Challenging the Biomedical Monopolies of Knowledge:

A Case Study of PharmaWatch

by

Kaye Buchholz
B.A. Communication, Brock University

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APPROVAL

NAME: Kaye Buchholz

DEGREE: MA

TITLE OF THESIS: **Challenging The Biomedical Monopolies Of Knowledge: A Case Study Of Pharmawatch**

EXAMINING COMMITTEE:

CHAIR: Prof. Alison Beale

Prof. Gary McCarron
Senior Supervisor, School of Communication, SFU

Prof. Pat Howard
Suprevisor, School of Communication, SFU

Prof. Catherine Murray
Examiner
Associate Professor, School of Communication, SFU

Date: April 14, 2005

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ABSTRACT

This thesis examines the emergence of pharmaceutical safety advocacy groups in contestation to biomedical knowledge monopolies. It questions: how can a pharmaceutical safety advocacy group influence change in a society dominated by biomedical monopolies of knowledge? To inform this question, historical ideas of monopolies of knowledge and expertise are discussed in their application to biomedical practices and the emergence of advocacy groups. A case study of the pharmaceutical safety advocacy group, PharmaWatch is presented to explain why and how they, along with other advocacy groups employ epistemological and political strategies to resist the dominance of pharmaceutical knowledge systems.

This thesis is dedicated to my mother.

Thank you for your strength and inspiration.

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

ADR – adverse drug reaction

BCPWA – British Columbia People with Aids

BCA – Breast Cancer Association

CADRMP – Canadian Adverse Drug Reaction Monitoring Program

CPS – Compendium of Pharmaceutical and Specialties

CTS – charitable tax status

DES – diethylstilbestrol

HC – Health Canada

OCAPI – Office of Consumer Affairs and Public Interest

PW – PharmaWatch

SDR – Society for Diabetic Rights

SBD – Summary Basis of Decisions

TPD – Therapeutic Products Directorate

CHAPTER ONE: INTRODUCTION

In the last decade, advocacy groups concerned with pharmaceutical safety have steadily emerged to challenge biomedical knowledge systems. Organizations such as the Canadian based PharmaWatch are sceptical of the great reliance and trust placed in the state, industry and medical authorities' information sources and decision-making processes. This biomedical knowledge structure is comparable to Harold Innis' critique of authorities capacity to hold "monopolies of knowledge" (1950) – that is, a body of knowledge exclusively controlled by a select set of members of society. In relation to the multi-billion-dollar pharmaceutical industry, for instance, industry and the state are the controllers of knowledge and decision-making processes concerning the regulation and marketing of various drug products. Furthermore, these institutions produce and control the regulated pharmaceutical information distributed to the public. Increasingly however, data pointing to the questionable safety of various drugs and irrational pharmaceutical prescribing trends have emerged alongside consumers' personal stories of adverse reactions to pharmaceuticals. Yet, many unsafe pharmaceuticals remain on the market, some with sales that continue to soar.

Consequently, consumers who have had dire pharmaceutical experiences have been motivated to form consumer-led organizations such as PharmaWatch. Since 2003, this Canadian advocacy group has developed strategies to educate

the public about pharmaceutical safety issues, monitor pharmaceutical industry practices and spark regulatory change. PharmaWatch believes that in order for the state and industry to uphold their responsibility of regulating appropriate and safely marketed drugs, a system that widens the current knowledge-sharing practices and integrates consumer engagement in monitoring pharmaceutical drug safety policy is essential.

Through this research I examine the emergence of pharmaceutical safety advocacy groups and address the question: how can a pharmaceutical safety advocacy group influence change in a society dominated by biomedical monopolies of knowledge? To inform this question, I present a case study of PharmaWatch and argue that in contestation to biomedical knowledge systems the organization has incorporated a strategy that challenges the system both epistemologically and politically. Overall, there are two key components of PharmaWatch's epistemological challenge. First, the organization is laying a new foundation for thinking about the role of experts in legitimizing interest-laden knowledge. Second, PharmaWatch is alerting the public, health authorities and government officials about the rights and responsibilities of consumers in pharmaceutical consumption. PharmaWatch's political challenge involves gathering enough force to influence decision-making concerning the design, regulation and enforcement of safe pharmaceutical drugs. Ultimately, PharmaWatch and other pharmaceutical advocacy groups must integrate strategies that will challenge how the public, industry and state think and act to ensure pharmaceutical safety and confirm the legitimacy of consumer

experiences and knowledge. For PharmaWatch, during its first year of development, this strategy involved: 1) establishing an identity focused on consumers through representing legal and ethical principles of pharmaceutical consumer and institutional rights and responsibilities. Politically, this involved establishing a forum for pharmaceutical consumers to engage in knowledge transfer while advancing the validity and application of consumer reporting; 2) converging with technology through establishing a technological mandate, infrastructure and user policy while understanding the opportunities and limitations of the Internet for consumer empowerment; 3) competing with the mainstream media's controversial framing and the bombardment of commercial pharmaceutical messages; 4) maintaining autonomy without being co-opted by mobilizing alliances, building a network of like-minded organizations, and establishing interest-free funding.

While this chapter serves as an introduction, Chapter Two incorporates communication and sociological critique to theoretically situate the discussion. Chapter Two addresses the question: How can Harold Innis' notion of "monopolies of knowledge" be employed in a critique of contemporary biomedical knowledge systems? Furthermore it asks: How are these ideas connected to the emergence of advocacy groups and oppositional challenges? To inform these questions, existing works on monopolies of knowledge, knowledge societies and expertise are presented and employed in a discussion of biomedical knowledge systems. Illustrating this connection are the political and economic forces at work in the provision of pharmaceutical drug regulation. A monopoly of knowledge is

apparent in the way select medical expert knowledge influences policy decision-making and dominates over the real life experiences of citizens. This issue has triggered wide critique from the public, and leads to subsequent discussion regarding the rise of pharmaceutical safety advocacy groups in opposition to the monopoly of biomedical knowledge systems. Williams' and Popay's (1994) notion of lay knowledge and the privilege of experience is introduced as a point of departure for subsequent examination of how advocacy groups may initiate epistemological and political challenges to these systems.

Chapter Three presents the research methods used to empirically examine what these challenges actually look like. Throughout the course of a year I conducted a case study of the emerging advocacy group, PharmaWatch. Qualitative research methods were used as the main techniques for data collection. These included participant observations, informal and formal interviews, open-ended questionnaires and document analysis. An integration of these techniques allowed for triangulation of the data.

Chapter Four presents the research findings and discussion. Specifically, it addresses the question: what strategy does an advocacy group concerned with pharmaceutical drug safety use to epistemologically and politically challenge pharmaceutical knowledge systems? The findings suggest that the organization adopted an integration of strategies in the attempt to present an epistemological and political challenge to pharmaceutical knowledge systems.

Chapter Five provides concluding remarks. While PharmaWatch initiated integrated strategies to enhance consumer education and engagement in

pharmaceutical safety issues and policy, the organization's battle will continually be met with two central challenges. First, PharmaWatch is challenged to uphold its commitment towards shifting society's trust in the pharmaceutical expert knowledge system. Second, while the organization is keen to maintain autonomy and initiate forceful advocacy, it must constantly find resourceful strategies to acquire funding.

The focus of this work is pharmaceutical safety and the wave of critique that has emerged in an attempt to challenge the current knowledge structures that influence the drug regulatory system, however, this subject cannot be discussed without identifying other central issues concerning pharmaceutical safety. Related critical issues such as women and health protection, the transparency of clinical trials, and direct-to-consumer pharmaceutical advertising are touched upon but not given the full critical attention they demand. References to further studies addressing these specific issues are provided in the "Recommended Readings on Pharmaceutical Safety" section of the bibliography.

CHAPTER TWO: THEORETICAL OVERVIEW

This chapter presents a theoretical discussion that addresses the question: How does Harold Innis' notion of "monopolies of knowledge" translate into a critique of contemporary biomedical knowledge systems? Furthermore, it asks: How are these ideas connected to the emergence of advocacy groups and oppositional challenges? To answer this question, the discussion first elaborates upon Innis' idea of monopoly of knowledge. It then connects this concept to historical ideas of the role of expertise in knowledge societies and sociological perspectives on biomedical knowledge practices. Interconnecting these ideas illustrates the prevalence of monopolies of knowledge and expert legitimacy in Canadian pharmaceutical drug provision and regulation. In this example, monopolies of knowledge become evident in the collusion of government authority, industry financial power and the use of medical expert opinions regarding drug safety to ignore consumers' actual experiences with pharmaceuticals. Consequently, it is argued, this phenomenon has triggered critique from drug consumers and has prompted the emergence of voices from the periphery in the form of drug safety advocacy groups working to break the current knowledge practices that govern pharmaceutical drug regulation.

Breaking Down Monopolies of Knowledge

According to Harold Innis, at various points in history societies have been influenced by an institutional centralization of power that controls communication

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practices. In the *Bias of Communication*, Innis provides a thorough breakdown of historical periods of civilization in relation to communication media. Throughout this work, Innis uses the economic history of knowledge to suggest that all civilizations can be traced by a monopolization of communication. This monopolization represents the collusion of political authority, economic power (Beale, 1998), and a disturbance of social equilibrium. For example, Innis states:

> I have attempted to trace the implications of the media of communication for the character of knowledge and suggest that a monopoly or an oligopoly of knowledge is built up to the point that equilibrium is disturbed. (1951, p.3-4)

Throughout his work, Innis provides multiple examples of the prevalence of institutional monopolies of knowledge. For example, monopolies of knowledge dominated by priestly organizations and protected by complex scripts such as cuneiform and hieroglyphics were followed centuries later by monopolies of knowledge controlled by copyist guilds in large cities (1951). In this instance, the monopoly was built by guilds of copyists who set a high price for books, which in turn invited attempts to produce books at lower costs. In both cases, the dominating institutions held centralized control over the production and dissemination of information. Throughout the centuries, control over knowledge and communication media has been interconnected with political and financial power.

In relation to the advent of industrialization, Innis' critique of knowledge monopolies extends towards the mechanization of communication. Innis expressed concern that society's increasing mechanization of knowledge has

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produced dangerous monopolies that threaten freedom of thought. According to Innis:

> Mechanization has emphasized complexity and confusion; it has been responsible for monopolies in the field of knowledge; and it becomes extremely important to any civilization, if it is not to succumb to the influence of this monopoly of knowledge, to make some critical survey and report. The conditions of freedom of thought are in danger of being destroyed by science, technology, and the mechanization of knowledge, and with them, Western civilization. (1951, p. 190)

Innis contends that members of society must recognize the significance of mechanized knowledge as a source of power and its subjection to the demands of control through the instrument of the state (1951). Throughout his work, he suggests that there is an inherent public realization of knowledge imbalances that serve as a forceful impetus for monopolies of knowledge to eventually break down. Innis points to Hume, who states: "As force is always on the side of the governed, the governors have nothing to support them but opinion" (1951, p.4).

From a social science perspective, adopting the idea of knowledge monopoly presents the opportunity to investigate the limits of Innis' ideas and point out their possibilities. For instance, the implications of Innis' notion of monopolies of knowledge can be further understood through connection to theories of knowledge societies, expertise, contemporary biomedical knowledge practices and social advocacy.

Monopolies of Knowledge and Expertise

While Innis points to the pivotal role played by institutions in attaining monopolies of knowledge, theories of knowledge societies take it a step further,

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suggesting the prevailing role of the expert in influencing social control. Theories of knowledge societies emphasize the dominating role of experts and institutions as controllers of knowledge. For example, Nico Stehr suggests that contemporary society can be characterized as a knowledge society with increasing dependence upon expert knowledge (1994, p.160). Within knowledge societies, Stehr suggests, the expert becomes a mechanism for rationalizing, decision-making, and balancing public confidence and loyalty. Knowledge developed from these experts functions to shape the provision and regulation of numerous facets of public policy.

For centuries, ruling groups have consulted advisors and counsellors for various decisions affecting the ruling of social order. Regardless of the era, working principles for an effective practice of expertise have included both belief in the validity of knowledge and trust in expert advice (Stehr, 1994). In the contemporary context, Giddens concurs by suggesting that life in modern society is bound by "the cement of expert knowledge and trust in the solidity of expert knowledge" (1990, pp. 89).

Theories of knowledge monopolies and dependence on expertise resonate with Habermas' theory of a legitimacy crisis. Habermas argues that the tension between capitalism and democracy has fuelled a 'legitimacy crisis', whereby support for both government and economy is systematically eroding (1975). The term "crisis" implies that the state's operations are extending beyond the scope of public consent. Consequently, responsibilities are increasingly taken out of the state realm and delegated to experts. This interferes with the process

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through which people do or do not give consent to be governed, as expert knowledge becomes the predominant influence in decisions made by and for the modern state (Habermas, 1992). Habermas' ideas concur with those of Max Weber. Weber suggests that because the predominant form of legitimacy in modern social order is legal-rational authority, bureaucratic commands are now only considered authoritative and legitimate so long as they have been issued "from the correct office, under the appropriate regulations and according to appropriate procedures" (in Stehr, 1994, p.119). Similar to Habermas' legitimacy crisis theory, Weber argues that the modern state is in a "legitimation deficit" as it cannot be legitimate by an absolute standard (Stehr, 1994, p.119).

Weber's discussion of the role of expert knowledge at institutional, political and economic levels bridges Innis' theory of monopolization of knowledge and Habermas' idea of the legitimacy crisis. Weber argues that historically, the role and influence of knowledge, as well as the type of knowledge, varies from institution to institution (1968). In the economic sphere, Stehr argues it is Weber's view that in the economic sphere,

> expert knowledge of private economic interest groups in the field of business is superior to expert knowledge of the bureaucracy. This is so because the exact knowledge of facts in their field is of direct significance for economic survival. Private enterprise, Weber argues, is relatively immune to the intervention of bureaucratic authority. Private enterprise is able to guard 'secrets' as a means of power, much more closely. (in Stehr, p. 72)

In the political sphere, Weber emphasizes the critical role of knowledge in the steering of bureaucratic institutions. Weber contends that bureaucracy does not only accumulate knowledge but attempts to protect it from access by 'outsiders'

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(Weber, 1968, p. 338). This notion is comparable to Innis' scepticism regarding institutional authorities' tactics of knowledge control. Weber suggests, "bureaucratic administration means fundamentally the exercise of control on the basis of knowledge" (Weber, 1968, p. 338). Weber further argues that the primary source of bureaucratic authority lies in the role of technical knowledge, which has become indispensable in the development of modern technology and the production of goods. Consequently, regardless of whether the economic system is organized on a socialist or capitalist basis, bureaucracy is able to reach levels of efficiency and modes of rational control which no other forms of authority can accomplish.

This section outlined the intricate interplay between theories of monopolies of knowledge, knowledge societies and expertise. In each case, institutional domination over the production and dissemination of knowledge prevail and work as central mechanisms for enforcing social control. An illustration of this phenomenon is evident in its application to the structure of biomedical knowledge practices. The subsequent discussion examines this correlation through reference to literature on the sociology of medicine. It points to critical issues arising within the Western system of biomedical expertise and the steering of pharmaceutical policy and practices.

Biomedical Monopolies of Knowledge and Expertise

In medical sociology until the late 1960s, the widely accepted definition of medicine was a profession that used its expert knowledge and special skills rationally and benevolently (Kelleher, Gabe & Williams, 1994). This ideology

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stemmed from the rational discourse of Enlightment philosophers, in which science was used to control natural resources for the benefit of all (Giddens, 1990). With a decline of organized religion, doctors assumed the role of secular priests whose expertise not only encompassed the treatment of bodily ills, but included advice on how to live the good life and how to distinguish right from wrong behaviours. Doctors became gatekeepers to a range of pharmacological products generally perceived as enhancing the ability to save life and minimize personal discomfort (Kelleher, Gabe & Williams, 1994). The medical profession was what Lawrence refers to as a 'bounded profession' that held an objective view of disease based on specific causal links (1995). At the forefront of expert medical practice beliefs was the notion that the layperson was obliged to be the passive object of medical knowledge. This is similar to Harold Innis' concept of monopoly of knowledge, which argues that knowledge is bound to particular institutional groups. In a similar vein, Bury argues that medicine as an expert culture was founded upon and legitimated in terms of 'formal knowledge', which was articulated in terms unfamiliar and inaccessible to many (1998).

In the mid-1970s, a wave of sociological thought emerged that criticized discourses of knowledge and expertise and suggested the medical profession served as an apparatus of social control. Controversial characterizations of the medical professions were advanced, suggesting medical expertise was a dominating profession that objectified and monopolized the provision of health services. Michel Foucault's theory of the 'clinical gaze' suggested that social control was concealed within medical expertise, which placed the patients in a

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'docile body' caught in a web of medical knowledge and power (Scambler & Higgs, 1998). Critics further contended that medicine itself was responsible for creating the need for its service by medicalizing common problems of everyday life (Bury, 1998; Friedson, 1970). Williams and Popay suggest that explanations in biomedicine are becoming so reductive that they exclude virtually all matters of significance from the person's own point of view (1991). Friedson argued, "the recognition, labelling and legitimation of illness is transferred from the 'life-world' of the person to become part of the monopoly of the profession of medicine" (1970). This notion of a medical monopoly has serious implications in the policy arena. In contemporary society, for instance, the use of scientific rationality has become the pre-eminent form of rationality, fuelling the current neo-liberal governance and economic based decision-making process. Policy legitimation becomes increasingly linked to privatization of knowledge and information gathering (Sassen, 2001). In translating this concept to medical care, this rationale ultimately supports decision-making is increasingly justified through cost-benefit analysis. The political and economic ordering within Canadian pharmaceutical drug provision and regulation illustrates the potential perils of how institutions use the rationalization of medical expertise to support the monopolization of knowledge. The relationship between the state and the pharmaceutical companies in developing pharmaceutical drug provision and regulation demonstrates the industries' financial interests and the industriy's dominance of the current medical expertise system. In Canada, the decision-

making process and inadequate transparency of clinical-trial information which influences pharmaceutical regulation, exemplifies this dominance.

Pharmaceutical companies like Pfizer, Eli Lily and Wyeth employ university "experts" in the development of new drugs. They then sponsor "independent" university studies to support the efficacy requirement of their new drug in the approval process. The pharmaceutical companies simultaneously depend on industry sponsored lobby groups to encourage regulatory bodies to endorse their new drug approval submission. Once the pharmaceuticals have been approved by Health Canada they advance to phase-four testing, the product education process. This process involves educating influential medical experts about their product. Physicians then willing to mobilize patients for phase-four drug testing receive lucrative kickbacks. In other words, pharmaceutical companies give physicians monetary incentives and/or bonuses to prescribe and report on these new drugs. This occurs because the pharmaceutical companies have to provide some form of initiative for post-market pharmaceutical surveillance. Through this process physicians relay the information they gain from patients to pharmaceutical companies to be utilized for product marketing/off-label prescribing and further research legitimization.

Under the Access to Information Act, the information within clinical trial studies, used to approve new drugs is considered commercially sensitive and confidential (Lexchin & Mintzes, 2004). Health Canada's, Therapeutic Products Directorate (TPD), will not release clinical information without the manufacturer's approval. Consequently, critical information regarding drug safety and efficacy in

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unpublished reports or trials submitted to the TPD is generally inaccessible to

researchers, physicians and patients. As Lexchin and Mintzes argue, this

situation can potentially lead to the improper prescribing and use of medications

(2004). This lack of peer or public scrutiny of critical drug safety information is

just the beginning of the control mechanism the pharmaceutical industry has in

place to influence the political arena and protect their economic interests. State

efforts have proven inadequate to mitigate the risks inherent in such an industry-

minded, secretive and closed system of drug regulation. In Canada, examples of

controversial programs include the "Smart Regulations", Summary Basis of

Decisions (SBD) and Health Canada's Canadian Adverse Drug Reaction

Monitoring Program.

Health Canada recently cancelled the Food and Drug Act to introduce

"Smart Regulations." Smart Regulations are a 40-point action plan that will

streamline Canada's regulatory approval processes with the U.S. in areas such

as drugs and biotechnology. These regulations are supposed to improve

productivity for Canadian companies. However, essentially they are strategies

that will take Canada away from health protection and towards risk management.

As Michael McBane from the Canadian Health Coalition states, '

> The method used in this industrial risk approach to health hazards has a built-in bias in favour of technological benefits and against the risk factors. Instead of preventing disease and ill health from happening in the first place, 'Smart Regulation' will manage the damage after the fact. The damage to be 'managed' is preventable illness and death (March 29, 2005).

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Ultimately, Smart Regulations will result in the abandonment of the precautionary principles within the drug regulatory processes. This holds major implication on the safety of marketed pharmaceutical products. When federal agencies combine guardian functions with trade and industry promotion, drugs like Vioxx get fast approval and then crash, killing thousands (IBID).

The secretive aspects of state incentives are prevalent in Health Canada's effort to address the issue of transparency of clinical trial. In 2004, the TPD announced it would create a summary basis of decision (SBD) following the final approval of regulated pharmaceuticals. In a study that examines the adequacy of SBDs, Lexchin and Mintzes assessed two pilot SBDs published to date, "one for rosuvastatin, a cholesterol-lowering medication, the second for agalsidase beta, an enzyme replacement for use in Fabry's disease" (2004, p.1363). They conclude that Health Canada's SBDs lack adequate information on clinical trial design, methods and outcomes.

Furthermore, Health Canada's Canadian Adverse Drug Reaction Monitoring Program (CADRMP) proves inadequate in delivery critical drug safety information. This program is supposed to gather and deliver critical information about people's experiences with adverse drug reactions to all pharmaceutical drug stakeholders including the public, physicians and drug manufacturers. However, as a program that receives $35,000/year out of a $3.1 million dollar drug monitoring budget versus $31 million for drug approval (Lexchin, 2003), the reliability and accessibility of the ADR reporting information is controversial. Critics argue that the system is under-staffed, inefficient and under-budgeted

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(Lexchin, 1999; Moride, et al., 1997). Furthermore, it is argued that the system is a "black box" in which data is unaccounted for and inaccessible. In 2004, the Canadian Association of Journalists awarded Health Canada the "code of silence award" for demonstrating "remarkable zeal in suppressing information" and "concealing vital data about dangerous drugs" (Kermode-Scott, 2004). Paul Schneidereit, the association's president, said, "Government officials everywhere hide vital information that they think might embarrass them, their departments, or their political leaders" (Kermode-Scott, 2004). According to the association, over a period of more than five years, Health Canada denied journalists or members of the public any "meaningful" access to the CADRMP database of pharmaceutical drugs that collected consumers' experiences with adverse drug reactions. Once the data was released, it was delivered in a computerized format that prevented deeper analysis. Overall, the inadequate transparency of critical drug safety information and the current ADR reporting mechanism reflects a system that discourages public scrutiny, engagement and knowledge transfer in decisions concerning critical drug safety issues.

Health Canada enables this economic process to occur under the guise of unilateral communication between biomedical authority experts and pharmaceutical companies. This is done in the interest of maintaining the economic growth spurred by the current rapid expansion of a multi-billion dollar pharmaceutical industry[1] as a result of a favourable regulatory environment. For example, despite increasing safety worries, Pfizer's COX-2 inhibitors, Celebrex®

[1]The total spending on drugs in Canada is expected to have reached $21.8 billion in 2004, an increase of 8.8% over the previous year and five times the amount spent on drugs in 1985 (Canadian Institute for Health Information, 2005).

and Bextra® have helped quadruple the company's 2004 sales figures, with an increase of sales following Merck's Vioxx withdrawal in 2004. Worldwide sales of Celebrex® topped $3.3 billion and Bextra® sales totalled nearly $1.3 billion in 2004 (Datamonitor Industry News, February, 2005).

The perilous consequences of this economic interests added by a monopolization of biomedical knowledge include the distribution of unsafe pharmaceuticals and diminished space for citizen commentary and meaningful engagement in pharmaceutical policy formation. Since the practice of pharmaceutical prescribing has escalated, there has been a concurrent increase in consumer experiences with serious adverse reactions to drugs, such as thalidomide, diethylstilbestrol (DES), benzodiazeptine, anti-depressants and COX-2 Inhibitors being only the best known. Adverse effects have also been propelled by increases in off-label prescribing, a practice in which doctors prescribe drugs to patients for conditions other than that for which the drug has been approved for. In other words, while Health Canada may approve a drug for one condition or segment of society, once it reaches the market, doctors are prescribing it for another. For instance, Diane®35 was approved in Canada for the treatment of severe acne for people who failed to respond to other treatments. Yet it is widely prescribed as a birth-control in young women despite safety warnings of its risks of venous thromoemolism (VTE). A further example is the prescribing of anti-depressants to children. Health Canada does not regulated the prescribing of anti-depressants for people under 18 years of age, yet it is a practice that continues to occur.

As the industry and government use experts to maintain their monopoly of pharmaceutical knowledge and rationalize regulatory approvals, opposition is on the rise. Appalled by institutional negligence of public safety, pharmaceutical safety advocacy groups are emerging and using innovative means of communication to counterbalance this monopoly of biomedical knowledge. As Innis states, "Inventions in communication compel realignment in the monopoly of knowledge. A monopoly of knowledge incidental to specialized skill [...] which weakens contact with the vernacular will eventually be broken down by force" (1951, p. 4). Both international and Canadian pharmaceutical safety advocacy groups illustrate this oppositional force.

The Emergence of Advocacy Groups

The predominant biomedical expert bodies and decision-making powers of the state and industry have forced the emergence of a critical public. In medical sociology, this idea is supported by post-modern theorists who argue that there is a cultural shift towards a more pluralistic medical setting characterized by growth in media based information systems, self-help groups and alternative medicine practices such as naturopathy and homeopathy (Kelleher, Gabe & Williams, 1994). This perspective challenges that of the white-coated 'modern' expert, the source of rational scientific knowledge. This challenge is increasingly occurring in a knowledge society where members of the public are becoming more reflexive in their efforts to assimilate and evaluate increasing amounts of information about health risks. Access to medical libraries and on-line information are media facilitating this public knowledge gathering process. Further, as Giddens argues,

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these processes are producing a 'contestable culture' in which trust in abstract systems is frequently threatened (1990). This is particularly the case in such matters as health risks from the environment, food production, pharmaceutical products and other medical treatments. Kelleher argues that the competence of medical experts is being challenged as a result of the disillusionment citizens feel as a consequence of the dehumanizing effects of biomedicine. This is said to be the result of the lack of interest doctors display in treating patients as persons and of the failure of medicine to uphold its responsibility to deal safely and effectively with a wide range of common symptoms (1994).

Williams and Popay support these challenges when they suggest a critical need for lay knowledge to move beyond individual sentiment or complaint into a public voice that will set the foundation for collective action for policy change (1994). A critical position in their argument suggests that the involvement of lay knowledge in the public and environmental health arena can potentially challenge the dominance of medical professions through epistemological and political challenges to medical expertise. Such challenges to the monopolies of biomedical knowledge are appearing in the formation and activities of drug safety advocacy groups. This counteractive force is illustrated through the activities and political positioning of various advocacy groups such as: DES Action; the Benzodiazepine Addiction, Withdrawal & Recovery Group; Women's Health Protection; the Cancer Action Network; Health Action International; and PharmaWatch. These advocacy groups share similar concerns regarding the current state of drug safety regulation and public safety. While the specific drug

concerns of these groups differ, they share the overall objective of advocating for enhanced public education and engagement in pharmaceutical regulatory decision-making processes.

The epistemological challenge to expert knowledge suggested by Williams and Popay is a process of contesting the alleged objectivity and impartiality of biomedical knowledge philosophies in order to permit a further understanding of contemporary health problems (1994). Through this challenge, lay people refuse to accept that scientific knowledge is impartial simply because it is produced by scientists. They further insist that local knowledge based on shared biographical experiences cannot be invalidated by reference to objectivity claims derived from abstract scientific knowledge (1994). DES Action is a group demonstrating such a challenge. The organization uses its website, mass media coverage and various forms of literature to advocate for a more informed public regarding DES, a drug prescribed to millions of pregnant women in Canada and the United States between the 1940s and the 1980s to prevent miscarriages. In 1948, two Harvard University physicians provoked great enthusiasm in the medical community with a paper that claimed that DES was an ideal drug for the prevention of miscarriages. Heralded as cheap and easy to produce, DES was the first synthetic estrogen. In 1952, however, studies cast doubt on the drug's safety and effectiveness. A subsequent study proved scientifically that DES was ineffective in high-risk pregnancies and in fact appeared to increase the chances of miscarriage. DES was finally taken off the market in 1971 when research directly linked the occurrence of vaginal cancer in daughters to their mothers who

were prescribed the drug. This led to the creation of DES Action, an organization founded in 1982 by concerned citizens who wanted to raise public awareness about the potential perils of pharmaceutical drugs and ensure that occurrences of drug safety negligence are reported and companies, doctors and regulators challenged (DES Action Canada, 2004).

Similarly, the Benzodiazepene Addiction, Recovery and Withdrawal group is a virtual community dedicated to sufferers of iatrogenic benzodiazepine tranquillizer addiction. Physicians prescribe benzodiazepines (tranquilizers) and sleeping pills to help women cope with work or family stress; pre-menstrual syndrome; chronic illness and pain; grief and adjustment to life events such as childbirth and menopause. However, the addictive nature of benzodiazepines and their profound effects on the brain and body have been known for more than forty years, yet these drugs are among the most widely prescribed in Canada and the world today. The over-prescription of benzodiazepines to women was first identified as a critical health care issue in the 1970s, yet it is estimated that 3 to 15% of any adult population is using and may be addicted to this class of drugs. Women comprise 60 to 65% of this group. Consequently, in 2000 concerned members of the public launched a website that hosts more than 500 pages of articles and information, medical documents, news stories and personal accounts about Benzodiazepene so the public can have access to alternative information sources about the drug (Benzodiazepine Addiction, Withdrawal & Recovery, 2000).

These advocacy efforts exemplify Innis' suggestion that the public adopts communication initiatives to converge and challenge popular perceptions about institutional knowledge. The above-mentioned collectives represent citizens who have taken initiatives to gather alternative information about pharmaceutical drug risks, when orthodox experts are either silent or unreliable. Ultimately, these advocacy groups are rallying personal experiences to challenge the public, government and industry's perception of pharmaceutical drug safety.

The political challenge discussed by Popay and Williams is the extension of the epistemological challenge. This involves strategies to influence the formation of public policy (1994). Efforts by organizations such as Health Action International (HAI) and PharmaWatch represent such opposition. These organizations are undertaking initiatives to both encourage public awareness of pharmaceutical safety issues and to lobby the government to improve drug safety and drug regulation. For example, HAI campaigns for better controls on drug promotion and the provision of balanced, independent information for consumers and those who prescribe drugs. This non-profit organization is a network of health, consumer and other public interest groups advocating for a more rational use of medicinal drugs in more than 70 countries. Representing the interests of consumers in drug policy, the organization believes that all drugs marketed should be acceptably safe, effective, and affordable, and should meet real medical needs (Health Action International, 2004).

In Canada, PharmaWatch represents an advocacy effort attempting to both educate the public and influence the public's perception of drug safety and

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the drug regulatory process. The group's board members include concerned physicians, drug policy analysts, wary citizens and social academics. PharmaWatch is attempting to give the voice to citizens experiencing adverse reactions from all classes of drugs. To launch its advocacy efforts, PharmaWatch partnered with DES ACTION on a project that illustrates how patient advocacy groups are challenging the current system of medical expertise. These groups propose to collaboratively develop a nation-wide direct-from-consumer ADR reporting system to enhance public awareness, empowerment, and accountability in drug safety. The cornerstone of their project is a web-based adverse drug reaction reporting system to collect, collate and deliver reliable information about personal experiences with ADRs to the public, health professionals and government. These advocacy groups want to see a reporting mechanism that is more reliable and efficient than Health Canada's current ADR monitoring system. They demand a program that (1) encourages the Canadian public and the medical communities to recognize and report suspected adverse drug reactions; (2) provides access to information regarding a broader range of product-specific problems already identified through other reporting mechanisms; and (3) offers earlier sentinel warnings of adverse drug effects. PharmaWatch is an organization that brings together voices from various patient groups and independent health organizations to challenge government and industry information control in order to ensure that consumers are properly advised about unsafe pharmaceutical products. As board member Dr. Warren Bell stated, "people's voices are being dismissed. We need to stand up and validate

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consumer experiences" (2004, PharmaWatch conference). However, this proves difficult because PharmaWatch must contend with two adversaries. First are the pharmaceutical industries, which have a firm grasp on drug provision under the guise of a medical expert discourse. Second is Health Canada, which is criticized for failing its responsibility to design and implement a drug policy that ensures access to safe drugs and therapies, for inadequately seeking and listening to patients and their relatives accounts of adverse drug experiences, and for delivering insufficient drug safety information to the public. Overall, recognizing the contentious history of Canadian pharmaceutical policy and practices, and its connection to the monopoly of biomedical knowledge, helps to explain the emergence of drug safety advocacy groups and why they are working to present epistemological and political challenges to the current system.

Conclusion

This chapter began by discussing the idea of monopolies of knowledge in relation to knowledge societies and expert systems. It proceeded to suggest a relationship to sociological critiques concerning assumptions of knowledge and expertise in modern biomedicine. The relevance of knowledge monopolies and the prevalence and misuse of expertise to exclude and delegitimate other knowledge, particularly within Canadian pharmaceutical knowledge practices, were demonstrated. This phenomenon is illustrated through identifying the political and economic forces at work in the provision and regulation of pharmaceutical drugs. Furthermore, monopolies of knowledge are apparent as

medical expert knowledge informing pharmaceutical policy dominates over drug consumers' real-life experiences.

This chapter subsequently discussed the emergence of advocacy groups in contestation of pharmaceutical practices. It further presented Popay and Williams' (1994) idea of a dual approach towards epistemologically and politically challenging medical expertise, and suggested how advocacy efforts can theoretically function to effectively change current knowledge structures and policy. The following chapters further deliberate these ideas by exploring what this challenge looks like in pragmatic advocacy efforts. They specifically examine and discuss the epistemological and political strategies that the drug safety advocacy group PharmaWatch uses to counterbalance biomedical monopolies of knowledge.

CHAPTER THREE: RESEARCH METHODS

In order to explore and describe strategies advocacy groups use to challenge biomedical knowledge structures, this work presents a single case study of the consumer drug safety organization, PharmaWatch. Case study research is a methodology that allows a holistic, in-depth investigation of an environment and phenomenon. Furthermore, case studies are designed to bring out details from the viewpoint of participants by using multiple sources of data (Feagin, Orum & Sjoberg, 1991).

This research involved two phases of data collection. The first phase adopted an ethnomethodological research approach, which included a series of participant observations. The second phase adopted a phenomenological research approach, which included semi-structured interviews and open-ended questionnaires. Using multiple sources of data collection allowed triangulation of the results to ensure that the study was examined from different viewpoints (Silverman, 2000).

The core of this research was conducted in Vancouver from September 2003 to October 2004 with PharmaWatch board members, participants from the 2003 PharmaWatch conference and other consumer or patient oriented organizations. The sample of participants was selected after initial meetings with founding members of PharmaWatch and as the research evolved. The sample participants are a relevant group as they have been pivotal in contributing to the

development of the organization. Background information and analysis was gathered from a variety of sources including academic and public documents, the September 2003 Parliamentary Standing Committee on Health, and various websites.[2]

Phase One

Ethnomethodology, utilized in the first phase, derives from the theoretical conception of social phenomena and encourages researchers to see (or attempt to see) the process through which social environments are created and sustained. This research orientation provides a foundation for the researcher to observe how actors produce and treat information in their exchanges and how they use language as a resource (Coulon 1995). Furthermore, ethnomethodology encourages researchers to analyze commonsense beliefs, socially organized conduct, and everyday actions such as communicating, making decisions and reasoning.

Participant observation is the popular method for executing ethnomethodological research. Participant observation was used as a field technique to document the everyday interactions and language of PharmaWatch board members regarding how they talked about and acted to nurture the growth of the organization. Through this process the organization's values, dynamics, internal relationships, structures and conflicts were observed from their actions and everyday talk rather than from their (normative) statements of what "is." A total of fifteen participant observations were conducted at various PharmaWatch

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[2] See Bibliography for a list of websites consulted

board meetings, committee and community outreach meetings, and the 2003 national PharmaWatch conference. In these settings, specific data was collected regarding the setting, the human and social environment, activities and behaviours, informal interactions and unplanned activities, the language of participants, non-verbal communication, documents and what did not happen. A contact summary sheet was created after each participant observation (Silverman, 2000). The contact summary sheet addressed questions such as: what people, events or situations were involved? What were the main themes or issues in the contact? On which research questions did the contact bear most centrally? What new hypotheses, speculations or guesses about the field situations were suggested by the contact? Where should the most energy during the next contact be placed and what sorts of information should be sought? Ultimately, the contact summary sheet worked as a guide for organizing follow-up contact and functioned as a basis for data analysis.

A limitation of the ethnomethodology orientation was its focus on the process of talk and action. Therefore, in order to complement the participant observations and further inform the research, a phenomenological approach – from which ethnomethodology derives – was used. This involved methods of semi-structured interviews and open-ended questionnaires. As the phase 2 discussion describes, these methods generated further data, which substantiated PharmaWatch board members' beliefs concerning their discourse and experiences.

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Phase Two

Phenomenology, utilized in the second phase, looks at the way the experiential world, which people take for granted, is produced and experienced by members. In this framework, language is used to convey information to describe reality. The meaning of a word is taken for what it is referred to, corresponds with or stands for in the real world (Holstein & Gubrium, 1994).

To begin this phase of research, one in-depth semi-structured interview was conducted with a PharmaWatch board member. The selected board member was one of the organization's founders and had been intimately involved with the organization's daily operations. The interview questions were constructed from observations that surfaced in Phase 1 of the project. The interview sought the board member's opinions and beliefs regarding things said and done during Phase 1 of the research. This was in regards to various decisions that board members made while developing the strategy for PharmaWatch's drug safety advocacy efforts. These questions were further focused and disseminated as open-ended questionnaires to PharmaWatch board members. The questionnaires surveyed PharmaWatch board members' opinions and beliefs regarding issues that were documented during observations and the in-depth interview.[3] Nine months into the PharmaWatch project, eight questionnaires were distributed to all PharmaWatch board members. Six out of eight board members responded to the questionnaires.

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[3] See Appendix – PharmaWatch Board Member Interviews and Questions

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PharmaWatch board members were initially contacted by e-mail to request their participation in the interviews and questionnaire. The participants e-mailed their responses attached in a text document. All participants were given the option of personal non-attribution and anonymity, as well as the opportunity to complete the survey in writing or by phone. Five board members responded via e-mail and one board member chose to discuss the responses over the phone. The phone respondent's answers were written down and immediately transcribed into a text document formatted in the same way as the other board members' responses.

Research Limitations

In developing and implementing this research, issues in theory and practice of qualitative research methods emerged. Challenges in conducting this single case study included dealing with the inevitability of boundary judgments and the validity and reliability of the findings.

Boundary judgments

Boundary judgments or biases are "the result of our inability to consider the whole system of all the conditions that might have practical bearings on the way we see an issue of concern" (Ulrich, 2001). Feeling passionate about the issues that PharmaWatch addresses, it was important to reflect on whether a personal bias that questions pharmaceutical ethics was problematic for the validity of the research findings. For instance, my interest in the study stems from concern with pharmaceutical safety. Personal family experiences with adverse drug reactions

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prompted my curiosity in understanding the great trust we place in our medical system and knowledge of pharmaceutical products. I was eager to critically explore this sweeping social trust in rational science structures and how this can be challenged. I felt drawn to the subject matter and had to work hard towards discerning what was stated by respondents and observed in situations versus my personal beliefs and principles about situations. For example, in the initial days, when board members were focused on establishing an organizational identity and decided that they would represent themselves as a consumer group, I was challenged. I did not agree with this consumer designation and sought to discuss with board members ideological implications of the term. Shortly following various conversations with board members about the subject, I realized I needed to more thoroughly reflect upon how my role as a participant influenced my role as a researcher. Throughout the year, as a participant, my personal involvement with PharmaWatch activities was significant. I attended and participated at various board members, assisted in organizing aspects of the 2003 PharmaWatch conference, the press release as well developed a database of potential funding agencies. I recognize that these activities hold influence on the categorization and coding of my field notes and thus my research findings.

Silverman suggests that, "every way of seeing is also a way of not seeing" (2000, p. 177). In other words, coding schemes are often based upon a select set of categories that create a powerful conceptual grid that is difficult to break away from. In this research, meeting this challenge involved recognizing my personal bias in various situations, executing a constant process of critical reflection and

continuing to explore and ask questions that the research may not answer.

Validity

Another critical research limitation that surfaced during the research process concerned the validity of the research. It was particularly crucial to address validity problems of a single case study.

While conducting this case study it was important to reflect upon generalizations and the extent to which an account or category that was created actually represented a social phenomenon. This research considered Stake's (1995) argument for "naturalistic" generalization, an approach that focused on intuitive, empirically-grounded generalizations. Stake proposed that there exists a harmonious relationship between the reader's experiences and the case study itself. Stake suggested that the data generated by case studies would resonate experientially with a broad cross section of readers, thereby facilitating a greater understanding of the case study.

The validity of this study was further challenged by the idea that qualitative research and the technique of participant observation should be dismissed as subjective and invalid (Dietz, Prus & Shafflir, 1994). In this research, however, participant observations provided firsthand experiences with aspects of the organization's advocacy role in a more comprehensive sense. It was superior to straight observation as an interactive means to get closer to the lived experience of the organization. Overall, participant observation provided an opportunity to gain insight into board members' views and practices, as well as their ongoing commentary and interactions in personal exchanges and actions.

The validity of in-depth interviews and open-ended questionnaires must also

overcome critique. For example, Denzin lists a number of problems with

interviewing, mainly concerning factors that may distort interviewees' responses.

Three of the main examples which could impose limitations on this research

include: 1) the problem of "fleeting" relationships to which respondents have little

commitment and so can fabricate tales of self that belie the actual facts; 2) the

relative status of interviewer and interviewee; and 3) the context of the interview,

for example whether the interview was completed at home or at work (1994). It

could be further argued that the open-ended questionnaire was its own form of

social control, with the potential to shape what respondents said.

Fielding and Fielding offer a counter-perspective with their argument that all

methods of data collection, whether quantitative or qualitative, ultimately are

analysed qualitatively. In other words, regardless of the method, the act of data

analysis is a matter of interpretation and therefore involves the process of

selective rendering (In Silverman, 2000).

Triangulation of methods was used throughout this research to deal with

issues of validity. To reiterate, this process involved using multiple methods

through the two phases of research described above, for constant consideration

and comparison of the data. This allowed the data collected from the initial

participant observations to be further examined through in-depth interviews and

open-ended questionnaires with PharmaWatch board members. In addressing

the validity of data analysis, it was crucial to think critically about refuting

assumed relations within the phenomenon and finding alternative cases through

which to test out hypotheses. This process involved comprehensive management of the data, where all parts of the data were studied and analysed. Furthermore, it involved actively seeking out and addressing deviant cases in the data.

Reliability

Finally, this research process was challenged by questions concerning the reliability of findings. The concern here was how to ensure that the consistency of data within categories could be deemed reliable. Overall, the reliability of the findings was strengthened by using field note conventions. These included: 1) documenting each procedure used for data collection; 2) systematizing the field notes through recording what was seen, what was heard; and 3) expanding the field notes beyond the immediate observations. Furthermore, to manage the reliability of the research findings, the language advisor's used in their responses was clarified follow up questions. This ensured that the meaning of advisors interactions and discussions was never separated from a mutual interpretation of ideas. These procedures helped ensure that the categories reported were consistent throughout the data.

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CHAPTER FOUR: FINDINGS AND DISCUSSION

PharmaWatch's advocacy has been an effort to enhance public awareness, empowerment, and accountability in pharmaceutical safety issues, monitor pharmaceutical industry practices and spark regulatory change. On the basis of one year of participant observations and interviews with PharmaWatch board members, the findings present central tactics and issues the organization faced during the first year of its advocacy efforts. The following chapter presents and discusses the research findings, focusing on the strategies that PharmaWatch used to present epistemological and political challenges to pharmaceutical knowledge systems. This process involved the following four key strategies: 1) establishing an organizational identity focused on consumer rights; 2) converging with technology and understanding its role in consumer empowerment; 3) competing with the mainstream media to deliver pharmaceutical safety information; and 4) maintaining autonomy and avoiding co-optation. Combined, these initiatives work towards influencing knowledge practices that inform pharmaceutical policy. The presentation of the findings integrates descriptions of observations and the opinions and beliefs of PharmaWatch board members. Throughout the chapter, in order to retain anonymity of board members, a number from 1-6 is used to identify each board member.

Establishing an Identity Focused on Consumer Rights

The establishment of a clear identity was a central strategy used by PharmaWatch board members during the first year of the organization's pursuit of epistemological and political challenges of expert knowledge. In this context establishing an identity suggests developing a compelling sense of the organization's need, its vision and reason for existence. An organization's identity is ultimately the backbone of its efforts. Without a clear identity, an organization ceases to have unifying principles to guide its convictions and actions.

During initial participant observations of PharmaWatch meetings, disputes were observed surrounding the construction of the organization's language used to identify its advocacy efforts (November 13, 2003). For instance, prior to PharmaWatch's official launch, an on-line debate between board members addressed issues of language, in particular identifying the organization as a "consumer rights" group versus a "patient group" or "citizen group." In the end, consensus was reached and PharmaWatch board members adopted the term "consumer" to represent their advocacy efforts. Board members were later questioned about the organization's decision to employ the term "consumer" over "patient" or "citizen" and whether they believed potential repercussions existed because of this language choice. A number of board members justified the use of the term consumer based on the idea that the practice of purchasing and consuming pharmaceutical drugs falls within a consumer model. The following are from board members 3 and 6:

> [3]...PharmaWatch is a "consumer" group interested in safety and value for money, whereas "patient" groups these days tend to be

just interested in fighting for more access and funding for specific things. In Europe, the word consumer is not equated with over-consumption and market solutions - but consumer rights such as right to safety, information, choice, representation, remedies and affordable basic needs.

[6] All reports of ADRs will be coming to us from individuals who have consumed the drug in question; at that fundamental level, they are all consumers. Of course, there is always a potential problem with using a narrower term. However, it is my impression that all members of the [PharmaWatch] board have a strong sense of what a "citizen" is, so I don't think we will lose sight of the larger context and role.

Other board members approved the use of the term "consumer," yet they also recognized potential discrepancies with its use. This is indicated in the following replies from board members 1, 2, 4 and 5:

[1] In Health Canada, there is distaste for the term consumer, and they insist to call people patients, not clients. Similarly, in medical practice, the term patient is used over consumer, as people receive a service, not paid for directly. Both of these sectors identify patients as entitled to democratic citizen rights. On the other hand, the health industry employs the term consumer in attempt to identify them as consumers with money, not rights. In health protection, people are also referred to as consumers for once they're out of the doctor's office, people shop in drug stores and are buyers. These people are not identified as citizens with democratic rights, but as active consumers, purchasing in the market place.

[2] As far as I'm concerned the terms consumer, public or citizen could be used interchangeably. These are all legitimate terms because drug safety is an issue for more than just the people who actually use the medications. Those who care for medication users need to very involved in drug safety issues. The only problem that I see in using the term "consumer" instead of "patient" is that the word consumer may tend to imply a commodity relationship with medications and in my view medications are not commodities the same way that laundry detergent or automobiles are.

[4] Patient is a very disempowering term. Consumer implies a certain commercial relationship. Citizen is probably the best because it implies a contribution...However; consumer is used, as

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people are worried about waiting lists and buying medicine. The whole purpose of the ministry of consumer corporate affairs is because everyone knows consumers can get burned. Now, I don't know if that justifies it, in our case.

[5] The term means buy, buy, buy...but I use it all the time. Public or citizen would be better. I feel people need to reduce their drug consumption. Drugs are a LAST resort.

The findings indicate that while many of the board members were comfortable employing the term consumer, they were aware of potential problems with their designation. The organization's consumer-based identity was described in terms of its legal and ethical need to protect drug consumers from unfair pharmaceutical practices. Legally, board members expressed concern for the regulation of marketed drugs and the reliability of available drug safety information. Board members stated ethical concerns regarding the laissez-faire attitude that both the government and the industry have adopted in past years towards the gathering of consumer knowledge through post-market drug surveillance. For instance, board members 3, 4 and 6 stated:

[3] PharmaWatch is needed to fill a major...gap in identifying problems/side-effects far too long after drugs are on the market; to expose and make a point that the regulatory and governance system for the approval, marketing, and prescribing of drugs in Canada is failing people and our society badly; to create an entity that can speak out given the increasing limitations on other voices to protect citizens in our society; to kick ass for a change - by bringing together a powerful group of recognized experts with integrity who cannot be cowed by industry and provide a trustworthy place for consumers with problems to turn.

[4] The organization is needed based on the completely inadequate post market surveillance of drugs in Canada. There is a clear sense that the fed government is not doing what needs to be done in receiving adequate adverse drug information.

[6] PharmaWatch is needed because ADR reporting is abysmal, by regulators, health professionals and industry, and because citizens are the ones who have a real vested interest in reporting ADRs.

PharmaWatch and consumer rights

Overall, PharmaWatch board members established the organization's identity based on a consumer rights paradigm. PharmaWatch board members identified drug safety advocacy as a consumer rights issue by equating medicine to a consumer model, recognizing problems within the model, and consequently advocating for legal and ethical protection of consumers.

Identifying the organization as a consumer group, rather than as a patient or citizen group, was justified on the premise that the practice of knowledge gathering, purchasing, and consuming of one or many pharmaceutical products requires engaging with the market economy of pharmaceuticals. From this perspective, people are not simply passive patients who surrender to the expert knowledge of medical practitioners. Rather, people are consumers of pharmaceuticals, who have a responsibility to actively seek out knowledge about the benefits and risks of pharmaceutical products and develop opinions about their consumption experience. In other words, 'caveat emptor'. This perspective epistemologically challenges current pharmaceutical knowledge practices by encouraging people to rethink their role in drug safety and decide whether their rights to safe and timely pharmaceutical information and products are fulfilled.

From certain sociological critiques, such a consumer-centric focus carries problematic repercussions. For instance, Stuart Ewen would argue that a focus on consumerism replaces ideals of citizenship (1976). Bryan Turner argues that

citizenship can be described as a set of practices that define a person as a competent member of society, and which consequently defines the flow of resources to people or social groups (1993). As a general theory, Turner suggests citizenship addresses concerns with: "a) the content of social rights and obligations; b) with the form or type of such obligations and rights; (c) with the social forces that produce such practices; and (d) with the various social arrangements whereby such benefits are distributed to different sectors of a society" (1993, p.3). These principles of citizenship are threatened in a society that defines and represents its members as consumers rather than citizens and where the exercise of political will is conceived as a consumer right. While PharmaWatch board members expressed awareness of the philosophical repercussions of using the term consumer, they argued overall that it is suitable to classify the organization as a consumer-based advocacy group. Board members believed their consumer-based identity represents fundamental principles of public and institutional rights and responsibilities. Whether using the term consumer, patient, or citizen group, PharmaWatch's concerns and fundamental principles regarding ethical issues and legal rights challenge how the public, the government and industry think about their obligations as pharmaceutical consumers, producers and distributors. The values of citizenship are foundational to PharmaWatch's advocacy effort, in their effort to ensure that consumers' rights to safe pharmaceuticals and reliable information about their effects. According to PharmaWatch board members, the creation of a forum

where consumer voices can be heard by other drug users, manufacturers and regulators is essential for such a process to occur.

Consumer engagement in pharmaceutical knowledge transfer

Identifying PharmaWatch as a consumer group encourages pharmaceutical drug users to know and question their rights as consumers. It also encourages them to become involved in the transfer of knowledge surrounding drug safety issues with other drug consumers, government and pharmaceutical practitioners/manufacturers. On a political level, establishing an identity based on consumer rights works to circumnavigate the current expert control of pharmaceutical knowledge by encouraging enhanced consumer engagement in pharmaceutical knowledge transfer.

PharmaWatch board members believe that their initiative has the force to influence public policy. Board members particularly identified the role they could play in pharmaceutical knowledge transfer, particularly the research, monitoring and sharing of information and analysis regarding adverse drug reactions. For example, board members 2 and 6 stated:

> [2] PharmaWatch can influence public policy in a number of ways. Its very existence (even without receiving drug reports) says to Health Canada (and the media) that there is a group that has serious concerns about the issue of drug safety. That alone means bringing attention to the issue and sparking further debate. Once PharmaWatch starts to get reports and analyze data it will be able to influence public policy by pointing out how consumer reporting is an important component in ensuring safe use of medications. By putting consumers back in the centre of the process that will also influence public policy. Finally, the educational work that PharmaWatch does will help consumers to push Health Canada independently of what PharmaWatch does.

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[6] By being able to collect information, provide information and more important education, expose issues, and be available to people who want to know more. I.e. the real decision makers are the public. Of course, encouraging and working with enlightened and informed professionals like pharmacists and doctors is important too. We are an example of the power of "one" - not blaming each other, but solving problems.

In Canada, the current pharmaceutical knowledge transfer process is predominantly one-way. Consumers do have access to pharmaceutical information from their pharmacists, doctors, patient information leaflets created by the manufacturers, and copious amounts of questionable information on the Internet. However, inadequate initiatives exist to encourage consumer feedback about pharmaceutical experiences. As discussed in previous chapters, the one Canadian program in place to gather consumer experiences and knowledge about pharmaceutical products, the Canadian Adverse Drug Reaction Monitoring Program, has by no means been easily accessible to consumers. Although the program began in the 1970's, it was only in 2004 that consumers actually had access to some of the data. It took three years of lobbying by the Canadian Broadcasting Corporation (CBC) through the Access to Information Act to have the database made accessible to the public (Kermode-Scott, 2004). Regardless, there is currently little accountability for the actual use of pharmaceutical experiences reported by consumers. For PharmaWatch, the aim is to improve the communication process and encourage consumers to be active participants in pharmaceutical knowledge sharing and gathering. Through establishing this critical consumer collective, the organization intends to work as a force to call the

government and industry to task over the approval and marketing of unsafe and ineffective drugs on the Canadian market.

Positioning the organization as a consumer group further speaks the economic language of industry and government. To date, the two main governmental bodies lobbied by PharmaWatch are Health Canada and the Office of Consumer Affairs and Public Involvement. Both of these arms of the Canadian government discuss and identify the Canadian public as consumers.

Overall, PharmaWatch's decision to establish an identity based on consumer rights challenges pharmaceutical drug users, the pharmaceutical industry and the Canadian government to take accountability and action in ensuring that consumer knowledge and experiences with pharmaceuticals are contributing to the institutional think tank that controls the regulation of pharmaceutical drugs on the Canadian market. Alongside this process, however, PharmaWatch board members must devise effective strategies to challenge the myth that debunks the legitimacy of consumer reporting.

Defending the validity of consumer reporting

A critical strategy used by board members to challenge current biomedical knowledge structures was defending the validity of consumer reporting and the value of personal narratives. This issue was evident throughout both participant observations and interviews with PharmaWatch board members. In one meeting for example, board member 1 stated, "The value of stories and personal experiences should not be lost. The idea of this type of narrative has a different

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value. Our aim of encouraging general consumer reporting and narrative is to ultimately influence policy" (March 1, 2004). The value of personal experiences and consumer reporting is explicitly stated in all of PharmaWatch's public documents (including their website, press releases and funding proposals). Consider this excerpt from the organizations self characterization on its website:

> PharmaWatch believes that consumers and patients have unique perspectives and experiences. They can provide information and insight that contributes to the effective and safe use of medicines. Reporting by patients and consumers can provide an early warning signal to regulators, manufacturers, physicians, health professionals and other consumers. The goal of PharmaWatch is to highlight and validate consumer experiences and heighten consumer involvement in adverse drug reaction reporting. (PharmaWatch, 2004).

The issue of the validity of consumer reporting versus the adequacy of drug regulation was raised during a community outreach discussion. A member of the BC People with Aids Society (BCPWAS) asked, "You mention a lot of ADR reports submitted from patients who use a number of drugs. How does one decipher the causes? If a pharmaceutical company says it's effective, how is it approved in the first place?" In response to this question, PharmaWatch board member 1 replied, "The job is not to establish links to a particular drug. The job is to provide suspected links. If you have accumulations that are similar, Health Canada needs to follow up. [You] don't need to be a scientist, [you] need to suspect there is a link" (April 10, 2004).

When PharmaWatch board members were later asked how they deal with criticisms concerning the quality and reliability of drug safety information reported by consumers, the following reasons were used to defend the quality of

consumer information. Board members commonly suggested that there is a clear distinction between the way consumers express their experience with side effects and the way that doctors report them. Overall they identified the need to validate the voices and experiences of people affected by pharmaceutical drugs through rethinking what 'objective', 'quality' information implies and encouraging drug consumers to record and tell their own stories. Examples of this are in the following statements from board members 2, 3 and 6.

[2] There are concerns with the type of reports submitted by doctors and pharmacists also. While it is true that consumer reports may not be as "sophisticated" as reports by health care professionals, at the same time there is a great deal to be learned from the way that consumers express what is happening to their bodies. If you read what patients have written it is often much more nuanced than how their experiences are expressed in written reports.

[3] If you mean the reliability of consumer reporting, I say that is just as reliable as a doctor's initial diagnosis of disease - or drug reactions. I worked as a nurse for 30 years. In 30 years of nursing, I came to recognize that the observations of patients - particularly chronically ill patients - related to drug reactions or problems - ultimately showed up in the CPS or would be widely recognized a decade later. Yet usually, patients' observations were routinely denigrated and denied by most health professionals at the time. How many examples of new wonder drugs with mega problems down the road do you want? In almost every case, I can tell you that I heard patients complaining about these problems afterwards. Nonetheless, it is difficult for both patients and doctors and nurses to sort through whether or not the problems are coming from a drug, a disease or the environment. I also had a mother (and a good friend) who was throughout her life - was super sensitive to drugs - and her responses were never at the top of the bell curve, but often the problem turned out to be the drug. Patient's initial reports are as accurate at physician's initial reports. Most often, doctors diagnose based on ruling out other causes, but often don't have the time to go through this often laborious and time-consuming process. If patients can understand the risks/benefits, how to keep journals, and identify linkages this would be a great service to all. My favourite saying is that "non-compliance" with patients is just a difference in opinion - and often the patient is right.

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[6] We point out that what little data there are points to the fact that information on ADRs generated by consumers is more robust and vivid and detailed than that arising from other sectors. We believe that it is therefore a valuable contribution to what is now a pathetically mishandled issue, and that the deficiencies of such information are far outweighed by its strengths.

Throughout its first year, PharmaWatch board members routinely dealt with criticism concerning the quality and validity of consumers' narratives describing their experiences with pharmaceutical drugs. By sharing a combination of their personal and professional experiences with drug safety and ADR reporting, board members argued that the insights and early warnings consumers can provide are valuable, critical, and in some instances superior to the quality of reports submitted by doctors. Throughout board meetings, public talks, media inquiries and at conferences, board members insisted that local knowledge based on shared experiences should not be invalidated by reference to what is considered objective facts derived from scientific knowledge. Ultimately, PharmaWatch board members worked to challenge the myth that treated clinical drug studies and debunked the actual experiences of consumers as the gold standard of objectivity, validity and reliability.

PharmaWatch board members' insistence on the validity of consumer reporting is supported by a recent United Kingdom study by Medawar and Herxheimer (2004). The study compared the quality of adverse drug reaction reports by professionals and patients reports of the same suspected adverse drug reaction with the drug paroxetine (an antidepressant, also known as Paxil®). The report concluded that the quality of professional reporting and interpretation of data was poor and inferior compared to that provided by

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patients. Medawar and Herxheimer suggest that flawed and miscoded analyses of Yellow Cards (the ADR reporting form in the UK) have resulted in an under-estimation of the risks of the relationship between withdrawal and dependence, injury and poisoning and suicidal behaviour with changes in drug concentration. They suggest the enforced level of responsibility and accountability of health professionals produces a systemic or structural problem. Patients' time with doctors is increasingly cut short because doctors are pressed for time. Filling out a report is not a priority for doctors; it is therefore increasingly becoming the patient's responsibility to account for their own information. As with critics of the Canadian drug safety system, Medawar and Herxheimer suggest the Yellow Card is both chaotic and misconceived. This offers a partial explanation for the emergence of consumer organizations like PharmaWatch. PharmaWatch is one of a select number of organizations in Canada concerned with drug safety and advocating for a system that acknowledges the validity of patient narratives and does not allow biases of biomedical knowledge to deligitimate these voices. In order to facilitate the sharing and reporting of personal experiences with pharmaceuticals, PharmaWatch converged with technology to develop a consumer-operated on-line ADR reporting forum.

Converging with Technology

In its first year of development, PharmaWatch employed communication technologies to challenge the alleged objectivity and impartiality of biomedical knowledge. PharmaWatch board members developed a technological mandate, infrastructure and user policy during this process.

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The development of a technological mandate involves establishing what

the organization wants to accomplish, and the milestones to monitor what they

are accomplishing. While PharmaWatch board members did not explicitly reveal

a technological mandate, the observations suggest that their mandate was

framed by a deterministic attitude towards the Internet. In the initial days of the

organization, board members celebrated the Internet's emancipatory potential as

well as its capacity to expose PharmaWatch to a wide public audience, to gather

personal experiences and to network with allied associations – essentially, to

break monopolies of biomedical knowledge. For example, board members

attending an initial board meeting agreed with the statement:

> The hypothesis is that stimulating consumer reports means more
> information rapidly. In order for this to work, we need awareness
> and a web based system (for people who want information and
> support) to create a two-way system. This is an attempt to support
> informed choice (Board member 1, September 5, 2003)

Once the website was up and running later in the year, board member [1]

distributed an e-mail to PharmaWatch board members which stated:

> Our website is up and running -- finally! It's at
> www.PharmaWatch.net. Many thanks to the folks at Memorial
> University who have helped us to get up and running in
> cyberspace. There are still a few wrinkles that need to be worked
> out, but at least we're out there and -- even more amazing --
> findable on Google, the true test of legitimacy (March 31, 2004).

Technological infrastructure organizes and manages the flow of

information. PharmaWatch's main technological infrastructure included its

website, e-mail list and phone line. In terms of infrastructure, board members

developed a consumer adverse drug reaction data collection of reports. This

included an on-line form including name, condition, other drugs used, adverse drug effects, permission to relay to Health Canada, telephone number and a link to highlight where to access information and navigate to alternative sites (e.g., CADRMP, BC NurseLine, companies, etc.). A further option was telephone reporting and speaking with a PharmaWatch representative who would directly input the consumer information into the database.

The user policy addresses issues of rights and permissions. It answers questions such as who has the right to the information, including the right to post and edit messages. It also deals with what links will be included, such as medical journals, news clippings and bulletins. Finally, it addresses how feedback, if any, will occur. The initial user policy issues that were predominantly discussed by PharmaWatch board members included protection of privacy use of data, and how consumers' would distinguish their website from Health Canada's existing CADRMP. A computer scientist from Memorial University of Newfoundland (MUN) developed the site and dealt with these issues with the PharmaWatch president as they evolved. A user access and privilege policy was designed to allow adverse drug reaction reporters (including pharmaceutical consumers' family and friends) to post and update messages. With this design, ADR reporters do not have access to each other's data; rather it is collected and hosted on a MUN server. PharmaWatch executive members have access to this data and monitor the reporting trends.

In a later interview, board members were asked about their beliefs about the use of the Internet for data gathering and sharing. Overall, board members

remained confident in their established on-line presence. The Internet was

described as a tool for both connecting the board and providing an efficient

mechanism for consumers to report adverse drug reactions. The few problems

identified concerned privacy and frustrations with using the technology. The

following statements reflect the beliefs and concerns of PharmaWatch board

members 2, 3 and 4:

> [2] The Internet can be either a good or a bad way to gather information. Some people want the anonymity of reporting through the Internet while others need to hear a human voice. I think that PharmaWatch has to offer both ways of getting in touch with the organization.

> [3]...what is interesting is that the people on the board had been working in isolation in different parts of Canada...on many of the same issues - and from different perspectives for years and years...and all come to similar conclusions about the problems around drug safety. Also, while I do get frustrated with the technology and the Internet at times, I think that probably another significant factor was the penetration of personal computers and Internet options which did not exist to the same extent in the early 1990s and the potential for this kind of virtual board to exist. Even opening documents was a problem until the late 1990s.

> [4] The Internet is a tool and needs quality control. Whether people are reporting by phone or fax, the Internet makes it faster and easier.

As the year progressed, the number of reports actually made to the

website encouraged board members to rethink the emancipatory function of the

Internet. An equal number of adverse drug reaction reports were submitted via

the telephone line.

The Internet and consumer empowerment

Throughout the year, PharmaWatch's expectations concerning the use of the Internet as a mechanism for consumer convergence and institutional resistance differed from their actual experiences with the technology. After six months of the on-line database trial, PharmaWatch board members were asked to comment on its effectiveness and whether the Internet met the organization's expectations. Board members responded by expressing concerns about confidentiality, privacy and the need to "fool-proof" their website.

The elementary mechanism PharmaWatch can use to deal with privacy issues is ensuring the anonymity of names and emails, establishing strict user settings and ensuring that the server is behind advanced firewalls. In order to maximize the Internet's potential for data gathering and sharing, these are precautions PharmaWatch will have totake to overcome potential ADR reporters fears. This is a difficult comfort level to achieve as the public is constantly reminded that nothing is completely 'safe' or 'secure' on the Internet. Furthermore, the gap in the Internet's accessibility and use in a large percentage of the population, especially the elderly and people within rural settings limits PharmaWatch's consumer reach.

Critical questions concerning technological uptake are essential to understanding further how the organization can adopt and provide the most effective consumer reporting mechanism. Such questions include: Are drug consumers comfortable reporting on-line? How can their privacy and confidentiality be ensured? How do other organizations with similar strategies

work out these issues and how can PharmaWatch learn from them? There exists only one other organization that resembles PharmaWatch's advocacy efforts – the Sweden-based Consumer Institute for Medicine and Health (or Kilen). This organization has twenty-seven years of experience gathering data from people suffering from adverse drug reactions. Kilen uses its database as an instrument for the early detection of drug side effects, which the organization compiles and disseminates to government agencies, other relevant parties, and at times on their website. PharmaWatch could learn from organizations like Kilen, how to effectively and legally collect, assess and use patient narratives of adverse drug reactions. For instance, after its first year, PharmaWatch was monitoring the ADR reports consumers were submitting to the organizations database with the intention of 'alarming' Health Canada of drug safety indicators that emerge. In order for PharmaWatch to improve the quality of ADR data collection and analysis, further research that focuses on assessing the development of an independent Canadian system for analyzing consumer reports and how to legitimately present findings to Health Canada is critical.

Overall, caution must be taken to avoid over-dependency on the Internet. Board members were humbly reminded that the Internet is just one tool for raising awareness and participation. If PharamWatch wants to use the Internet as a means for advocacy after its first year, it must use an integrated strategy that employs a variety of mechanisms to raise the organization's profile and project its voice.

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Competing with the Mainstream Media

A crucial strategy employed by PharmaWatch for breaking knowledge monopolies and presenting an epistemological and political challenge to current pharmaceutical information practices involved developing an understanding of the role the mainstream media play in exposing advocacy efforts. During the organization's first year, this process entailed challenging how both the public and reporters understood and conveyed ideas surrounding pharmaceutical drug debates. In using the mass media as a mechanism to expose itself to the public, PharmaWatch had to articulate a convincing message concerning pharmaceutical drug safety, while packaging it in a way that did not make people afraid of the message. The journalistic framing of consumer advocacy and the bombardment of commercial pharmaceutical messages were two critical factors that influenced and challenged this process.

Framing PharmaWatch

PharmaWatch and other advocacy groups must recognize that when they become media figures, they also become players within an inevitable journalistic battle. Public advocacy stories are often crafted as an "us vs. them" conflict of competing viewpoints because the mainstream media believes in objective reporting (as per the codes of journalistic professionalism). Consequently, advocacy voices that speak out publicly about issues of drug safety are inevitably represented through a controversial frame.

Prior to the organization's public launch at the 2003 PharmaWatch conference, PharmaWatch disseminated a media advisory and press release

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and hosted a news conference. The press release was disseminated to provincial and national media. It highlighted the conference as a gathering of consumers and drug policy experts to launch the organization as a consumer-based Canadian pharmaceutical 'watchdog' dedicated to post-market monitoring and drug safety. While the press release presented a subtle tone of critical remarks pointing to the Canadian government's ineffective adverse drug monitoring program, it depicted the conference as an arena for vigorous discussions regarding the conflict between consumers and industry and government drug safety practices. For example, PharmaWatch president Colleen Fuller is quoted as saying, "...[T]here is often a kind of snobbishness within the medical community and Health Canada about the quality of consumer reports." She further stated, "...we can develop a powerful and authoritative voice on drug safety and policies needed to support informed choice" (PharmaWatch News Release, 2003). Overall, the news release was framed in a way that teased reporters' appetite for controversy. In an attempt to gain the media's attention, PharmaWatch press writers ultimately fed reporters their own spin. The crafting of the first media release suggests that PharmaWatch was aware of media framing and ready to publicly engage in a controversial light.

Overall, the media release proved effective in gaining the attention of independent media sources. In total, fifteen local, provincial and a few national media representatives attended the news conference. The immediate news coverage regarding PharmaWatch's drug advocacy efforts was mainly provided by local news groups such as Vancouver's *Georgia Straight* and *The Tyee*.

These pieces presented a critical portrayal of the pharmaceutical industry and promoted PharmaWatch as a timely and necessary consumer organization. The coverage used a combination of sound bites from PharmaWatch representatives who have experienced adverse drug reactions and medical professionals who serve on the PharmaWatch board as voices of authority regarding drug safety issues.

While the mainstream media did not immediately pick up the PharmaWatch story, a media blitz surrounding the pharmaceutical drug safety controversy unfolded shortly after the PharmaWatch launch. Radio stations such as Vancouver's, CKNW: 980 hosted a discussion between PharmaWatch board member Dr. Barbara Mintzes and Canadian Medical Association president Dr. Sunil Patel about the advertising of prescription drugs. It was anticipated that the show would present a heated debate between a drug policy academic/drug safety advocate and a medical expert. In the beginning, Dr. Patel was introduced as having been quoted in the *Globe and Mail* saying, "Canadians want more information about drugs and advertising regulations should be changed." This point was never actualised in the discussion; rather, both sides voiced concerns and reaffirmed the need for pharmaceutical information regulations. While Dr. Patel suggested conflicts of interests in drug information, stating, "pharmaceutical advertising leads to greater demand and makes the drug more expensive, yet it is not proven as more beneficial," Dr. Mintzes furthered his notion, demanding that the public has a right to a full range of information and

pointing out the need for an independent organization like PharmaWatch (CKNW 980: The Bill Good Show. January 13, 2004).

In February 2004, not long after the radio exchange between Mintzes and Patel, a *Vancouver Sun* health columnist presented a critical piece entitled "Health Consumers Need a Voice." Quoting PharmaWatch board member Alan Cassels, this piece presented the need for enhanced consumer involvement in health issues rather than misleading representation from industry-funded special interest groups.

The CBC subsequently produced a special documentary series called *Generation RX: Faint Warning*. This coverage investigated Health Canada's post-market drug surveillance system and issues surrounding Health Canada's adverse drug reaction database. The series was featured on CBC Radio, Television, Newsworld and cbc.ca throughout the week of February 16, 2004. This series included pieces such as: *Kids on Viagara; When Treatments Go Wrong; Problems in the System;* and *Pushing for Change*. Furthermore, in February and March 2004, four articles regarding drug safety within Canada were released on CBC News Online. Combined, these pieces functioned as a powerful critical exposé of the poor state of Canadian pharmaceutical drug safety regulation and enforcement. An underlying theme throughout the series was scepticism about the Canadian government and pharmaceutical industry's lack of transparency of critical drug safety information. For instance, each piece questioned the accessibility and openness of Health Canada's adverse drug reaction database to public scrutiny. They highlighted the fact that CBC

underwent a five-year legal battle through the Access to Information Act to gain

the right to access and publicize the information. The database was used by

CBC reporters to present the public with stories regarding hidden discrepancies

with various drug classes (*The Current,* February 17, 2004). Furthermore, three

PharmaWatch board members were interviewed and referred to throughout the

series as advocates for changes in drug policy and Health Canada adverse

reaction reporting mechanisms. For example, Terrance Young the father of 15

year-old Vanessa Young who collapsed to the floor with heart failure after being

prescribed Prepulsid® for vomiting, stated:

> Nothing significant has changed at Health Canada since Vanessa
> died...[T]hey fiddle around with their 1-800 numbers, and they've
> improved their web page, and they're working on a template, and
> they'll give you all kinds of nice, nice words but nothing significant
> has changed. So what happened in my family could happen in your
> family (When Treatments Go Wrong, February 17, 2004).

While the CBC presented a critical view of drug safety issues, the

newsgroup continued the inherent controversial framing of public advocacy. The

story of the battle between drug consumers and media reporters held captive by

the government and pharmaceutical industry 'information mobsters' was

interwoven throughout the series. For most PharmaWatch board members, the

overall framing of consumer advocacy within the media as a controversial subject

did not appear to be an issue. PharmaWatch board members valued the

coverage provided by the CBC. As board member 1 stated:

> CBC did a fantastic job on drug safety coverage. Bob Carty and
> Dave McKie are really committed people. Dave McKie proposed
> the whole scandal and Bob comes from the same social orientation

and was able to get the databases. People are all over the databases (March 1, 2004).

Yet, board member 2, expressed scepticism about the media's potential to sensationalize PharmaWatch's mission.

> I think that the media can help make the PharmaWatch name known and therefore can be very positive. At the same time we need to be careful that the media does not "sensationalize" what we are doing...

When PharmaWatch board members were asked about their opinions of the media's role in framing and delivering PharmaWatch's consumer advocacy efforts and drug safety message, board members generally agreed that the media plays a critical but positive role. As board members 3 and 4 stated:

> [3] I see linkages with the media as being critical in today's world for anyone trying to get out information. There is great interest because we are not yammering about public/private - but an important safety issue that everyone has a stake in. And media are busy folks who appreciate things being packaged well and provided by people they can trust. Again, in my view PharmaWatch and integrity should walk hand in hand. We may not be big and splashy, but we are trustworthy.

> [4] [The media's role is]...absolutely vital...I think "Market Place" is one of the few media outlets that does consumer stuff well. Stuff done on drugs is top notch. Remember Terrance Young, he said, "the month before his daughter died, CBC had done a program on the dangers of Propaulsid®, that there were serious reports." He said, if I had seen that program my children would still be alive. In terms of the power of media it is unbelievable, that could have stopped his daughter from taking a dangerous drug.

The number of adverse drug reaction reports received by the organization immediately following the exposure suggested that the public was not dismissive of controversy. Rather, the coverage attracted the public's attention. One month

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following the media coverage, PharmaWatch had continual phone calls and on-line reports submitted to their database. However, when the PharmaWatch president was asked about public response to the PharmaWatch launch two months after the media coverage, she stated:

> In terms of the public calling into the organization to report ADRs, nothing has unfolded. It doesn't surprise me, though. To have people using the reporting line, you always have to have it out there. Reporting increased on a fairly consistent basis the month following the conference. What I mean by that is people were phoning in response to news reports about PharmaWatch. People were writing letters about PharmaWatch, encouraging our efforts. It's like we have a fan club on its way. Currently however, we aren't getting reports, because we haven't been getting out there. We need to develop a strategy so people know about us. Consumers respond to media attention (April 5, 2004).

This quote states the obvious: "having it out there" means that mass media coverage is essential for building PharmaWatch's public presence. By the spring of 2004, once the mainstream media buzz concerning PharmaWatch's drug safety advocacy efforts slowed down, so did feedback and consumer reporting to the organization.

The bombardment of commercial pharmaceutical messages

The mainstream media has and played an important role in delivering PharmaWatch's message concerning the need for enhanced consumer awareness and involvement in drug safety issues. These messages are crucial in the organization's attempt to challenge the public's understanding and actions towards ensuring they receive safe, effective pharmaceuticals and timely, relevant pharmaceutical information. Overall indications suggest that PharmaWatch's media coverage from October 2003 to February 2004 critically

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exposed drug safety issues in the public arena. However, PharmaWatch will have to contend with the notoriously poor quality of reporting about pharmaceuticals in Canadian newspapers and the increasing presence of direct-to-consumer pharmaceutical advertising.

Drug critics argue there is poor and unrealistic reporting of pharmaceutical information in Canadian newspapers. In April 2003, the Canadian Centre for Policy Alternatives published the report: *Drugs in the News: How well do Canadian newspapers report the good, the bad and the ugly of new prescription drugs?* (Cassels, Hughes, et al). Created by researchers in the health and drug policy field, this report discussed findings from a study examining the quality of information provided on new medicines in Canadian newspapers. The researchers examined media coverage of five prescription drugs launched in Canada in the last five years. Researchers identified one-hundred and ninety-three articles describing the health effects of these drugs in twenty-four of Canada's largest daily newspapers. The articles were then examined for the way in which the drugs were reported. The report found that newspaper articles frequently emphasized the benefits of new drugs and paid little attention to potential problems they might cause, regardless of the article's length. For instance, 68% of the articles made no mention of the possible drug side effects. Furthermore, benefits were most often identified in the first quarter of the article, while harms were identified in the article's third quarter. Contraindications – the circumstances under which it is not safe to take the drug – were mentioned only four percent of the time. Only one in six articles mentioned non-drug treatments.

Finally, behind the scenes financial interests were infrequently discussed. Most

spokespeople for patient groups or academic researchers were quoted without

any discussion of their financial links to drug manufacturers. The report suggests

that newspapers provide poor quality pharmaceutical information and may

promote unrealistic expectations regarding the benefits of drugs.

Newspapers with inadequate reporting of pharmaceutical drug information

are one of many information sources PharmaWatch must compete with in

spreading its drug safety message. PharmaWatch's other forms of mainstream

media competition include direct-to-consumer advertising initiatives, which

appear in Canadian newspapers, television and magazines, as well as on

billboards and radio. PharmaWatch should not technically have to compete with

pharmaceutical advertising in the Canadian market. However, with loosely

enforced regulations, pharmaceutical advertisements have permeated Canadian

airwaves, magazines and billboards. One can see this with the presence of "I did

it my wayyyyy," Viagra ads or Diane 35 billboards. Pharmaceutical industry

lobbyists are demanding that drug manufacturers be able to legally advertise

their products directly to consumers. However, PharmaWatch board members

are working to challenge this perspective. According to PharmaWatch's Barbara

Mintzes, "the public has the right to a full range of information, for public safety

reasons...what is needed is an independent organization to access

pharmaceutical information. If one has a problem with a drug [one] should know

where to report it. If one is seeking information on drugs, [one] should know what

other people have experienced." That, she stated, is the intention of PharmaWatch (January 13, 2004, CKNW 980).

The mainstream media's exposure of PharmaWatch has to date been primarily delivered in a frame of controversy. However, initiatives like the CBC "Faint Warning" series and critical writers from independent newspapers such as the *Georgia Straight* and *The Tyee* have demonstrated that the controversy angle may be working to deliver their contestative message. Furthermore, the number of PharmaWatch consumer reports and patterns of reporting suggest that the media plays a critical role in shining light on the organization as an active advocacy group within the public sphere. This interpretation is reinforced by PharmaWatch board members' perspectives on the media.

The increasing number of commercial messages promoting the benefits of pharmaceutical drugs, from newspaper articles to direct-to-consumer advertising, suggests collusion between industry and state forces. While policy is in place to regulate commercial pharmaceutical publicity, little to no enforcement is provided. Consequently, the financial interests of pharmaceuticaland media industries take precedence over consumer safety. Like the pharmaceutical industry, PharmaWatch uses commercial media to present its position. Yet in order to package a compelling message that challenges popular notions about pharmaceutical information practices, and confronts biomedical knowledge monopoly, PharmaWatch must continue to use the mainstream media as just one strategy for the dissemination of its message.

Maintaining Autonomy without Being Co-opted

The organization's ability to maintain autonomy without being co-opted has been central to PharmaWatch's epistemological and political challenge to current pharmaceutical practices. During its formative months, discussions regarding the best strategy for PharmaWatch to maintain its autonomy were raised in board meetings and at the PharmaWatch conference. Board members expressed intentions to mobilize alliances and build networks while remaining an independent public/consumer oriented organization, separate from government and industry influence. Board members suggested this would involve mobilizing alliances and building networks with like-minded advocacy groups. The organization also sought to remain committed to independent and interest free funding – that is, funding from sources that would not produce conflicting interests or influence over PharmaWatch's principles or actions (Bell, 2004).

Mobilizing alliances and building networks

PharmaWatch is composed of board members who are epistemologically and politically minded in their drive to induce change in pharmaceutical industry practices. They are particularly concerned with how, by whom and in whose interest drug safety information is produced and disseminated to consumers. PharmaWatch board members have had various personal and professional experiences with the health care and drug industry. The core of the PharmaWatch board represents voices of Canadians who hold both personal and political interests in drug safety advocacy, from patients who have had adverse reactions to medical doctors, former nurses, and drug activists.

Since its inception, founding members of PharmaWatch have been building a network of academics, consumer health advocates, media, government representatives, and community groups to form the organization's foundation. The roots of the organization stem from the development of a Montreal-based consumer advocacy group, DES Action, the first of its kind in Canada. DES Action became affiliated with the Women's Health and Protection Board of the Women's Health Network, for which PharmaWatch co-founder Colleen Fuller (a health writer) had been writing. As a diabetic, Fuller had personal experiences with the adverse side effects of doctor prescribed medication. After having been switched from natural animal insulin to genetically engineered human synthetic insulin, Fuller fell into a coma five times and was hospitalised for months. This inspired her, and her established peers, to collaborate with DES Action founders to form PharmaWatch, a group that would represent the voices of consumers who have experienced adverse effect from drugs. After conversing with other citizens concerned about drug safety, including community activists, academics, medical doctors and concerned citizens, they organized a nationwide non-profit organization that would represent the voice of drug consumers and build awareness about drug safety issues.

When Pharmwatch board members were questioned about their purpose and the extent of their involvement with drug safety advocacy, board members expressed comparable sentiments. A majority of members indicated that they were initially "independent" advocates with particular interests in exposing drug

safety issues at both personal and political levels. The following are responses are from PharmaWatch board members 2, 3, 5, and 6:

> [2] I was contacted by [board member 1] because of my long-standing interest in drug issues. Although I am a health care professional I have close contacts with the consumer movement in this area and have been supportive of more active involvement of consumers.

> [3] Well, it really sort of started back with the National Conference on Pharmacare - post the National Forum - in my view. It brought together the 300 most knowledgeable people in Canada on drug safety and payment issues all hyped to design Canada's new Pharmacare Program. They gave us an agenda that treated us all like people off the street who had never looked at these issues before, and wanted us to simply sit around in small groups and discuss how to "knit one and purl two." ...We were so ticked, about 40 of us met in a meeting room after the registration...for the first time, a bunch of knowledgeable, competent activists from all sorts of backgrounds got together, worked together... we all exchanged coordinates - and that's how the (anonymous) list-serve got started eventually....(T)hat is how PharmaWatch was born - a group of citizens from all political spectrums saying that the people who take these drugs need to be respected and valued and listened to - and saying that it is just plain wrong to so blatantly disregard the harm caused to them by drugs. And damnit, if the government won't help, we'll do it ourselves as a consumer co-operative - the old fashioned way.

> [5] I am an advocate for people trying to get off psychotropics. Their stories are dreadful and some cannot succeed. I realized that I needed to work at the political and personal level.

> [6] I got involved through my membership in the (anonymous) list-serve, coupled with my longstanding commitment to equity in health care, and my evidence-based realization that ADR reporting would never progress otherwise.

The above-mentioned anonymous Internet list-serve has been a central source for PharmaWatch board members to network and build alliances. This list-serve was started and is maintained by Women and Health Protection, going back to

1997. It was formed to link citizens concerned with pharmaceutical drug issues and women's safety. A majority of PharmaWatch board members have been active on this list-serve, which is composed of members from a variety of organizations across the globe who share common critical perspectives on the pharmaceutical industry's motives and actions. This list-serve functions as a networking tool for PharmaWatch board members as well as a forum for watchdog activities related to pharmaceutical industry practices.

PharmaWatch has evolved as a pro-active autonomous organization through the networking of like-minded drug safety advocates. The choice of who PharmaWatch linked to its website is just another indicator of its effort to mobilize alliances with like-minded coalitions. The website included links to organizations such as: the Australian Adverse Drug Reaction Reporting; Bayerwatch; Benzodiazepene Addiction, Withdrawal and Recovery; Canadian Health Coalition; CBC Disclosure; DES Action; Health Action International; Kilen; Public Citizen; Therapeutics Initiative; and Women and Health Protection.

The process of expanding the organization's alliances and network extends beyond building ties with any and all members of health organizations. A few critical issues arose during the year that challenged the ease of expanding PharmaWatch's network. These include debates surrounding membership. The findings suggest that for PharmaWatch, the process of networking and building alliances is quite a political process.

For example, during various board meetings the topic of establishing a PharmaWatch membership base was explicitly discussed (December 9, 2003,

December 12, 2003, March 1, 2004). Responses were consistent when board

members were questioned about their personal opinions regarding a

PharmaWatch membership base and whom they would include or not include.

While a majority of board members agreed with some form of membership, most

expressed concern about workload, changes in organizational structure and how

to ensure that members do not hold conflicts of interest. The following are from

board members 2, 5 and 7:

[2] I'm not sure what membership would involve so I haven't thought much about the positive and negative side of this question. However, if PharmaWatch were to become a membership organization then we would have to figure out some way of allowing people all across the country to actively participate in discussions and voting. This would probably require some lateral thinking to come up with ways of facilitating this. If we were to offer memberships the only people that I would restrict from joining would be people employed by the pharmaceutical industry.

[5] Honestly I hadn't given much thought. It is one of those things that have pros and cons on either side. I do know that managing members is a big hassle, and before going ahead we have to make sure it is worth the effort. That's all I can say about that.

[7] PharmaWatch is already affiliated with several organizations, the most important connection being, of course, with DES Action. We are also connected to several other "civil society" entities related to ADR reporting, and we can comfortably relate and affiliate with any legitimate non-profit (i.e. not a "front" group) that shares our concerns.

Identifying potential allies and the opportunities and challenges they may

pose was a frequent topic of discussion during meetings (November 12, 2003,

November 23, 2003 and December 9, 2003), a public talk (April 10, 2004) and

within the PharmaWatch 2003 proposed fundraising mandate. At one board

meeting, for example, the topic of building alliances and the tension that certain

groups could cause was discussed. As board member 1 stated:

> We need to continue to build alliances with groups such as DES,
> SDR (Society for Diabetic Rights), BCA, Benzo Awareness
> Network, Depropravera Group (just initiating) and the Paxil group.
> Often these groups emerge around lawsuits.

> However, we do need to talk about what to do with larger disease
> groups. PW doesn't want their money, [we] don't want alliances, but
> access to their members. Arthritis society...doesn't mind being the
> total front group for the industry. They don't deny it either. They are
> so in bed with the industry. They formed the Best Medicines
> Coalition...all of the money for the coalition came from
> pharmaceutical industry. This makes it easy for disease groups to
> join. [The pharmaceutical industry] poured money to form them.
> Glaxo completely paid for [the Arthritis Society] website, PR,
> lobbying federal government, etc [March 1, 2004].

PharmaWatch board members expressed reservations about the question

of affiliation with pharmaceutical industry- funded patient groups. When asked

their views on establishing relationships with industry funded patient

organizations, PharmaWatch board members expressed caution about the

complex nature of such a relationship. The following are from board members 2

and 4:

> [2] I don't think that there is a blanket yes or no answer to the
> question [of building a relationship with pharmaceutical-industry
> funded organization]. There are some pharmaceutical funded
> groups that consistently take very pro-industry positions and I
> would not want to associate with them. On the other hand, some
> groups like CTAC while funded [by the pharmaceutical industry]
> take very principled positions. I think that we would have to look at
> each group individually – examine what kinds of positions it has
> taken on issues that are important to us and then make a decision
> about whether to ally with it.

> [4] It depends on what the relationship is. I would love to go to
> theses organizations and do presentations and make pleas to them

about why get consumers involved with reporting. [However], in terms of day-to-day activities of collecting reports, anything involved with [the pharmaceutical industry] will be dangled down and may result in a misrepresentation of drug safety issues. This could be dangerous.

Most PharmaWatch board members agreed that in its efforts to maintain autonomy, the organization should focus on affiliating with and modelling itself on other successful consumer advocacy groups rather than focusing on building alliances with the surplus of industry-funded patient groups. Some of the highlighted organizations include: DES Action; Women's Health Protection; and US Public Citizen. For instance, board members 2, 5 and 6 stated:

> [2] I think that there are a number of advocacy groups in Canada that have been able to maintain their autonomy – DES Action was able to do so for a long time; Women and Health Protection, although exclusively funded through Health Canada, has been able to speak out on issues with a strong independent voice. The trick is for an organization to have a clear sense of what it wants, to maintain an open dialogue with its members and to take action in principled ways.

> [5] Staying in touch with the public and their needs. Talking to the public and being in touch with consumer groups that represent the public – not accepting industry funding...being careful of industry influence.

> [6] ...We have a consensual vision that includes a deep level of shared commitment to citizen empowerment, and so we have no desire to attach ourselves to the regulator community, professional bodies, or industry and its various sectors. For successful groups, look no further than our major partner, DES Action.

However, board member 3 expressed scepticism towards the pursuit of autonomy:

> [3] I'm a cynic. In Canada today, only small groups involving a number of people with Joan of Arc syndromes can successfully maintain autonomy - or those with a close relationship with someone in a funding agency (sponsorship stuff). While the unions can be helpful, they can also compromise autonomy. The only real successful group I know is Duff Conacher's Democracy Watch. The most critical factor in my mind is

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diverse funding...Part of my strategy these days, is to "just say no" when government wants to consult and make me work but do nothing. I send them a copy of the report instead. I find it interesting the way new groups get sucked in, but think there still is some value of keeping track of what is happening.

With whom and how the organization would mobilize its alliances and build its network was a critical issue that would influence PharmaWatch's development during its first year. PharmaWatch board members consequently engaged in a thoughtful analysis to ensure they allied with organizations whose principles and actions represented the interests of consumers rather than those of the pharmaceutical industry. In the patient/consumer advocacy sphere, the issue of affiliations and interests creates a clear divide between organizations. The central divisive factor is funding interests. This very issue surfaced at a meeting with the BCPWAS. At the meeting, a BCPWAS member asked the PharmaWatch representative, "Where do you get your funding?" and proceeded to state, "Could you not see the advantage of pairing with a pharmaceutical company to raise some money?" BCPWA members discussed how their "society operates in relation with other organizations. For example, the CDA (Canadian Diabetes Association) receives money from broad funding sources. It's shallow (accepting funding) but it offers wide opportunity" (April 10, 2004). For PharmaWatch and any consumer interest group, a critical question that will influence the scope of the organization's network and financial prosperity is whether there is an ethically and publicly acceptable way to affiliate with and accept pharmaceutical industry funding. Throughout the year, PharmaWatch board members' position on this matter was clear: No.

Establishing "interest-free" funding

The organization Patient View conducted a study in 2002 that examined how the proliferation of charities has made fund-raising a highly competitive business for all groups. With lucrative financial incentives, there is increasing industry involvement in health campaigners' fundraising efforts. While most health campaigners would prefer not to take money from the pharmaceutical industry, there are few, if any, viable alternatives. The study examined 68 campaigners in Australia, Europe and North America to account for the extent to which they accessed money from both the medical device and the pharmaceutical industry. An obvious hypothesis as to the pharmaceutical industry's motives for funding health campaigners is to drum up demand for their medical products. As a consequence, organizations such as the Cancer Advocacy Coalition represent a proliferation of special interest groups claiming to speak for the consumer. As Paul Wilcocks emphasizes, "the cancer coalition is doing important work. But it doesn't speak for consumers. Its goal is to make cancer the No. 1 health care priority in Canada, not to advocate for better health care. And like virtually all major health advocacy groups, the cancer coalition depends on funding from big pharmaceutical companies" (2004, p.18). PharmaWatch expressed a firm position on the issue while PharmaWatch board members brainstormed and proposed fundraising initiatives throughout the organization's first year.

During the first annual PharmaWatch board meeting, board members discussed the need to attain external funding to support their development

(November 13, 2003). Board members emphasized the need for a focused

fundraising program and affiliations with funding organizations that shared

principles similar to PharmaWatch's advocacy efforts. The overall consensus

was to approach three main funding sources: foundation money; project money

related to the government; and independent funding. One board member

produced a formal "PharmaWatch Fundraising Strategy" following the

conference. This document, distributed to PharmaWatch board members,

expressed opposition to seeking industry sponsorship and encouraged the

organization to find alternative "interest free" funding including individual,

government and foundation support. As the general preamble stated:

> PharmaWatch is a citizen-based enterprise striving to be free of
> influence from materially vested interests of any kind. As such, it
> needs to seek material support from sources that will not imply or
> engender any influence over its spirit, perspective or actions. Any
> and all solicitation of external sources of funds must therefore be
> carefully directed to comply with this proviso...

> ...With these general provisions in mind, the following is an outline
> of a fund-raising strategy that PharmaWatch can pursue which will,
> hopefully, avoid pitfalls leading to a loss of the organization's
> integrity, and provide it with material security in the short and long
> term (PharmaWatch Fundraising Proposal, 2004).

The proposal suggested that internal funding be made through

membership fees paid in two ways: annual solicitation or on an automatic

deduction basis. This would involve PharmaWatch establishing a "fee structure

for individual membership...[that would] be graded, to allow for degrees of

involvement, and for different levels of income" (Bell, 2004). Board member

responses to the proviso appeared positive, though one board member

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expressed concern about the idea of mixed individual funding. One member suggested that this would be a major investment of time and effort. There was a suggestion by board member 1 to "start with a limited number of people and develop before asking for more money" (February 8, 2004). To date, the organization has not followed through with implementing a focused membership parameter.

Project money related to government funding was also emphasized in the proposal. Applying for project money became a high priority in PharmaWatch's fundraising efforts during the first year. PharmaWatch's initial funding was provided by in-kind donations from a board member and through a University of Victoria granting program. This money helped sponsor a part-time staff member contract. By the end of November 2003, board members had taken on an Industry Canada funding proposal. The challenge was that Industry Canada perceived PharmaWatch as a health group rather than a consumer group. For a successful Industry Canada proposal, a distinction between health and consumer issues had to be made. Consequently, a strategy for funding had to be developed to tackle this as a consumer issue. A group of PharmaWatch board members agreed that highlighting how much money was lost to industry through adverse drug reactions and the cost to industry itself if drugs are removed from the market could be an effective approach. Board members developed a rationale to discuss the cost of drug safety to the economy for this proposal. They further suggested a need for a better-informed producer/consumer feedback loop concerning drug safety (November 24, 2003).

The Office of Consumer Affairs and Public Involvement (OCAPI) was another funding source approached by PharmaWatch board members. PharmaWatch's strategy was to first send a statement of intent about their project and then gather feedback regarding its congruency with OCAPI's research methods to discuss how a budget could be created and negotiated around their priorities. After a follow up meeting with OCAPI, board member 5 stated her impression that "they [OCAPI] just don't understand" the need for drug safety advocacy. OCAPI representatives talked about the system and aggregate data, but when it comes to project implementation, "OCAPI thinks in a way that doesn't get the input from the consumer. There is a fundamental challenge in their priorities and methods of data collection" (December 12, 2003). In July 2004, PharmaWatch had a meeting with members from OCAPI and the Health Canada Marketed Health Products Directorate. Board members appeared confident with their positioning prior to the meeting. One member stated, "we already have feedback from them, which is a positive thing" (June 24, 2004). In the end however, the meeting with OCAPI did not generate any funding commitment. While reflecting upon that meeting, board member 1 stated: "We had an informal follow up. I went to a stakeholder consultation that discussed what criteria should be used to include advisory committees to Health Canada. There was supposed to be a follow up idea of training people to participate in training, but it hasn't happened yet" (October 25, 2004).

PharmaWatch board members also worked towards developing proposals to various foundations. Board members proposed approaching organizations

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such as: the Vancouver Foundation – Health and Social Development Practice; the Atkinson Foundation; the Rockefeller Foundation; and the Canadian Centre for Philanthropy. During their first attempt at applying for foundation money, however, PharmaWatch board member 1 speculated they dealt with conflicts of interest. When PharmaWatch board members submitted a proposal to the Vancouver Foundation, they applied under the Health and Social Development category. Before PharmaWatch board members applied to the Foundation, they reviewed the board members of each funding category and realized that board members on the Medical Services category had potential conflicts of interests with ties to the pharmaceutical industry. In the end, the Vancouver Foundation took the initiative and submitted PharmaWatch's proposal within the Medical Services category and PharmaWatch's application was rejected. This experience was a reminder that industry interests are embedded within many funding organizations, which poses an added barrier to obtaining diverse funding.

The charitable tax status debate

Board members' position on the charitable tax status (CTS) debate was an additional factor that challenged PharmaWatch's access to significant funding. Organizations structure themselves and apply for federally registered charitable tax status in order to develop opportunities to attract private donors and increase their financial position (Consumers' Association of Alberta, 2003, p. 15). Becoming a registered charity allows an organization to provide official receipts for gifts received, reducing the individual donor's income tax payable and the

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taxable income of a corporate donor. Furthermore, once an organization is registered it is exempt from paying income tax.

Registered charities risk loss of their status if they speak out or act outside of the regulated provisions. Organizations applying for CTS are only considered if purposes and activities fall within the legal concept of a charity. An organization will be disqualified if it attempts to persuade the public to adopt a particular view on a broad social question or bring about or oppose changes in the law or government policy. This stipulation is controversial as there are clear biases in what constitutes 'public persuasion.' For instance, the Fraser Institute holds CTS, yet it clearly functions politically to further the interest of conservatively-minded bureaucrats. The CTS parameters are clearly incongruent with PharmaWatch's mandate. When asked during an informal interview for a perspective on PharmaWatch's alignment with charitable tax status, board member 1 was critical of the CTS requirements and policies. The respondent stated:

> [PharmaWatch] wants to be more politically independent than [they] can be through CTS. Requirements for CTS are nonsense. My point of view is not keen; however, I'm beginning to see the disadvantage of not have CTS. The funding strategy has to be very specific...with CTS you can't do advocacy, only education... (March 1, 2004).

When the remaining board members were asked their views regarding CTS and whether PharmaWatch should register for CTS, respondents expressed similar cautions concerning program restrictions. Others articulated belief in the program's potential to deliver benefits and opportunities. PharmaWatch board members 2, 3, 4, 5 and 6 stated:

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[2] Charitable tax status restricts the amount of advocacy work that an organization can do and therefore, in the case of PharmaWatch may limit what we can say and do. However, if our activities can be termed "educational" then we can still accept charitable donations. In general, I would be in favour of trying to get charitable status if we feel that we can accomplish our goals through educational activities.

[3] [CTS] would destroy us, and our ability to be effective, unless the rules change drastically over the next little while (which I don't think they have) - and because I do not believe we would be successful in getting this status given our current work. It would make us too vulnerable - unless we put the consumer reporting under a separate charitable organization, and then created an advocacy arm, but one can't cross fund, it would be a nightmare for accounting, etc...

[4] Yes. Having said that the process is a bloody hassle. Don't know if it's worth the hassle. We have relationship with DES Action. Would like to partner with them and use their charitable tax number in terms of us applying and going through hoops.

[5] Yes, but I don't know the background yet.

[6] We could of course apply; it is always advantageous when seeking funding to have charitable status. But it is not essential. Sometimes a parallel organization can be formed that has status and is solely in place to bestow tax receipts to donors. It depends on how PharmaWatch's attempts to gain status proceed.

As the year proceeded and funding had not picked up as the organization

had hoped, the president stated:

PharmaWatch fundraising is hampered by the fact they can't have CTS. It's hampered because not getting funding. Groups support them, however can't give money because of the mandate. PharmaWatch has reached a point where funding is needed. It's not just an issue of status. We need to do more work to establish credibility on the ground (April 5, 2004).

In order for PharmaWatch to be a force against knowledge monopolies,

the organization needs the armor to do battle with other institutional forces. CTS

could hypothetically serve as such armor. Charitable tax status would open and increase available finances and resources, while allowing philanthropists to receive tax receipts. Volunteers would be able to donate consulting fees and services. It has the potential to create a more publicly acceptable organization.

Whether or not PharmaWatch should apply for charitable tax status depends on its projected growth. CTS is not a feasible route if the organization is run solely by one or two individuals, however, PharmaWatch will need CTS if the organization wants to expand. As discussed in the recommendations, to fulfill this process, PharmaWatch must first develop a mandate and the proper infrastructure so that its ultimate pursuit of breaking down monopolies of knowledge and influencing drug safety policy is not jeopardized.

Chapter Summary

Overall, PharmaWatch has endured a challenging process as it strives to break monopolies of biomedical knowledge and encourage a paradigm shift in how pharmaceutical drug safety is thought about and acted upon. After nine months of participant observation and informal and formal interviews with PharmaWatch board members, findings surrounding the strategies and processes the advocacy group endured were documented. The research found that epistemologically and politically challenging current pharmaceutical practices involved: 1) establishing an identity based on consumer rights; 2) converging with technology; 3) competing with the mainstream media; and 4) maintaining autonomy without being co-opted to ultimately influence drug policy. Armed with an integration of strategies, PharmaWatch's advocacy efforts are but one

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demonstration of the force required in the process of breaking down knowledge

monopolies.

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CHAPTER FIVE: CONCLUSION

This research asked how a drug advocacy group can influence change in a society dominated by biomedical monopolies of knowledge. The analysis drew upon Harold Innis' idea of monopolies of knowledge, Jurgen Habermas' notions of legitimacy and expertise, and medical sociological critiques to suggest the prevalence of social control through medical, industry and governing authority's monopolization of knowledge. It further identified the emergence of a counter-hegemonic force, vis-à-vis drug safety advocacy groups concerned with the transparency and timeliness of pharmaceutical safety information. This work pointed to Williams and Popay to argue that these advocacy groups are dealing with a knowledge monopoly by epistemologically and politically challenging conventional beliefs concerning pharmaceutical expert knowledge systems. To demonstrate this phenomenon, a twelve month case study of the drug safety consumer advocacy group, PharmaWatch, was conducted. Data was collected and analysed after a series of participant observations and interviews.

The findings suggest that the group's epistemological and political challenges involved four central strategies including: 1) establishing an identity focused on consumers through representing legal and ethical principles of pharmaceutical consumer and institutional rights and responsibilities. Politically, this involved establishing a forum for pharmaceutical consumers to engage in knowledge transfer while advancing the validity and application of consumer

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reporting; 2) converging with technology through establishing a technological

mandate, infrastructure and user policy while understanding the opportunities

and limitations of the Internet for consumer empowerment; 3) competing with the

mainstream media's controversial framing and the bombardment of commercial

pharmaceutical messages; 4) maintaining autonomy without being co-opted by

mobilizing alliances, building a network of like-minded organizations, and

establishing interest-free funding. These strategies represent PharmaWatch's

advocacy efforts to epistemologically and politically challenge prevailing

knowledge systems.

PharmaWatch's advocacy efforts are to better inform and engage

consumers in pharmaceutical safety issues and encourage better regulatory

policies. After PharmaWatch's first year of advocacy, a number of questions

remain: Were the organization's efforts enough? Are PharmaWatch's strategies

really working to empower the public and influence pharmaceutical policy? What

can other advocacy groups learn about epistemological and political challenges

and monopolies of knowledge? This work proposes two key suggestions. First,

transforming the public's trust in conventional knowledge is an inherent and

continual challenge for any advocacy pursuit. Second, strategic funding is critical

for advocacy to remain autonomous while influencing public policy.

1. **Challenging conventional knowledge – in this case, society's trust in**
   pharmaceutical expert knowledge systems – is an inherent
   component of any advocacy pursuit.

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PharmaWatch has laid the foundation of an important campaign for pharmaceutical consumers. However, the very nature of PharmaWatch's mission means it will have to continue to tackle an inherently popular belief in expert knowledge systems. Challenging epistemological beliefs or how the public, government and industry think about pharmaceutical drug safety, will involve a continual commitment to diversified public, industry and government advocacy. For example, PharmaWatch's efforts to gain a public presence and disseminate alternative messages through technological uptake and the mass media are important steps, yet they must not be solely depended upon. An integrated advocacy strategy that engages allied organizations is vital. A focused outreach strategy that continues to involve grassroots organizations such as labour unions and minority groups must be incorporated. Furthermore, PharmaWatch can learn from and model successful allied advocacy groups such as the Media Doctor, Kilen and the Consumer's Health Forum of Australia. As Paul Willcock reports,

> The Consumers' Health Forum of Australia for instance is almost 20 years old, formed with government support after consumers demanded a health care voice. Only organizations that represent consumers -- not providers or care workers or corporations -- are eligible. The forum represents the public, takes complaints, publishes articles and newsletters, and, most importantly, speaks to the government on behalf of the consumer. All for about $750,000 a year from government and a bit more from members -- no drug company donations -- and with a staff of eight (2004, p.18).

These organizations provide a positive example of how a coalition of consumer voices can succeed in shifting popular perceptions of pharmaceutical knowledge and lead to progressive action.

2. Remaining autonomous while influencing policy takes strategic funding.

An essential component for effective consumer advocacy is retaining an autonomous existence while influencing regulatory policy. The process of actually influencing public policy involves steady competition with hard-hitting industry interests, a contest made more challenging by industry's deep pockets and ties to pharmaceutical regulators. Consequently, a strategic funding plan is essential for a consumer advocacy group to acquire the resources it needs to compete with these interests.

Throughout its first year, PharmaWatch's funding pool was limited because of the charitable tax status debate. While this status has its advantages, it places organizations at risk of losing their capacity to engage in advocacy. To move forward, PharmaWatch needs to adopt a clear position on the charitable tax status debate. In order to exploit the program's advantages while retaining its autonomy, PharmaWatch could be divided into two branches: an education branch and an advocacy branch. The education branch could focus on educational development and delivery of drug safety material through website development, public meetings/conferences, etc. The organization's advocacy branch could serve as the political side, lobbying, conducting research, and developing intellectual property. The education branch could subsidize the advocacy branch by accepting financial donations from individuals and philanthropic organizations. For example, the website and public discussions/conferences could be managed under PharmaWatch's education

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branch. This branch would buy its intellectual property/material on drug safety from the research conducted by PharmaWatch's advocacy branch, thereby financing PharmaWatch's political advocacy efforts. Disadvantages of this structure include a complex accounting procedure with increased bureaucracy; a collective of members who would have to be very cautious of conflict of interests; and a body of organizers who would have to remain cautious about what projects each organization manages. Furthermore, this type of structure would require an accountant, a lawyer, and a draft charter. Board members could not sit on both boards, and work would have to be carefully divided between organizations. Nonetheless, this would allow PharmaWatch to launch an aggressive funding campaign that would allow it to compete for the pool of funding resources provided by independent, government and foundation sources.

In Summary

With access to alternative information sources, the public has shown signs of scepticism towards the knowledge practices and rationale that directs pharmaceutical practices and policy. In Western society, the tension between public and industry interests concerning pharmaceutical practices forces the state into a vulnerable position. To mitigate the public's concern, the state relies on pharmaceutical experts to devise research studies that will convincingly suggest that patented drugs on the market are safe and effective and worth the monopoly prices. Furthermore, they depend on information systems such as the CADRMP as their vehicle for post-market drug surveillance. In the meantime, damaging effects and even death due to harmful drugs on the market have

increasingly emerged. Drug consumers' personal adverse drug experiences are increasingly becoming public issues as they hope to find answers, share their stories and have their voices heard. To counter the knowledge monopoly, consumers are rallying together to break the popular perception that personal pharmaceutical experiences are subjective and irrational. Advocacy Group collectives are emerging to challenge the current expert decision-making processes and monopolies of knowledge that justify and control unsafe practices in the regulation of marketed pharmaceuticals.

PharmaWatch's consumer advocacy efforts encourage a shift in how consumer interests in pharmaceutical safety are thought about and acted upon. If the Canadian government and pharmaceutical stakeholders were seriously interested in improving Canadians' health through pharmaceutical products, perhaps consumers (the real stakeholders) would be central players in the knowledge transfer, development and post-marketing of the drugs. Until that time, the current biomedical knowledge system that increasingly threatens the safety and effectiveness of drugs marketed in Canada will be challenged by the advocacy efforts of groups like PharmaWatch. Such advocacy demands that the public rethink their rights and responsibilities as drug consumers and take pro-active initiatives to gather and share knowledge about drugs and their effects.

Overall this work contributes to the exploration of critical thought on various social levels. First, at the academic level further study examining pharmaceutical provision, safety and advocacy from a communication perspective could take a number of dimensions. For instance, a study could look

at pharmaceutical safety advocacy as a movement. This could involve conducting research that adapts new social movement theory or health movement theories to further understand the broader phenomenon of drug safety advocacy. As well, research could adapt a political economy analysis and/or a further extension of Innis' knowledge monopoly theory to discuss issues in pharmaceutical intellectual property and patent protection. Specifically this could examine intellectual property rights in the pharmaceutical sector and explore what kind of legislation and regulation should govern policy in the area of patent protection and pricing.

Secondly, this work is an important contribution at the community level. This approach works as a tool to remind and assist PharamWatch and advocacy groups alike how to break down and understand critical aspects that have influenced their development and the strategies they have employed. Deconstructing organizational strategies at epistemological and political levels helps uncover tacit organizational knowledge and foster an understanding of what the organization is doing, why they are doing it and implications of their actions. This work can help advocacy groups to reflect upon and understand the strategies used and how they can think about working on epistemological and political levels to further leverage their position.

Finally at the individual level, this work serves as an important reminder of the critical role of both individual and advocacy efforts in representing public interests and challenging predominating political and economic structures. For instance, in the last year and a half I have engaged in many thought-provoking

conversations with people in regards to this research. While many shared their personal experiences and questions regarding pharmaceuticals, many were surprised by the gaps in pharmaceutical information policies and practices. It is my intention to continue challenging people's critical understanding of safety issues deriving from this steadfast pharmaceutical prescribing phenomenon – even though it is a hard pill for many to swallow.

APPENDIX:
PHARMAWATCH BOARD MEMBER
INTERVIEW QUESTIONS

- Why the need for PharmaWatch?
- How and why did you get involved with the organization?
- What is your ideal vision of PharmaWatch?
- What do you believe are key priorities for the growth of PharmaWatch in the next year? In the next five years?
- In its advocacy efforts, Pharamwatch uses the term 'consumer'. Why has PharmaWatch employed this term? Do you see any problems with using the terminology "consumer" over 'patient', 'public' or 'citizen'?
- How do you deal with criticisms concerning the quality and reliability of drug safety information reported by consumers?
- What role do you see the media plays in PharmaWatch advocacy? In your opinion, is the media presenting a positive or negative spin on the organization? If possible, give examples. For instance, are you satisfied with the CBC coverage of 'Faint Warnings'?
- Are you aware of or concerned with any issues arising out of the use of the Internet for data gathering and sharing? If so, how do you believe PharmaWatch should address these?
- What do you think about the idea of a PharmaWatch membership? Who would you include/not include?
- Do you believe PharmaWatch should build relationships with patient organizations that are pharma-funded? Why or why not?
- Do you believe PharmaWatch should apply for Charitable Tax Status? Why or why not?
- Do you believe there can be an ethically and publicly acceptable way for the pharmaceutical industry to fund drug safety advocacy groups? Do you believe PharmaWatch could ever foster a relationship with the pharma-industry?
- How would you describe PharmaWatch's relationship with the Canadian government? – you can speak specifically to Health Canada or any other governmental agencies.
- How do you believe PharmaWatch or any advocacy group can maintain its autonomy? Do you have examples of successful groups?
- How do you envision PharmaWatch influencing public policy?
- Any other comments?

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Therapeutic Initiative: http://www.ti.ubc.ca/

Women's Health Protection: http://www.whp-apsf.ca/en/

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Recommended Readings on Pharmaceutical Safety

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Mintzes, B. Baraldi, R (2001). *Direct to consumer drug advertising: When Public Health is no longer a priority.* A discussion paper for the Women and Health Protection. Retrieved November 14, 2004, from http://www.whp-apsf.ca/en/documents/doc_index2.html

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