environment**







**Figure 5 Actors and Themes for the Narrative Down-Home Support and Education**



**Figure 6 First Translation: Grassroots Groups Appear before the Parliamentary Committee**

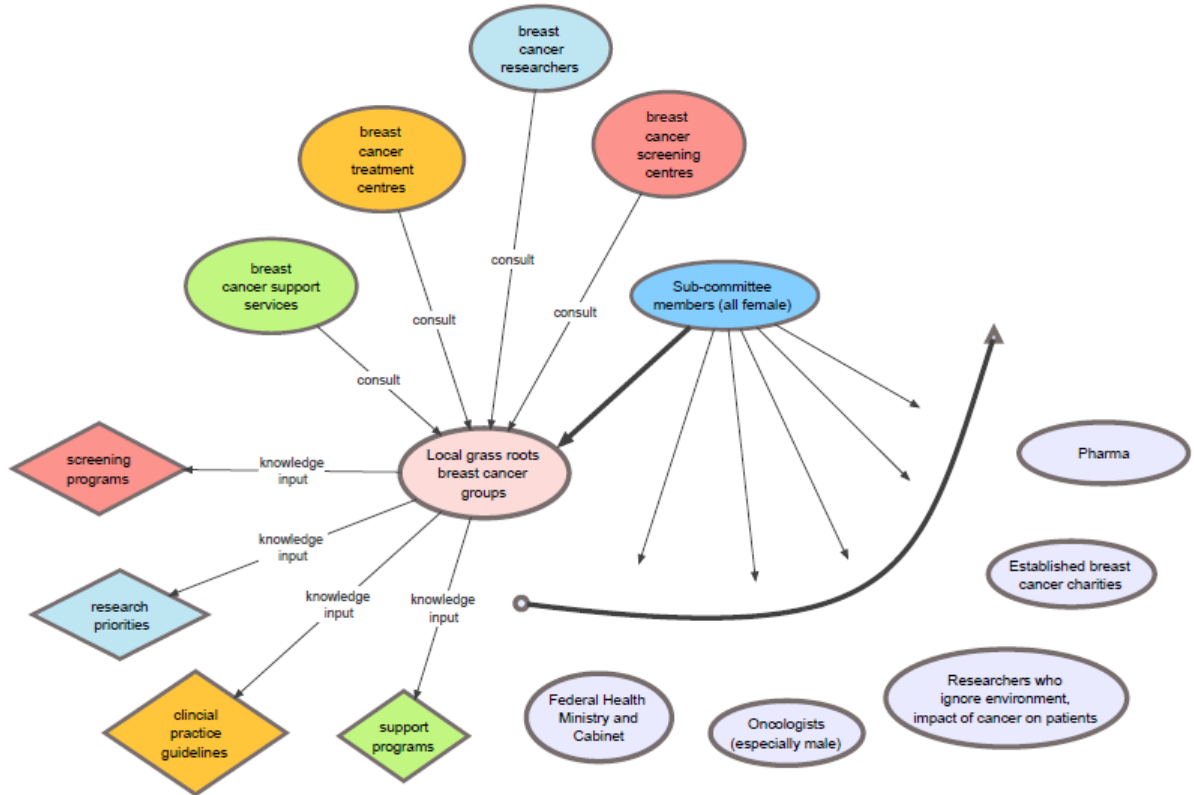


Figure 5.1. First translation: House of Commons subcommittee studying breast cancer makes grass roots groups an obligatory passage point for all cancer-related policy questions.  
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**Figure 7 Mobilization Following the National Forum on Breast Cancer**

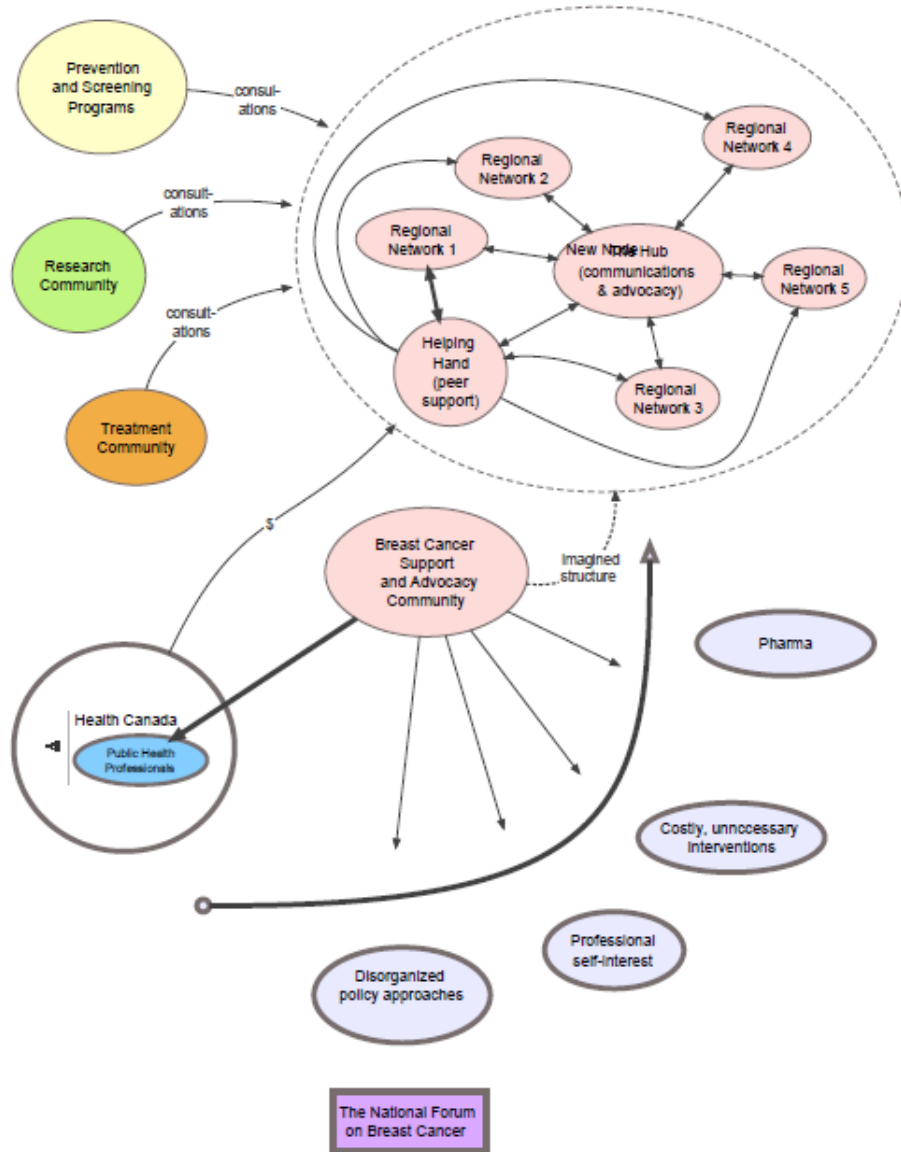


Figure 5.2. Mobilization: National Forum on Breast Cancer includes patient advocates and groups in planning and as delegates and endorses funding for a national organization and a network of groups across the country. The Forum raises the profile and legitimacy of patients' organization in the cancer arena.

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**Figure 8 Key Events in the Grass Roots Period**



**Figure 9 Translation at Together to an End**



Figure 5.4. Second Translation: The conference Together to an End introduces new discourses about breast cancer advocacy groups that challenge the legitimacy of advocacy groups funded by government and propose systemic collaborations with industry for advocacy and the preparation of educational materials. Advocacy goals are defined as 'timely access to the most appropriate treatments' and government regulators are identified as the natural targets. A claim is made for superior breast cancer survival rates in the U.S. and aggressive adjuvant chemotherapy treatments in a privately-funded system are proposed as the key to better outcomes.

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## **APPENDIX A      CRITICAL ADVOCACY'S CORPORATE POLICY**

From the CAPC Website, accessed June 27, 2007

[Home page](#)

### **Policy on Corporate Contributions**

(Adopted by the Board of Directors, March 15th, 2001)

#### Introduction

*Critical Advocacy to Prevent Cancer (CAPC)* recognizes that the effectiveness of our work in public education, advocacy and coalition-building depends on the organization's credibility, particularly in the eyes of its members and the people it serves. The funding sources of any advocacy organization can appear to affect its political legitimacy, particularly in situations where corporate support raises the possibility, inference or perception of a conflict of interest.

CAPC 's corporate contributions policy aims to reconcile the need to ensure the long-term financial health and longevity of the organization with the desire to avoid potentially real or perceived conflicts of interest related to corporate giving.

#### Guiding Principles

The following principles will, therefore, guide CAPC 's corporate fundraising strategy:

1. In order to provide unbiased information about the primary prevention of breast cancer, its diagnosis and treatment, CAPC must be free of any appearance of conflict of interest. Accordingly, CAPC will not accept financial support from corporate entities whose products or services are known to CAPC to include cancer diagnosis or treatment.
2. CAPC advocates the precautionary principle that calls for acting on the weight of the evidence that links environmental carcinogens to breast cancer and other cancers rather than waiting for absolute proof of cause and effect. Consistent with this position, CAPC will not knowingly accept funding from corporate entities whose products or manufacturing processes directly endanger environmental and/or occupational health or may possibly contribute to cancer incidence, nor will CAPC knowingly accept donations from corporate entities that work to weaken or circumvent environmental and occupational regulations that would protect the public health and might decrease cancer incidence.
3. Furthermore, CAPC will not officially support any organization or event that accepts funding from sources unacceptable to CAPC.

#### Unacceptable Corporate Contributions

Based on these guiding principles and CAPC's mission statement, CAPC will not knowingly accept funding from the following categories of corporations. (The following list is not necessarily comprehensive and may be modified.)

1. Pharmaceutical companies
2. Chemical manufacturers
3. Biotech and agri-business
4. Oil companies
5. Tobacco companies
6. Private cancer diagnosis and treatment facilities
7. Companies that develop and market cancer-related technology

This policy does not require CAPC to engage in exhaustive review of every corporation in order to trace the sources of income, but recognizes that the activities of many corporations change rapidly, and that CAPC will periodically need to evaluate new information about corporate donors and the implications of that information. We encourage our members and others to provide information about corporate activities that they believe have a bearing on this policy.

CAPC will continue to focus its fundraising efforts on individual giving, either through direct contributions or through workplace giving programs, as well as corporate donations from industries other than those listed above. This policy shall not be construed to prohibit CAPC from accepting: (a) matching gifts from corporations that are initiated by donations from an individual corporate employee or a group of corporate employees, or b) corporate contributions made in memory or honour of someone, at the request of the honoree, or of the deceased or her/his family

From website FAQs.

Why doesn't *Critical Advocacy* accept contributions from pharmaceutical companies?

In order to provide unbiased information about the primary prevention of breast cancer, its diagnosis and treatment, CAPC must be free of any appearance of conflict of interest. Accordingly, CAPC will not accept financial support from corporate entities whose products or services are known to CAPC to include cancer diagnosis or treatment. (For more information on this, go to CAPC's home page and click on our Policy on Corporate Contributions.)

## APPENDIX B SB'S EXCHANGE WITH THE HUB

Correspondence with the Hub about the DRAFT  
*Patients, Know Your Rights!* Document  
[E-mail from SB to *The Hub*, Feb 29, 2004;  
response from The Hub to SB]

At 07:22 PM 29/02/2004 -0800, you wrote:

Subject: "know your rights"

From: "SB" <sb@email.ca>

To: executivedirector@thehub.ca

Dear *Hazel, Hanna*, and other friends at The Hub:

I'm writing to send my reactions to the draft *Canadians with Breast Cancer, Know Your Rights* document, circulated a month ago. I realize your date for comments has passed; however, a two-week window for comments on an important policy document is not enough for meaningful feedback from the breast cancer community. Please note that I am intentionally sending the comments to *The Hub* staff and board, not to the PR company cited in your call for responses; the people I want to communicate with about this are The Hub staff, board and members at large.

The document circulated is distressing, even dangerous. It will not help breast cancer patients or any other Canadian who becomes seriously sick. Unless it is radically revised, I hope *The Hub* will discard it. You risk ridicule if this document is released in anything like its present form; you also stand to lose credibility as an organization engaged in health policy advocacy work.

I will only sketch my main concerns.

The central claim, from Section I (2) and I (8) is that patients have a right under medicare, to have ALL costs associated with breast cancer diagnosis and treatment covered -- including surgery, medications, treatments and aftercare -- REGARDLESS OF COST. This is pie in the sky. We would all like to have everything we want, all the time, without regard to cost, but no one, including cancer patients, have a RIGHT to unlimited, costly treatment. One can argue forever about what the appropriate level of resources for a functional universal health care system is, but no reasonable person would claim that these resources are infinite. To suggest that women with breast cancer should make these kinds of demands, and claim it is their right to have them fulfilled, is irresponsible in the extreme.



This type of vision is incompatible with universal health care, which you claim in your introduction to support.

Canadians should be fighting to have an excellent, universal health care system, for everyone who needs treatment (not only breast cancer patients).

This IS achievable, but only if spiralling costs are critically examined and if patients are educated to understand that exorbitantly expensive new treatments are not necessarily better than established ones. Even some promising new treatments are priced beyond what any health insurance system can be expected to pay. Patients' groups, if they are serious about representing patients' interests, have an obligation to confront profiteering and misrepresentation by drug companies and other players in the system. Is *The Hub* willing to take this type of leadership role?

Nothing in the draft *Canadians with Breast Cancer, Know Your Rights* document suggests that it is; in fact, the document undermines the chances of building a truly informed, critical patient population. If your document's naive concept of "rights" takes hold among *The Hub*'s members, the resulting demands will only contribute to pressures for a two-tiered system in Canada.

In reading the document, I could not help but suspect that the pharmaceutical industry had a hand in framing it. Certainly the industry stands to benefit far more than patients from a document that claims patients have a right to disregard treatment costs. I checked the website of your consulting firm, Courtney Rainey Group, and was not surprised to find that this firm has pharmaceutical clients. Am I right in guessing that the project was funded by the pharmaceutical industry?

I hope you will take this letter in the spirit intended. *The Hub* does a great deal of positive work; as one of its founders, I would like to see it grow and thrive. This particular initiative worries me a great deal, however. I hope you will rethink it.

I look forward to your response.

SB

*[See next page for response.]*

*Hazel*

Executive Director/Directrice générale

The Hub

Ottawa, ON Canada

Tel./Tél: (613) XXX-XXXX

Fax/Télec.: (613) XXX-XXXX

1-800-XXX-XXXX

E-mail/Courriel: [executivedirector@thehub.ca](mailto:executivedirector@thehub.ca)

Hi SB,

Thanks for letting us know about your concerns, some of which echo *The Hub's*. I should point out first that *The Hub* is not the lead player in the project - the lead player is *Helping Hand*. I have forwarded your e-mail to *Helping Hand* and the other groups involved in the project.

Three issues related to the Bill of Rights will be discussed at our upcoming Board meeting on March 28:

- 1) that all costs related to breast cancer be covered;
- 2) that the Bill of Rights limits itself to breast cancer;
- 3) that follow-up support has not been built into the project for women who attempt to use the document to obtain rights and fail. This latter issue is of prime concern to us and we have raised it repeatedly during meetings.

Best,

*Hazel*

# Patient Charter

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## Principles of Care Delivery for Breast Cancer Patients in Canada

Recognizing that the Canada Health Act guarantees Canadians the right to universal, high-quality medical care delivered in a timely manner, as Canadians, we need to ensure that all breast cancer patients have access to:

- Timely and appropriate care by a healthcare team;
- Optimum standard of care and best practices, including prevention, screening, diagnosis, surgery, treatment, support, follow-up, reconstruction and palliative care;
- Comprehensive information and data about the best evidenced-based treatments and the optimum standard of care appropriate to each diagnosis;
- Psychological, spiritual and emotional support (often called "psychosocial services") and related information for patients, families and caregivers, including specialized services of psychologists, social workers, and oncology nurses;
- Nationally certified, high-quality screening, diagnostic and treatment equipment operated by accredited professionals;
- Treatment in a suitably equipped and organized practice, hospital or cancer centre;
- Comprehensive coverage of medical costs through Medicare, and where costs are not covered, information on financial assistance.

As a breast cancer patient, you have the right to:

- Make your own informed treatment decisions (including the right to pursue alternative or complementary therapies or refuse treatment);
  - Define quality of life in your own terms;
  - Be fully informed of all treatment options and data about best evidence-based treatments, even if they are not available where you are being treated;
  - Information and educational material about treatment and available services;
  - Receive information about follow-up care, and regular follow-up visits with healthcare professionals to monitor progress and discuss treatment needs;
  - Be informed of the resources available to assist you with the financial implications and costs associated with your diagnosis;
  - Receive information about clinical trials for which you are eligible;
  - Refuse to participate in clinical trials without prejudice to your treatment;
  - Privacy, confidentiality and personal data protection;
  - Review your medical records;
  - Obtain a second opinion to provide confidence in your diagnosis and treatment;
  - Lodge a complaint;
  - Freedom from discrimination because of a cancer diagnosis;
  - Be treated by a qualified, interdisciplinary healthcare team that:
    - Communicates in simple, clear and understandable language;
    - Provides translation services if your first language is not spoken by healthcare team members;
    - Provides sensitive, empathetic treatment;
    - Respects your cultural, religious and sexual orientation;
    - Modifies procedures to minimize potential harm.
-