

Marching to Different Drummers: Health Advocacy Groups in Canada and Funding from the Pharmaceutical Industry

by Sharon Batt
Women and Health Protection, January, 2005

I. Introduction

The closeness of industry involvement in the health advocacy movement is beginning to undermine the good names of health campaigners, weakening their public reputation.

- *Health and Social Campaigners' News*, U.K., April 2004¹

Pharmaceutical reps will coach citizens how to lobby to get the new drug on the formulary, said Armstrong. "The pharmaceutical companies figured out who the real decision-makers are – the public."

- Wendy Armstrong of the Consumers' Association of Canada and PharmaWatch, quoted in *The Edmonton Journal*, October, 2003²

"The money has to come from somewhere," Mr. Stein said, "And thank God it's coming from these [pharmaceutical] companies because it's not coming from anywhere else."

- Barry Stein of the Colorectal Cancer Society of Canada, quoted in the *Globe and Mail*, January 2001³

These statements offer a glimpse into a debate that is currently active within the voluntary health sector. Since the early 1990s, advocacy by disease and consumer groups has become a force in health policy. Once passive patient organizations are now outspoken and governments are eager to engage the public in health policy decision-making.⁴ To advocate effectively, organizations need money for research, training, community consultation and public education. Government policies, which once supported community-based advocacy, have eliminated or restricted most funding to advocacy groups over the past two decades. Any group involved with advocacy is likely to confront the dilemma of ambitious goals and limited funds, especially for core operations and advocacy. Fundraising and grant writing have become overwhelming requirements for community groups and many, particularly those with a health protection rather than a disease mandate, have ceased to exist.

In parallel with these changes in government granting policies, both the pharmaceutical industry and the private sector in general have decreased their undirected donation programs and increased "partnership" projects and cause-related marketing activities. Government policies encourage charitable groups to form partnerships in the private sector; indeed, the Health Products and Foods Branch (HPFB) of Health Canada itself

became a partner with the pharmaceutical industry.^a Throughout the health sector, pharmaceutical companies are now an important source of funding. As part of their marketing strategies, drug companies provide grants and other support to patient groups and disease-specific organizations. As a result, many groups receive funds from the same companies that are directly affected by policy questions central to their advocacy. Organizations receive tens or hundreds of thousands of dollars annually, sometimes more,^b from the drug industry for projects such as conferences, publications, web sites, and advocacy training.⁵ This trend is occurring at the same time that health researchers, peer-reviewed medical journals, physicians' professional associations, bioethicists and whistleblowers within drug regulatory agencies are raising red flags over conflicts of interest arising from pharmaceutical company funding in their respective communities. The focus of the present discussion is Canada, but the same phenomenon has attracted attention in the US, Europe, Australia and New Zealand.⁶

Voluntary organizations with a mandate to influence pharmaceutical policies respond to corporate overtures with a range of reactions, from gratitude to caution to alarm. Non-profit advocacy groups that are independent of industry, such as Women and Health Protection, PharmaWatch, the Canadian Health Coalition and the Consumer's Association of Canada, support a strong government role in drug regulation by demanding rigorous safety standards, improved post-marketing surveillance, enforcement of the ban on direct-to-consumer advertising (DTCA) and controls on the proportion of health care funds that are devoted to pharmaceuticals. These groups typically define pharmaceutical funding of advocacy groups as problematic. Industry-funded non-profits, such as the Consumer Advocare Network and Best Medicines Coalition, contest the assumption that strict government regulations favour the public interest. Their demands tend to be consistent with those of industry: rapid drug approvals, legal DTCA and no limits on formulary drug spending. Although this dichotomy oversimplifies a complex and fluid picture, the tendency to polarization provides a useful context for the discussion of conflicts of interest.

This discussion paper explores these debates from the critical perspective of a women's health advocacy group that does not accept pharmaceutical company funds.

^a Pharmaceutical companies now pay the government a user fee to defray the cost of reviewing industry submissions. This undermines the government's status as an independent regulator; indeed the industry can now sue the government if reviews are not completed according to a pre-set timetable.

^b Exact figures are difficult to determine as groups are not required to disclose this information and rarely do. Amounts that have been quoted in newspaper articles include: Colorectal Cancer Society of Canada, pharmaceutical companies provide 70% of a \$500,000 budget (in Picard, A. see citation Endnote 3); Arthritis Society of Canada, \$1.8 million of a \$30 million budget came from pharmaceutical companies (in Picard, A. see citation Endnote 3); the Canadian Breast Cancer Network, in 2000, received \$100,000 from Ortho Biotech, a division of Janssen Ortho (in Nebenzahl, D. see citation, Endnote 5). PatientView's survey, based on annual reports and other relevant literature from nine Canadian health campaigning groups in 2001-2003, found that the Canadian Cancer Society, the Canadian Diabetes Association, the Canadian Mental Health Association, the Heart and Stroke Foundation of Canada, the Multiple Sclerosis Society of Canada and the Parkinson's Society of Canada all cited pharmaceutical company donors (see citation, Endnote 1: pages 22-23).

The discussion looks at current practices against a broad policy context, in particular, the transformation of Canada's social policies from a welfare state framework to a governance model that expands the role of private enterprise. The unique part that women's health organizations play in health protection advocacy is examined. Debates in drug policy are examined in light of the impact that funding by drug companies could have on policy decisions, on Canadian health care, on the democratic goals of including consumers and patients in policy discussions, and on advocacy organizations themselves.

The paper argues that drug company funding of health and disease advocacy groups creates a conflict of interest that needs to be recognized and addressed. At the same time, it acknowledges that advocacy groups operate in a larger policy environment where industry partnerships are now the norm and where the watchdog role of government regulators has been systematically weakened. The paper concludes with suggestions for potential remedies and recommendations for policy change.

II. Conflicts of Interest

A conflict of interest (COI) is said to occur when a person or organization has a primary moral obligation to act on behalf of another and, at the same time, has an interest with a third party that could interfere with proper judgment in the first relationship.⁷ A health campaigning group^c typically has a self-described mandate to serve the interests of a specific population. If a group presents itself as a voice for people with diabetes or breast cancer, or, more broadly, "Canadian consumers", "women", or "the public interest", the organization's primary moral duty is to act on behalf of this constituency. Funding sources obviously have the potential to create conflicts of interest, especially when the parties providing the money have a direct interest in the outcome of the group's advocacy, as drug companies often do.

Conflicts of interest don't have to be financial. Other conflicts, such as a desire for prestige and power, or a personal friendship, might also cloud judgment.⁸ A related question, now being debated vigorously in the medical literature, is how large a gift has to be to constitute a conflict. The Canadian Medical Association's guidelines place limits on what gifts a physician may accept, but allow "modest meals or social events that are held as part of a conference or meeting" and "patient teaching aids appropriate to [a physician's] area of practice provided these aids carry only the logo of the donor company and do not refer to specific therapeutic agents, services or other products (e.g., baby formula)."⁹

By contrast, No Free Lunch, a physician's organization concerned about conflicts of interest in medicine, argues that even gifts that appear trivial can bias a doctor's prescribing habits. The group makes its point humorously with a "pen amnesty" program to encourage physicians to turn in pens bearing drug company logos in exchange for plain ones. In the same spirit, No Free Lunch warns physicians about "bagel bias" (the

^c The term "health campaigner" includes a wide range of groups involved in advocacy, including self-help groups, groups dedicated to research, patient groups, consumer-based citizens' groups, alliances or partnerships among a mixture of bodies, and groups with an international focus.

potential for an inexpensive breakfast to influence prescribing practice). The “zero tolerance” position on pharmaceutical company gift giving is based in part on the culturally widespread expectation of reciprocity in gift giving. Gifts play a key role in many cultures and even small ones create social obligations of loyalty and friendship.¹⁰

Psychology experiments on decision-making confirm that self-interest distorts the way individuals weigh arguments. These biases are unintentional: even when researchers asked educated participants in a decision-making experiment about the way bias operates, people assumed they would not be biased by a reward but their opponent would be; or they drastically underestimated how strong their own bias would be. The same experiments show that bias is unconscious (people were unable to avoid bias even when it was in their best interest to do so). Finally, bias was indirect. Self-interest changes the way people seek out and weigh information.¹¹

Studies of actual physician behaviour suggest that these conclusions translate to the medical environment. House staff who attended grand rounds given by a pharmaceutical company speaker were more likely than their colleagues to prescribe that company’s drug as treatment, even though they did not remember what company sponsored the grand rounds. A study of medical residents found that 61% believed promotions did not influence their own practice, yet only 16% believed that other physicians were impervious to influence from promotional gifts. Another study found that 19 out of 20 physicians who attended medical education seminars sponsored by two drug companies denied the seminars would influence their behaviour before attending; in fact, use of the companies’ drugs did increase after the seminars. Research with physicians has found that bias is strong, even with small stakes. Based on their review of psychological and physician practice literature, these authors conclude that attempts to control bias by limiting gift size, by educational initiatives, and by mandatory disclosure are likely to fail because they rest on a faulty model of human behaviour. They conclude that the implication for industry gifts to physicians is straightforward: they should be prohibited.¹²

The existence of a conflict of interest does not necessarily mean that one’s judgment has been, or ever will be, compromised. The term refers to a potential for interference. Improper influence is often difficult or impossible to identify.¹³ Although steps to avoid COI may be resisted as unnecessary, even insulting, they help an organization have confidence in its own decision-making. From the outside, conflicts of interest can create a suspicion of bias that undermines public confidence in important institutions. Even the potential for wrongdoing, or the appearance of wrongdoing, is enough to undermine an institution’s authority.

Conflicts of Interest and Government Funding

Some advocacy groups, including Women and Health Protection, receive funding from the federal government. Because governments are not the primary constituency of health advocacy groups, and governments have a budgetary and political interest in what policies are enacted, government funding of advocacy groups must be characterized as conflicted. Unlike the private sector, however, governments have a responsibility to develop policies in the public interest.

In his analysis of pressure groups in Canada, political scientist Paul Pross notes that public funding of interest groups, “brings with it problems of uncertainty, dependence, and a tendency to distort the goals of their organization.”¹⁴ The government may see the group as an instrument in achieving its goals, while the group may “gradually and almost unconsciously accommodate itself to the funder over time.”¹⁵

Despite these problems, Pross argues that, if no advocacy groups received government support, some points of view would be excluded from public debate and the decision not to fund anyone would automatically favour the views of well-resourced sectors. Losing the voices of excluded parties “would weaken not only those sectors but the quality of public debate.”¹⁶ The real issue becomes finding a way “to structure the processes of group-state relations so that the dangers of intimidation, favouritism, and manipulation are minimized,” he concludes.¹⁷

III. Canada’s Health Policy Environment

In 2000, the HPFB established the Office of Consumer and Public Involvement (OCAPI)¹⁸ to encourage public involvement in the Branch’s priority-setting, programs and policy decisions. The *Policy Toolkit for Public Involvement in Decision Making*, published by Health Canada, defines the public as “individuals, consumers, citizens and special interest groups such as environmental, health, consumer and voluntary groups, and industry, scientific and professional associations.”¹⁹ Canadian consumer, health and patient groups testify regularly at public hearings on pharmaceutical issues, sit on policy committees where drug policy decisions are made, attend workshops and consultations, and meet with health department decision-makers to discuss changes to drug policy. Groups that take an active interest in pharmaceutical policy issues include the Best Medicines Coalition and its member groups,^d the Consumer Advocare Network, the Canadian Health Coalition, PharmaWatch and Women and Health Protection.

Some organizations, including Women and Health Protection, have pressed the HPFB and OCAPI to address the issue of conflicts of interest. At the time of this writing, OCAPI has circulated a draft proposal that would encourage groups participating in policy consultations to make voluntary statements about their funding sources and other organizational information. Unfortunately, experience shows that voluntary statements without enforcement have not worked for other sectors. Industry-funded scientists have not disclosed clinical trial results unfavourable to industry, top scientists at the National Institutes for Health in the US failed to disclose lucrative industry contracts to their bosses as required,²⁰ and authors whose articles appear in leading academic journals do not always comply with the journals’ conflict of interest disclosure policies.²¹

^d As of November 2004, members of Best Medicine’s Coalition included Arthritis Consumer Experts, The Arthritis Society, The Asthma Society, Canada’s Association for the 50-Plus, Canadian Arthritis Patient Alliance, Canadian Breast Cancer Network, Canadian Cancer Advocacy Network, Canadian Hemophilia Society, Canadian Hepatitis C Network, Cancer Advocacy Coalition of Canada, HepCURE, Multiple Sclerosis Society of Canada, Tourette Syndrome Foundation of Canada, and Yellowhead Tribal Council. Website accessed November 7, 2004 at: <http://www.bestmedicines.ca/members.html>

Current government policy actively promotes partnerships with industry, in the voluntary sector as well as within government itself. Non-profit groups that reject this model as inappropriate for their mandate risk marginalization, both because they are perceived as “not playing by the rules,” and because their access to funds is severely limited. As an example, OCAPI formed a partnership with the pharma-funded Best Medicines Coalition (BMC). At a meeting between OCAPI staff and Coalition members in December 2002, participants recommended that OCAPI “use BMC as an umbrella group in its patient consultation strategy.” While the report noted that OCAPI would also consult with groups representing the healthy population, BMC was characterized as “more appropriate to represent the Canadian *patient* population [italics from original].”²² Some patient advocates and patient groups, however, do not feel an organization funded by the pharmaceutical industry can address the concerns of *patients* for unbiased information about medications and policies that promote safety (see, for example, Colleen Fuller on p.9). By favouring BMC as the official voice of patient organizations, OCAPI devalues the perspective of independent patient groups, regardless of the quality of the arguments they bring.

This analysis exposes a policy contradiction. While voluntary groups have been called upon to play an expanded advocacy role, public funding for advocacy has been reined in, through funding cuts and a strict interpretation of the ten per cent rule for registered charities.^e The complaint that government policies have muzzled charities, while at the same time increasing their burden of service responsibilities, is widespread in the voluntary sector.²³ Health charities, pressured to find sources of funding outside of individual donors and government grants, have found that pharmaceutical companies welcome these new partnership opportunities. The inescapable question, however, is: whose interests do these reconfigured organizations represent?

IV. Health Protection Advocacy and the Role of Women

When the modern era of pharmaceuticals began in the 1940s, many drugs and medical devices were marketed solely or primarily to women, sometimes with disastrous effects. By the time the women’s health movement took shape in the late 1960s and early 1970s, thalidomide and diethylstilbestrol (DES) had alerted women to the dark side of prescription drugs, legally marketed with false promises and no safety warnings. Even the birth control pill, although generally welcomed by women, was rushed to market without adequate testing for dosage and harmful effects. When deaths from blood clots began to mount, drug companies suppressed the information.²⁴

Pioneering work by Canadian medical sociologist Ruth Cooperstock and her colleagues in the 1970s showed that sedatives were being prescribed twice as often to women as to men, primarily for social rather than medical reasons.²⁵ These findings galvanized women’s groups to protest the medicalization of anxiety. Other examples of runaway drug promotion have fuelled women’s anger over the medicalization of normal emotional

^e Canada’s tax law restricts policy-related advocacy by a registered charity to ten per cent of its donated revenues.

and physiological states, including the marketing of implants for small-breasted women and hormone-replacement therapy (HRT) for women who have passed menopause. Medicalization is often achieved through heavy promotion of drugs for off-label (unapproved) uses. One example is HRT, which was approved as a short-term treatment for menopausal hot flashes then promoted as a youth potion requiring indefinite use. Another example is Diane-35, approved in Canada as a second-line treatment for severe and difficult-to-treat acne, but promoted to treat mild skin problems and currently being used widely on university and college campuses for birth control.²⁶

The past two decades have brought women's health issues into the mainstream. Ironically, this evolution has obscured rather than highlighted problems of drug safety and over prescribing. The feminist critique of unsafe, over-hyped pharmaceuticals and medical devices now competes with messages from professionalized women's health organizations whose over-arching goal is to provide women with equal access to health services and treatment. Consistent with their contrasting perspectives on biomedical intervention, grass-roots advocacy groups and professionalized women's health organizations often differ in their attitudes towards corporate funding.

Some women's health groups^f still play a watchdog role towards both industry and government. These groups have raised alarms about the ties between the pharmaceutical industry and health advocacy groups. The dominant model in Canada, as elsewhere, however, is the professionalized health advocacy group with industry partnerships. These groups rarely criticize industry practices. Since drugs harmful to women's health continue to make headlines (some recent examples are HRT, Diane 35 and Accutane), the weakened influence of non-profit groups that speak out on health protection issues is a threat to women's health.

V. Conflict of Interest and Health Advocacy Groups

Advocates for Better Care: Myth or Reality?

Groups that have chosen to work in partnership with the pharmaceutical industry reject suggestions that these partnerships lead to co-optation. In a 2001 *Globe and Mail* article,²⁷ Denis Morrice of the Arthritis Society of Canada, Barry Stein of the Colorectal Cancer Society of Canada, and Durhane Wong Reiger of the Anemia Institute for Research and Education vigorously defended their decisions to accept funding from the drug industry. They saw such partnerships as a way to meet the medical and information needs of an increasingly sophisticated, demanding consumer who understands how the drug approval system works: "People want better patient care, that includes better drugs," said Barry Stein. Denis Morrice stated, "People with arthritis have to benefit or there won't be a partnership, no matter how much money is offered."

^f Examples are Women and Health Protection and some of its founding member groups: DES Action Canada, the Canadian Women's Health Network, la Fédération du Québec pour le planning des naissances, and Breast Cancer Action Montreal.

As evidence of their ability to maintain independence and uphold ethical standards, they cited policies of being “upfront” about industry financial assistance (Stein), of taking money from multiple companies, including those in direct competition with one another (Morrice), and a willingness to be selective about which companies they worked with (Wong Reiger). Durhane Wong Reiger stated that she ruled out companies who were “too obsessed with the bottom line” in favour of those that were “open-minded” or “truly benevolent.” Industry spokesman Murray Elston, speaking for the industry lobby group Rx&D Canada, echoed this vision of a new breed of information-hungry consumer, responding to government demands to take control of her health. In his view, leaders in the associations were part of an empowered vanguard, “starting to use that power to demand changes, and to ask some tough questions.”

If these groups represent an empowered public, how is that power being exercised? What “tough questions” are being asked? The article notes that groups like the Arthritis Society have become “far more militant and outspoken about issues like the slow approval of new drugs and reluctance to place new drugs on formularies.” Denis Morrice, the Arthritis Society’s president and CEO, considered it coincidental that these same issues also “happen to be foremost on the minds of corporations.”

The assertions in this article echo the views stated in other media accounts about “pharma partnerships” that have appeared in the past years.²⁸ These claims need to be closely examined since those who make them speak for groups whose mission is to represent the health interests of millions of Canadian patients.⁸ Recurrent themes are the assumption that the “newest” medications are the “best” treatments; that slow approval of new drugs is a pressing policy problem; that more information, including the content of advertisements, is necessarily empowering; that sick people have a right to all new medications on the market, with full coverage; that unlimited access to medications promotes better health; that groups can ensure independence from corporate sponsors with internal policies such as openness; and that drug company funds are the only option available to voluntary groups working in the health sector. Some of these claims are examined below.

Are new medications the best treatments?

New drugs are not necessarily better than older drugs; in fact, they are often neither as effective nor as safe. Even though there are many cases where older, less expensive drugs are better than newer drugs that replace them, the conviction that a newer drug must be better than an old one is pervasive.

Patients with diabetes had to lobby to keep cheaper forms of insulin they could use on the market when a newer product proved dangerous or fatal to some diabetics. Colleen Fuller was one of hundreds of diabetics in Canada and the US who suffered blackouts, disorientation and other severe symptoms (including sudden death) when they took the new drug. Fuller turned to the Canadian Diabetes Association (CDA) for help in

⁸ The Arthritis Society of Canada and the Colorectal Cancer Society are both members of Best Medicines Coalition, which claims to represent 10-15 million chronically ill patients in Canada. For full reference, see Endnote 52:8.

convincing Eli Lilly to keep animal insulin on the market, noting that 43 % of the CDA's members responded in a survey that they had trouble adapting to the new, genetically engineered insulin. The CDA said they had asked Eli Lilly, and a competitor that had also discontinued animal insulin, to keep the animal insulin on the market. When the drug companies said their decisions were final, the CDA (which in 2001-2003 acknowledged funding from Eli Lilly and 20 other pharmaceutical companies²⁹) did nothing to fight the decision.³⁰

The myth that new drugs are always better than old ones persists partly because new treatments are rarely tested against competing older drugs; rather, they are tested against a placebo. The fact that a drug is approved by a national drug regulator simply means it was found, in a small, limited-term experiment, to be better than nothing. Most "new" drugs are not actually therapeutic advances either. A substantial number are competing formulations of drugs already on the market, known as "me too" drugs. An example is the drug Nexium for heartburn, which AstraZeneca introduced and promoted when the patent was about to expire on its best selling Losec.

Are slow drug approvals a problem?

Before drugs can be sold on the Canadian market, the HPFB reviews and assesses the safety and efficacy data that pharmaceutical companies are required to provide. The industry has long complained that bureaucratic approval processes cause a "drug lag", which in turn denies life-saving new treatments to sick patients.

The same policies have also attracted patient and consumer group lobbies. Industry-funded groups generally align themselves with pro-industry positions. For example, members of Best Medicines Coalition, a national umbrella lobby for patient groups that receives funding from the pharmaceutical industry, argue that Canada's drug approval system is too slow and that patients are being denied prompt access to important new drugs. A number of groups which do not accept pharmaceutical company funding, including Women and Health Protection, PharmaWatch, the Consumers' Association of Canada and the Canadian Health Coalition, argue that the push to speedy drug approvals detracts attention and resources from the careful drug review and post-market surveillance needed to assure drug safety.

In the early 1990s, due to government cutbacks in Canada and restrictions in the US, the HPFB and the Food and Drug Administration (FDA) instituted user fees payable by industry. In return, the regulatory agencies agreed to speed up approvals.^h While this policy shift benefits the industry by bringing new, expensive drugs to market sooner, a number of studies of the FDA suggest the cost to consumers may be lower standards of drug safety. One study by researchers in the UK compared drug approval times and safety records in the US and the UK over a 20-year period. They concluded that the superior safety record of drugs in the US prior to 1992 came from a meticulous and rigorous review process and a political culture of independence from industry within the FDA.³¹ The Washington-based Public Citizen's Health Research Group (HRG) surveyed

^h In the US, faster approval times were written into law; in Canada, it was an understanding between the drug industry and Health Canada that approval times would be shortened.

FDA reviewers in 1998 for their reaction to the changes in the agency. Nineteen out of 53 medical officers identified a total of 27 new drugs in the past three years that they thought should not have been approved but were; 17 said that standards were “lower” or “much lower” than they had been three years previously.³² A subsequent survey by the Office of the Inspector General confirmed some of these findings. Although 64% of FDA respondents had confidence in the FDA’s decisions regarding the safety of a drug, at the same time, 40% who had been at the FDA at least five years indicated that the review process had worsened during their tenure, with less allowance for in-depth, science-based reviews.³³

Speedy access to experimental drugs is a hollow victory for patients if those drugs cause more health problems than they remedy.

Does the ban on DTCA deny information to patients?

All western countries heavily regulate prescription drug advertising to control fraud and the exploitation of fears about health and illness. Since the 1990s, drug companies have lobbied heavily for the right to promote their products directly to consumers. Their greatest success has been in the US, where the FDA relaxed restrictions on broadcast DTCA in 1997.

Some health campaigning groups have lobbied strenuously to have DTCA legalized in Canada while others have opposed DTCA. A brief to Health Canada by the Consumer Advocare Network, another national advocacy umbrella supported by the pharmaceutical industry, argues that the Canadian ban on DTCA denies patients their “fundamental right to information about prescription drugs, which includes direct-to-consumer advertising, or promotion, of drugs.”³⁴ Groups that maintain financial independence from the pharmaceutical industry oppose DTCA on the grounds that advertising does not provide patients with the unbiased information they need to make informed health decisions.³⁵

Do people have a “right” to new medications, with full insurance coverage?

Each province has a formulary that restricts drug coverage to a subset of all available drugs. After Health Canada approves a drug, each provincial or territorial government will assign that drug to one of three categories: covered, not covered or limited use (i.e., the government will only pay for the drug under certain conditions or, in some cases, prescriptions for that drug will be filled by a comparable lower priced drug). The high cost of many new drugs creates a dilemma for provincial governments, working within strained health budgets. A drug that has been approved will not necessarily be added to all (or any) provincial formularies if a government decides its cost exceeds the health benefit or if the drug is simply unaffordable.³⁶

Advocacy groups again differ in their responses if a province decides not to add the drug to its formulary. A common response has been for groups of patients who feel they are being denied a drug to demand that it be added to the formulary. These drug access lobbies often include a media appeal by a suffering patient, demands for formulary inclusion by the spokesperson from a relevant disease group, and statements dismissing concerns about the cost.

The Fabry Society of Canada launched such a lobby after Health Canada approved Fabrazyme and Replagal,ⁱ drugs which had been shown in clinical trials to make patients feel better but which had not yet shown any survival benefit. The Common Drug Review, an expert panel established in September 2001 to advise the federal, provincial and territorial governments on which drugs and devices to cover, recommended against having the two Fabry's treatments added to government formularies. The review panel based its ruling on the treatments' quarter-million dollar annual cost per patient, and the lack of demonstrated benefits based on clinical endpoints. When asked if the high cost of the drug was warranted, Ed Koning, a patient who chairs the Fabry Society of Canada, responded, "The cost is not the patient's issue."³⁷

Members of patient groups responded similarly when Wyeth-Ayerst's drug Enbrel^j was approved and the government of Newfoundland decided not to add it to the formulary.

The idea that drugs should be added to provincial formularies as soon as they are approved rests on the contention that patients have a "right" to any new treatment that might help them, regardless of costs. AIDS activists laid the foundations for this argument in the 1980s. They opposed the strict regulatory procedures that had been developed in response to the thalidomide tragedy and demanded free access to experimental drugs outside of clinical trials as a right.³⁸ Other patient groups have adopted the arguments of AIDS activists and expanded them to include patients suffering from illnesses that are not terminal. In a *Globe and Mail* article about disparities between provincial drug formularies, the president of Best Medicines Coalition, Kathy Kovacs Burns, was quoted as saying, that " 'cost containment' should not be part of any national drug plan," and the "best drugs" are not likely to be the "cheapest or oldest" drugs available.³⁹ Other industry-funded advocacy groups have suggested that patients have the right to sue provincial governments that don't add drugs for their condition to formularies.^{k 40}

By contrast, groups that remain independent of the industry focus on whether exaggerated claims have been made for the new drug, whether it is significantly more effective and/or safer than less costly treatments, and whether the pricing is excessive. Dr. Joel Lexchin, a member of the independent groups Women and Health Protection and PharmaWatch, commented to the *Ottawa Citizen* in an article on drug costs, "The market has a set of values and it does not operate in the interests of public health, it operates in the interest of making money." He added, "What general practitioners should be getting is comparative information: Where does this drug fit into the spectrum of therapy? But it is often difficult to get this kind of information."⁴¹

ⁱ Fabrazyme and Replagal, developed to treat a rare hereditary condition called Fabry's disease, are priced at \$240,000 and \$290,000 annually per patient respectively.

^j Enbrel, a drug approved for pain relief from rheumatoid arthritis, costs upward of \$20,000 per patient per year.

^k In November 2004, the Supreme Court of Canada ruled unanimously that Charter protection against discrimination does not require provinces to add an expensive treatment to their formulary.

Although drug prices are closely related to provincial formulary decisions, drug pricing in itself has been a neglected area for direct lobbying by patient and health advocacy groups in Canada. An exception is a 2003 brief by Richard Elliott for the Canadian HIV/AIDS Legal Network, which includes recommendations for amendments to the Patent Medicines Prices Review Board guidelines and the Patent Act. The recommendations include distinguishing between the pricing of “breakthrough” drugs and those that offer little or no therapeutic advantage over existing drugs, and allowing a “reasonable” profit margin over and above the costs of development and manufacture.⁴² More typical responses to rising drug costs from patient groups are those cited above – that drug costs are “not the patient’s issue” and cost containment “should not be the basis of any national drug plan.”⁴³

No public system can give every sick person everything they want. A public health care system implies sharing resources, spreading available resources across many services and prioritizing on the basis of need and evidence. Ultimately, the excessive cost of new medicines is a political issue that needs to be confronted, but industry-funded patient groups have not chosen to take this on.

Do industry-funded groups empower patients?

Patient empowerment is prominent in the rhetoric of industry-funded groups. The power supposedly comes from providing patients with information about new drug treatments for their disease, and from the muscle to lobby governments for access to these products. The close correspondence of advocacy group views with those of their industry sponsors suggests this empowerment is more illusory than real. True empowerment comes from having independent information about diseases and their treatments, and tools to critically analyze a problem. Is it coincidence that pharma-funded groups focus their criticism of government on issues like “drug lag”, formulary access to new drugs and the ban on DTCA, while groups independent of the industry critique government partnerships with industry that have weakened the government’s monitoring of drug safety and misleading claims? Based on the analysis presented in this paper, the answer is no.

This critique is not meant to suggest that health campaigners who form partnerships with pharmaceutical companies intentionally align their goals with their industry sponsors. Most groups would prefer not to accept funding from the pharmaceutical industry, but they have few alternatives.⁴⁴ The dilemma for many is that any funding is better than no funding and industry funding allows them to mount programs to serve their communities that they could otherwise not afford. Having accepted industry money, however, organizations become blind to its co-opting effects.

As discussed in section II, studies in the medical community and psychology experiments on decision-making show that conflicts of interest create very subtle biases. They are unintentional, unconscious and indirect – but that doesn’t diminish their potential for harm. Consider the two blockbuster arthritis drugs, Pfizer’s Celebrex and Merck & Co.’s Vioxx. In 2000, the Arthritis Society of Canada lent its logo to a newspaper supplement extolling the two drugs that had just come on the market. The Arthritis Society receives funding from both drug manufacturers. According to the president of the Arthritis

Society, accepting corporate funds from direct competitors is a strategy that “helps to keep the companies and the group honest.”⁴⁵ In 2004, both drugs were linked to heart attacks and strokes. Merck withdrew Vioxx from the market when David Graham, an FDA whistleblower, went public with research showing that the drug had caused an estimated 60,000+ deaths in the United States alone. The withdrawal caused a storm of controversy about safety warnings ignored and pressures on FDA reviewers to suppress findings. Graham, the Associate Director for Science and Medicine in the FDA's Office of Drug Safety, called Vioxx perhaps “the single greatest drug safety catastrophe in the history of this country or the history of the world.”⁴⁶

In response to the withdrawal, the Arthritis Society posted a letter on its web site from the Society's CEO, saying, “Merck Frosst deserves credit for making what must have been a very difficult decision corporately.” He added, “Merck Frosst has been a strong supporter of the work of The Arthritis Society, particularly with regards to increasing awareness about this painful and debilitating disease.”⁴⁷ The letter makes no mention of the company's corporate wrongdoing, nor does it express alarm that so many people with arthritis suffered strokes or heart attacks after taking Vioxx.

Perspectives on Partnerships

Groups within the health advocacy community have varied reactions to the boom in pharmaceutical partnerships. Some are reluctant or cautious partners, others welcome funding from drug companies. Still others have explicit written policies not to accept support from drug companies.

The most cynical partnership model is the front group, an organization created to covertly promote a product or political perspective. Such groups are often dubbed “astroturf” groups because of their fake claim to grassroots status.

In 2003, the American seniors' group AARP (the American Association of Retired Persons) charged that the pharmaceutical industry was funding the United Seniors Association, the Seniors' Coalition and the 60 Plus Association to lobby against proposed drug policy changes that would benefit older Americans.⁴⁸ AARP investigated the groups' tax returns and found that, since 2001, none listed any revenue from membership dues and virtually all their largest contributions were from the pharmaceutical industry. All three had links to a direct-mail entrepreneur with a shady past and all had been criticized for questionable fundraising practices, including misleading mailings. The groups' tactics included phone campaigns to defeat proposed prescription drug legislation in Minnesota and New Mexico. AARP discovered that the drug companies paid an intermediary company, which in turn hired callers who identified themselves as members of United Seniors. The callers phoned state residents, urging them to vote against the Democratic candidates who supported the legislation.

Some groups begin as legitimate grassroots organizations but undergo a process of “mission drift” which makes them hard to distinguish from astroturf groups. An analysis of the Society for Women's Health Research (SWHR) by health journalist Alicia Mundy illustrates how industry funding can promote mission drift.⁴⁹ The SWHR began in 1990

as a non-profit group with a mission to advocate for federally funded research on women's health. Founded by two highly respected physicians at the National Institutes for Health (NIH), the Society sponsored an annual congress attended by scientists, politicians and consumer advocates. By 1994, due in part to the group's efforts, women's health had become a growth area for research in the United States. Mission accomplished, the two founders turned their energies elsewhere.

A newly hired Executive Director, Phyllis Greenberger, began to collaborate in seminars and other events with pharmaceutical companies, including a 1999 panel about irritable bowel syndrome and a black-tie "Coming of Age" party in 2000 to celebrate the vibrancy of middle-aged women. The panel on irritable bowel syndrome was funded by the company Glaxo. It coincided with Glaxo's success in convincing the FDA to fast-track approval of its drug Lotronex on the grounds that many women needed a remedy. Ten months later the drug was linked to deaths and the need for colostomies and had to be withdrawn from the market (it was later reintroduced, with some restrictions). The gala to honour mid-life women was sponsored by Wyeth, manufacturer of the best selling hormone replacement drugs Prempro and Premarin. A week after the celebration, Wyeth presented the society with a \$250,000 cheque to mark the 60th anniversary of its drug Premarin.

Three months later the Women's Health Initiative, a large NIH-sponsored research project on women and aging, called a halt to its clinical trial studying the long-term effects of Prempro because the drug was found to increase the risk of heart attacks, stroke, blood clots and breast cancer. Instead of welcoming the landmark trial results, Greenberger began a media campaign charging that the researchers had frightened women by overstating their results and releasing the trial results too abruptly. Mundy was unable to determine what percentage of the Society's income comes from the pharmaceutical industry, either from the official non-profit tax form or from the society directly. She did learn that the organization's corporate advisory board includes Eli Lilly, Johnson & Johnson, Merck, Pfizer and Wyeth – all manufacturers of popular women's drugs.

Policy researcher Barbara Mintzes points out that drug companies can use patient groups to exploit policy loopholes. Because information and educational materials produced by patient groups are not subject to advertising regulations, a company that produces or co-produces information with a patient group can circumvent regulations that require information about a drug to be accurate and balanced. Patient groups are not obliged to acknowledge drug company sponsorships of their public events or educational materials.

One example of this strategy is a series of public seminars on migraines organized across Canada.⁵⁰ Ostensibly sponsored by a patient group, The Canadian Migraine Foundation, the seminars were actually organized by Glaxo Canada in the pre-launch stage of the company's new migraine treatment, Imitrex. The Canadian Migraine Foundation had been dormant for some time, but the company gave it grants to hold the meetings. Participants were charged five dollars for the popular seminars, a marketing strategy to increase the illusion that the events were independent of industry. Eventually the

Foundation objected to the company's heavy-handed involvement. Glaxo responded by transferring its support to another group, the Canadian Association of Neuroscience Nurses.

Groups that accept pharmaceutical company funds have developed strategies to maintain their independence and credibility. Project Inform, a San-Francisco-based AIDS Service Organization (ASO) promotes a model in which ASOs challenge pharmaceutical industry influence while at the same time accepting funds from the industry. Project Inform reasons that the pharmaceutical industry has a debt to AIDS patients. “[A]s the one most profiting from the epidemic, the pharmaceutical industry should be offering support back to the community. [But] support should come with the fewest possible strings,” a spokesperson told Canadian journalist Ann Silversides. To guide ASOs seeking to develop ethical partnerships with the pharmaceutical industry, Project Inform suggests three guiding principles: disclosure of financial support, a structured communications policy of who should talk to whom and – most critical – independence and ownership: “community agencies should control their own agenda and create their own programs.”⁵¹

Pat Kelly of the Cancer Advocacy Coalition of Canada (CACC) argues that corporate sponsorship can be a source of “principled, positive experiences” that enables “delivery of much-needed advocacy programs and services.”⁵² She reviews sponsorship guidelines that some Canadian disease groups have implemented to set the parameters for their corporate partnerships. Her review includes the CACC, the Canadian Diabetes Association (CDA), the Canadian Arthritis Society (CAS), the Canadian Cancer Society (CCS) and the Multiple Sclerosis Association (MSA). These “Best Practices” guidelines include maintaining autonomy of the group’s mission, educational materials and agenda (CACC, CDA, MSA); relying on the expertise of scientific advisors when advocating for regulatory and drug plan listings (CACC, CDA); accepting funds from corporations that have a “logical fit” with the organization’s mission (CACC, CAS, CCS, MSA); disclosing corporate support on an annual basis and responding openly to inquiries about said support, while disclosing exact amounts received from a partner company only with the permission of that company (CACC, CDA); allowing use of the organization’s logo only with permission (CCS, CAS); and not endorsing specific products or services (CDA, CAS, MSA).⁵³

Other patient organizations have concluded that accepting funds from the pharmaceutical industry is inconsistent with their mission. In August 1998, the San Francisco group Breast Cancer Action (BCA) rejected a policy that allowed the group to accept donations from any company or person, in favour of one that excludes pharmaceutical companies, chemical manufacturers, oil companies, tobacco companies, health insurance organizations and cancer treatment facilities. BCA’s rationale was that the funding of any advocacy organization can appear to affect its political legitimacy, “particularly in situations where corporate support raises the possibility, inference, or perception of a conflict of interest.” The list of off-limits corporations was compiled to exclude organizations whose interest in cancer diagnosis and treatment could bias, or be perceived as biasing, the information BCA provides about cancer treatments. A second

guiding principle was to exclude companies whose manufacturing processes or products may contribute to cancer incidence or environmental degradation.⁵⁴

As these examples show, people working in voluntary health organizations have radically different perspectives on the ethics of partnerships with the pharmaceutical industry. Most groups act pragmatically, putting the best face on their reduced funding options. More convincing analyses recognize the larger political realities behind partnering relationships. Inter Pares¹, a Canadian social justice organization that builds relationships of common cause with activist groups around the world, critically examines the neo-liberal ideology of partnership in a paper called “Rethinking Development”:⁵⁵

A devalued ideology of partnership has become pervasive, in which the conditions and terms of partnering relationships are determined and dictated by the partner with the money, whether donor governments, international financial institutions, corporations, or international NGOs. The symbolism of partnership usually masks the bitter realities of fundamentally unequal relationships that often represent a repudiation of sovereignty and self-determination.

An insidious contemporary variation is the so-called “social partnership”, dominated by corporations in the interest of social marketing and public relations.... Under this form of “partnership”, corporations that are notorious transgressors of the common good and acknowledged violators of human rights, environmental regulations and business ethics – particularly the vertically-integrated pharmaceutical, chemical and resource extraction industries – rehabilitate their reputations through cheap association with humanitarian agencies and their charitable “good works”.

Inter Pares uses the term “counterparts” to capture an ideal of co-protagonists and colleagues who collaborate, cooperate and conspire to change the structures and relations that perpetuate injustice and inequalities. The typical collaboration between pharmaceutical companies and health campaigning groups is a far cry from this ideal.

How Drug Companies See Partnerships

Drug companies target their support to health campaigners in three areas: education, “disease awareness” and advocacy. Understanding the industry’s goals and the infrastructure used to achieve these goals helps bring the ethical issues into clearer focus and, in turn, suggests potential remedies.

Murray Elston, then executive director of Canada’s pharmaceutical industry association Rx&D, acknowledged to the *Globe and Mail* that “at the end of the day, our focus is to have patients use our products,” but he described the approach as long-term: “Ultimately informed patients will be allies because they will demand the latest and most effective treatments and press politicians and bureaucrats to get them.”⁵⁶

A survey of corporations and organizations in Canada⁵⁷ indicates that, whereas companies used to sort through and select from requests for funding, they now use a

¹ Inter Pares is an affiliate of Women and Health Protection. The group’s funding comes from individual donations and from development funds, such as the federal government’s Canadian International Development Agency (CIDA).

targeted model, actively seeking partners that can provide a measurable return on investment. The new model, characterized as “layered” or “multifaceted”, involves a team with members from various departments within the company, and formal relationships with groups that share the company’s vision and goals. Voluntary organizations, for their part, no longer see themselves as supplicants seeking handouts. They are aware that they can provide the company tangible benefits, including credibility and the ear of regulatory agencies.

The survey found that in health campaigner/pharmaceutical company partnerships, a multi-layered “synergistic” arrangement might see the drug company providing targeted educational programs about its products to patients within the organization’s membership as well as seed money to allow the organization to grow by raising additional funds in the local community; in return, the patient group could help the company develop materials that will “pique physicians’ interest.”⁵⁸ Companies may set up a partnership advisory board with members from different departments, including communications, product management and corporate and government affairs.

Many companies and groups have developed “best practices” such as contracts that spell out the expectations of both sides, to avoid misunderstandings. If a contract is considered too rigid to accommodate a multi-layered relationship, the partners may opt for a document that specifies “principles of partnership” to which both sides agree.⁵⁹

Public Relations Firms, Invisible Intermediaries

The use of public relations firms as intermediaries contributes to a lack of transparency, notes an article in the *Wall Street Journal*. “The drug companies typically leave few fingerprints, running their disease campaigns through PR [public relations] firms, patient groups, ‘institutes’ and other third parties.”⁶⁰

Victoria researcher Alan Cassels investigated the drug industry’s promotional practices in a program for CBC Radio’s *Ideas*.⁶¹ He interviewed people who work in educational and public relations firms arranging partnerships for drug companies. The vice-president of strategic development for a patient education agency told Cassels:

We frequently bring together patient advocacy groups with our health education staff to create content outlines for materials and programs that we create, and then we bring the manufacturer in as part of that three-way partnership. By doing that, you get the credibility of the advocacy group or the non-profit organizations. Sometimes they’re willing to put their imprimatur on a piece. Other times they are part of our advisory board and review process.

As this interviewee explained, the main value of the group’s support is the credibility the name of a non-profit can lend to promotional material that a physician will perceive as unbiased. This doesn’t require mentioning the company’s product brand:

The manufacturer recognizes the value of having advocacy group support ... mostly, truly, as an endorsement of the credibility of its content. And when you look at surveys of physicians, their top request, of course, is for unbranded, “unproduct-specific” information

to be provided to them to give to their patients. So that when you can get an advocacy group to say that your content is credible, unbiased, even if it mentions your product along with others ...

The managing director of Ogilvy Public Relations in New York explained to Cassels how she had helped manufacturers of osteoporosis drugs create awareness of the disease:

What needed to be done in the field of osteoporosis for all the companies that had a stake in that disease was that we needed to convince women who were much closer to the age of 50 [as opposed to women in their 70s and 80s] that osteoporosis was something they needed to be thinking about then because there were steps they could take in their 50s and 60s to make sure they didn't end up being that little old woman that they saw on the street. ... we had formed a coalition of groups that were interested in this disease, and that ranged from women's groups to health groups to big employers where there were a lot of women in the workforce, who all banded together and agreed that osteoporosis education was something that it was important for them to take to their membership, to their constituency.⁶²

The awareness and education campaign evolved into lobbying for funding and education:

And I think what happened certainly was really putting osteoporosis higher on the agenda, certainly for public funding. There was a legislative component to that campaign where a lot of third-party groups came to realize that it was important that women have access to bone mass measurement. If the test wasn't paid for, there were a lot of women who, even if their awareness was heightened, weren't going to seek that test and find out whether or not they, in fact, had the early signs of that disease.

National Breast Cancer Awareness Month (NBCAM), created in 1985 by the manufacturer of the treatment drug tamoxifen, is one of the most successful disease awareness campaigns. Speaking on behalf of AstraZeneca Pharmaceuticals to the Public Relations World Congress 2000, Karen Miller explained that NBCAM positioned Zeneca [now AstraZeneca] as a leader in oncology and has been used as a model for other health care initiatives.⁶³ Corporations form partnerships with advocacy groups, Miller said, because they are a trusted source of information for their members/patients and for the media who see them as a knowledgeable source with first-hand disease experience. Another draw is the influence that advocacy organizations wield in local, regional and federal decision-making processes.

The goal of promoting drug safety is notably absent from these industry initiatives. In fact, advocacy partnerships can be used to diffuse public concerns about safety. In a case study of NBCAM, Miller noted one effect of the company's 12-year program had been to "mobilize advocates for support of product approvals and to diffuse controversy." The controversy in question involved Proposition 65, an initiative of the California legislature that publishes a list of all chemicals known to cause cancer. While tamoxifen is useful in inhibiting the growth of a second cancer in women who have had the disease, the drug has been shown in clinical trials to increase the risk of endometrial cancer – a carcinogenic effect. In 1995, the panel of scientists that updates the Proposition 65 list agreed that tamoxifen should be added to the list. After an unprecedented intervention by

the state governor, in response to pressure from AstraZeneca and the National Cancer Institute, the decision was reversed.^m In Miller's account:

Concentrated advocacy outreach resulted in: letters to editors; advocates' personal calls to legislators to stop Proposition 65; advocates' testimony on the issue to California State Committee; and testimony at Federal (Dingell) hearings.⁶⁴

Barbara Brenner, executive director of the San Francisco-based advocacy group Breast Cancer Action, had a different perception of Zeneca's Proposition 65 campaign:

The NCI's materials on this issue [the long-term safety of tamoxifen] and the behaviour of vested interests like Zeneca and the NCI in the Prop 65 controversy are daunting reminders of what breast cancer activists have long known: we cannot rely on the cancer industry to inform us about issues affecting our health.⁶⁵

In sum, industry partnerships lack transparency in both process and spending. Even with the best intentions of groups, the partnerships can shape the public's understanding of health and illness in a way that promotes excessive drug use and undermines public safety. The partnerships also threaten to undermine public trust in voluntary groups. Finally, the prevalence of the partnership model marginalizes women's health advocacy groups and other health campaigning organizations whose primary concern is drug safety and accurate information.

Conflicts of Interest or Corruption?

Ethicist Carl Elliott, who has written about drug industry funding throughout the medical community,⁶⁶ questions whether "conflict of interest" adequately captures the impact of such funding in the medical milieu. Elliott worries that the term individualizes what is in fact a systemic corruption of institutions meant to serve the public good. He points to particular practices, such as pharma-funded ghostwritten articles in peer review journals and the suppression of negative clinical trial results, which go beyond mere conflict of interest to corruption.⁶⁷

In the case of advocacy groups, the pharmaceutical industry's use of voluntary groups to covertly manipulate policy debates arguably falls into the latter category. More generally, the very pervasiveness of pharmaceutical money in medical research, medical publishing, medical education, bioethics, pharmaceutical regulatory agencies and patient advocacy organizations creates a for-profit environment that inhibits healthy debate of pharmaceutical policy issues. While this paper focuses on pharmaceutical funding of advocacy groups, this practice is best understood as one component of a broad marketing strategy in which advocacy groups are only one player. To have an appreciable impact, the recommendations that follow would be implemented in concert with other strategies aimed at restoring a public interest mandate to health and medical institutions.

^m Tamoxifen was, eventually, added to the list, but AstraZeneca's campaign was a successful delay tactic.

VI. Conclusion and Recommendations

Based on the experiences of the past 15 years in Canada, the industry/health campaigner group partnership model has failed in the realm of health protection. Specific problems in the voluntary sector which have contributed to drug safety failures at the Health Products and Food Branch are:

- a) Loopholes in regulations requiring balance, accuracy, etc. in drug promotion that allow pharmaceutical companies to use partnerships in the voluntary sector to avoid regulatory controls;
- b) A lack of transparency in funding agreements between industry and health campaigners with a resulting loss of public trust in all voluntary groups;
- c) Contradictory policies within Health Canada that promote public participation in drug policy development while denying the funds necessary to ensure meaningful advocacy by groups that have a health protection mission;
- d) The proliferation of industry-funded groups promoting free-market pharmaceutical policies that endanger public health; and
- e) A lack of clarity in criteria for public participation in drug policy consultations that allows groups with industry funding to overshadow the messages of groups with much smaller budgets.

Women and Health Protection proposes the following changes to address the problems above, while recognizing the diversity of views within Canada's health advocacy sector:

1. To ensure that drug companies are not using partnerships to avoid regulatory controls on drug promotion, the federal government should:ⁿ
 - a. Require that informational and educational materials sponsored by consumer groups and funded by pharmaceutical companies be subject to the same regulations governing drug promotion as materials directly produced by a company (e.g., accuracy, avoidance of false or misleading statements or promotion of unapproved uses, an adequate discussion of risks as well as benefits).
 - b. Require that regulatory guidelines for meetings targeting health professionals also apply to public meetings and educational events sponsored by consumer groups.
 - c. Require that consumer groups list sources of funding in all publications and at educational events.
 - d. Require that consumer groups have a written policy on quality assurance of information materials, including a procedure for peer review by individuals or organizations independent of the pharmaceutical industry.
2. To provide alternative sources of funding for health campaigning groups:
 - a. Health Canada should initiate capacity building programs for patient and citizen groups to engage in education and policy response activities.

ⁿ These recommendations are adapted from Barbara Mintzes, *Blurring the Boundaries: New Trends in Drug Promotion*, Amsterdam: HAI-Europe, 1998: 27.

- b. The Canadian Institutes of Health Research (CIHR) should expand its knowledge transfer mandate to allow patient and community groups to apply for funds.
 - c. The federal government should initiate the creation of an arm's length health advocacy funding agency (or agencies) for health campaigning groups. The agency/agencies could be entirely funded by government or could draw from a combination of sources. Tax laws and other federal mechanisms could be used to encourage pharmaceutical companies and foundations to support the agency/agencies.^o
3. To promote transparency in groups engaged in advocacy, we recommend that the federal government set up a lobby registry system for disease/health consumer groups. To ensure that groups with a health protection mission are heard in consultations concerned with health protection, and to prevent pharmaceutical companies from using consumer groups to promote corporate goals at these consultations, the proposed registry would recognize three categories of groups.
- a. Independent: groups that have a stated policy to refuse pharmaceutical company funding will be eligible for funding from an arm's length health advocacy agency. They will be required to disclose the amount of their funding from this agency (as well as from other sources) and the terms of reference of the advocacy projects funded through the agency. These groups will be among the primary groups sought for public policy consultations on health protection issues.
 - b. Groups that engage in open partnerships with industry but who view their mandate as independent will also be sought for public policy consultations, provided they comply with disclosure rules. Disclosure rules would include: annual disclosure of the amount of funding received from drug companies (or PR agencies and others representing drug companies), the names of the companies, the proportion of total funding in their annual budget that this represents, and the terms of the contracts with each company. These groups will also be eligible for funding from the arm's length agency to support health advocacy (e.g., programs for prevention and to promote low-cost or alternative therapeutic approaches that drug companies are not likely to fund).
 - c. Groups which are unwilling to make public their industry funding will be excluded from HPFB consultations unless they apply to appear as industry representatives. They will have to register on the lobby registry but will be ineligible for funding from the independent agency.

^o A similar proposal for "blind trusts" has been made by HAI International with attribution to D. Gilbert and A. Chetley. See Lisa Hayes and Barbara Mintzes, *The Ties that Bind: Drug Industry Sponsorship. HAI-lights*. Amsterdam: HAI-Europe. July/August 1997; 2(2-3); and D. Gilbert and A. Chetley. *New Trends in Drug Promotion. Consumer Policy Review*, Sept./Oct, 1997, 6:5:165.

Endnotes

- ¹ PatientView. Health Campaigners, Fundraising and Industry Involvement. *HSCNews: News for Health and Social Campaigners*, Plaish, Shropshire UK: April 2004 (6):10.
- ² Ruttan, Susan. Sugar-coated Pills. *The Edmonton Journal*, October 8, 2003.
- ³ Picard, Andre. Charities 'Thank God' for Drug Firms' Money. *Globe and Mail*, January 4, 2001.
- ⁴ See, for example, Abelson, Julia and John Eyles. *Public Participation and Citizen Governance in the Canadian Health System*. Ottawa: Commission on the Future of Health Care in Canada, July 2002; and Pivik, Jayne Renee. *Practical Strategies for Facilitating Meaningful Citizen Involvement in Health Planning*. Ottawa: Commission on the Future of Health Care in Canada, September, 2002.
- ⁵ Picard, A., cited in Endnote 3; and Nebenzahl, Donna. Do Drug Firms Call the Tune? *The Gazette* (Montreal), April 9, 2003: D1, D4.
- ⁶ PatientView. Endnote 1, above.
- ⁷ A number of formal definitions of conflict of interest exist in the medical literature. See, for example, Thompson, D.F. Understanding Financial Conflicts of Interest. *New England Journal of Medicine*, August 19, 1993: 328 (8):573-576 and A. Shafer, Biomedical Conflicts of Interest: A Defense of the Sequestration Thesis—Learning from the Cases of Nancy Olivieri and David Healy. *Journal of Medical Ethics*, February 2003, 30:8-24. Shafer takes his definition from the business literature: Davis M. Conflict of Interest. *Bus Prof Ethics J*, 1982, 1:17–27.
- ⁸ Thompson, D. F. 1993: 573. Endnote 7, above.
- ⁹ Canadian Medical Association. *Physicians and the Pharmaceutical Industry (Update 2001)*. Ottawa: CMA Policy: Citations from principles 24, 32 and 33. Accessed online January 27, 2005 at: http://www.cma.ca/multimedia/staticContent/HTML/N0/12/where_we_stand/physicians_and_the_pharmaceutical_industry.pdf
- ¹⁰ See: Mauss, Marcel. *The Gift: Forms and Functions of Exchange in Archaic Societies*. Ian Cunnison (Tr.). New York: Norton 1967; Katz, D., J. Merz and A. Caplan. All Gifts Large and Small: Toward an Understanding of Pharmaceutical Industry Gift-giving. *The American Journal of Bioethics*. 2003, 3(3):39-46; Krinsky, Sheldon. Small Gifts, Conflicts of Interest, and the Zero-Tolerance Threshold in Medicine. *The American Journal of Bioethics*, 2003, 3(3):50-52.
- ¹¹ Dana, Jason, and George Loewenstein. A Social Science Perspective on Gifts to Physicians from Industry. *JAMA*, July 9, 2003, 290(2):252-255.
- ¹² Dana, Jason and George Loewenstein, 2003: 255. Endnote 11, above.
- ¹³ Thompson, D. F., 1993: 574. Endnote 7; Schafer, 2003. Endnote 7, above.
- ¹⁴ Pross, Paul, *Group Politics and Public Policy*, 2nd edition, Toronto: Oxford, 1992: 22.
- ¹⁵ National Advisory Council on Voluntary Action. People in Action: the Report of the National Advisory Council on Voluntary Action to the Government of Canada, Ottawa: Secretary of State, 1977: 97, cited in Paul Pross, 207, Endnote 14, above.
- ¹⁶ Pross, Paul, 1992: 209. Endnote 14, above.
- ¹⁷ Pross, Paul, 1992: 209. Endnote 14, above.
- ¹⁸ OCAPI home page: http://www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/index_e.html
- ¹⁹ Health Canada, Online at: <http://www.hc-sc.gc.ca/hppb/phdd/collab/collab2.html>
- ²⁰ Weiss, Rick. NIH to Set Stiff Restrictions on Outside Consulting. *Washington Post*. August 4, 2004:A1. Online at: <http://www.washingtonpost.com/wp-dyn/articles/A37841-2004Aug3.html>
- ²¹ Goozner, Merrill. *Unrevealed: Nondisclosure of Conflicts of Interest in Four Leading Medical and Scientific Journals*. Washington, DC: Centre for Science in the Public Interest, July 2004. Online at: http://www.cspinet.org/new/pdf/unrevealed_final.pdf
- ²² Health Canada's Office of Consumer and Public Involvement and Best Medicines Coalition. *Consultation Workshop Report on Patient Involvement Strategy*. Ottawa: Health Canada. December 13, 2003. Online at: http://www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/best_medicines_coalition_e.html
- ²³ See, for example, Gordon Floyd, Canada's New Social Contract: More Responsibility but No Voice? *The Philanthropist*, 1996, 13(2):39-45 and Betsy A. Harvie, Institute for Media, Policy and Civil Society. *Let Charities Speak: Report of the Charities and Advocacy Dialogue*, 2002.
- ²⁴ Seaman, Barbara. *The Doctors' Case Against the Pill*. Alameda, CA: Hunter House, 1995 (1969).
- ²⁵ Cooperstock, Ruth. Psychotropic Drug Use among Women. *CMAJ*, Oct 23, 1976,115(8):760-763; Ruth Cooperstock, Sex Differences in Psychotropic Drug Use. *Soc Sci Med*. July 12, 1978, (3B): 179-186.

-
- ²⁶ Mintzes, Barbara. *Drug Regulatory Failure in Canada: the Case of Diane-35*. Winnipeg: Women and Health Protection, 2004.
- ²⁷ Picard, A. cited in Endnote 3, above.
- ²⁸ See Nebanzahl, Donna. Do Drug Firms Call the Tune? *The Gazette* (Montreal), 2003; and Promoting Drugs Through Patient Advocacy Groups, CBC-TV *Marketplace*, November 14, 2000.
- ²⁹ *HSCNews*, 2004, cited in Endnote 1: 22.
- ³⁰ Johnson, Erica (producer). Phase-out of Animal Insulin Spells Problems for Some Diabetics. CBC-TV *Marketplace*, February 13, 2001. Online at: <http://www.cbc.ca/consumers/market/files/health/insulin/>
- ³¹ Abraham, John and Dr. Courtney Davis, 2002. Mapping the Social and Political Dynamics of Drug Safety Withdrawals in the UK And The US: Final Report to ESRC. Sussex, England: University of Sussex.
- ³² Lurie, P. and S.M. Wolfe. FDA Medical Officers Report Lower Standards Permit Dangerous Drug Approvals. Washington, DC: Public Citizen. 1998.
- ³³ Office of Inspector General. FDA's Review Process for New Drug Applications: A Management Review. Washington: Department of Health and Human Services, March 2003. Online at: <http://oig.hhs.gov/oei/reports/oei-01-01-00590.pdf>
- ³⁴ Wong-Reiger, Durhane. A Case for Regulated Direct-to-Consumer Promotion of Prescription Drugs. Toronto: Advocare (Consumer Advocare Network), August 18, 2003. Accessed online December 1, 2004 at: <http://www.consumeradvocare.org/index.php/ca/content/view/full/57/>
- ³⁵ See, for example, Mintzes, Barbara and Rosanna Baraldi. Direct-to-Consumer Prescription Drug Advertising: When Public Health is No Longer a Priority. Montreal: Women and Health Protection and DES Action Canada, 2001. Online at: http://www.whp-apsf.ca/en/documents/dtca_priority.html/
- ³⁶ Rabinovitch, Simon. Evaluation of the Romanow Commission's Recommendation for a National Prescription Drug Formulary. Student Working Papers on Health Law and Policy, University of Toronto, 2004: 8. Online at: http://www.law.utoronto.ca/healthlaw/docs/student_Rabinovitch-NationalFormulary.pdf
- ³⁷ Branswell, Helen. Fabry Patients Fight on After Panel Urges Government Not to Cover Drug Costs. Canadian Press. November 28, 2004.
- ³⁸ Hilts, Philip J. *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*. NY: Alfred A. Knopf, 2003: 236-254; Schuklenk, Udo. *Access to Experimental Drugs in Terminal Illness: Ethical Issues*. New York: Pharmaceutical Products Press.
- ³⁹ Abraham, Carolyn. Health Talks Offer No Remedies for Disparities in Drug Policies. *Globe and Mail*, September 18, 2004.
- ⁴⁰ Somerville, M. Do We Have a Legal Right to the Best Cancer Treatments? *Cancer Care in Canada*. Toronto: Cancer Advocacy Coalition of Canada, Fall 2000:6.
- ⁴¹ Duffy, Andrew, with files from Shelley Page and Glen McGregor. A Nation's Costly Addiction: Canada's Soaring Prescription Costs. *Ottawa Citizen*, January 19, 2002.
- ⁴² Elliott, Richard. Controlling Drug Costs for People Living with HIV/AIDS: Federal Regulation of Pharmaceutical Prices in Canada. Montreal: Canadian HIV/AIDS Legal Network, 2003. Online at: <http://www.aidslaw.ca/Maincontent/issues/cts/DrugPricingE/toc.htm>
- ⁴³ Quotes from Ed Koning (Fabry Society of Canada) and Kathy Kovacs Burns (Best Medicines Coalition), cited above in Helen Branswell, Note 12, and Carolyn Abraham, Note 13.
- ⁴⁴ PatientView. Endnote 1, above.
- ⁴⁵ Picard, A. Endnote 3, above.
- ⁴⁶ Graham, David, MD, MPH, testimony before the Senate Finance Committee on Vioxx, November 18, 2004.
- ⁴⁷ Website of the Arthritis Society of Canada. Available at: <http://www.arthritis.ca/toolbox/media%20centre/news/releases%202004/01102004/default.asp?s=1>
- ⁴⁸ Hogan, Bill. Pulling Strings from Afar: Drug Industry Finances Nonprofit Groups that Claim to Speak for Older Americans. *AARP Bulletin Online*, February 2003. Accessed December 12, 2004, at: <http://www.aarp.org/bulletin/consumer/Articles/a2003-06-30-pullingstrings.html>
- ⁴⁹ Mundy, Alicia. Hot Flash, Cold Cash. *The Washington Monthly*. January/February 2003. Accessed online February 24, 2003 at: http://www.washingtonmonthly.com/features/2001/0301_mundy.html
- ⁵⁰ Mintzes, Barbara. *Blurring the Boundaries: New Trends in Drug Promotion*, Amsterdam: HAI-Europe, 1998: 23-28. Online at: <http://www.haiweb.org/pubs/blurring/blurring.intro.html>

-
- ⁵¹ Silversides, Anne. *The AIDS Gravy Train: Pharma People are Always So Gosh-darn Nice. Xtra!* Toronto: Pink Triangle Press. Dec. 16, 1999. Online at: <http://www.xtra.ca/site/toronto2/arch/body382.shtm>
- ⁵² Kelly, Patricia. *Begging You Pardon: Exploring the Impacts of Pharmaceutical Industry Funding of Non-Profit Organizations*. MA Thesis. Victoria, B.C.: Royal Roads University, December 2002: 8.
- ⁵³ Kelly, Patricia. See Endnote 52, above: 17-21.
- ⁵⁴ Anonymous. New BCA Corporate Donations Policy. *BCA Newsletter # 50*. San Francisco: Breast Cancer Action. October/November 1998. Online at: <http://www.bcaction.org/Pages/SearchablePages/1998Newsletters/Newsletter050G.html>
- ⁵⁵ Rethinking Development: Promoting Global Justice in the 21st Century. Inter Pares Occasional Paper Series, No. 6, November, 2004. http://www.interpares.ca/en/publications/pdf/rethinking_development.pdf
- ⁵⁶ Picard, A. Endnote 3, above.
- ⁵⁷ Cohn & Wolfe. Partnership Report. Toronto. 2003.
- ⁵⁸ Cohn & Wolfe. See Endnote 57: 14-15.
- ⁵⁹ Cohn & Wolfe. See Endnote 57: 12, 34.
- ⁶⁰ Miller, W. Creating a Buzz: With Remedy in Hand, Drug Firms Get Ready to Popularize Illness. *Wall Street Journal*, April 27, 1994. Cited in Barbara Mintzes, *Blurring the Boundaries*, Endnote 50, above: 13.
- ⁶¹ Cassels, Alan. Manufacturing Patients. *Ideas*. Toronto: CBC Radio (AIR DATE: 2003).
- ⁶² Cassels, Alan. Endnote 61, above: 6-7.
- ⁶³ Karen L. Miller. *Patient Advocacy: Leveraging the Newest Dimension of Health Care Public Relations*. A presentation to the Public Relations World Congress 2000, October 24, 2000. Accessed online November 7, 2003, at: www.ipranet.org/workbook/page10.htm
- ⁶⁴ Miller, Karen, L. Endnote 63, above: 9.
- ⁶⁵ Barbara Brenner. Tamoxifen and You – What You Don’t Know Can Hurt You. *BCA Newsletter #34*. San Francisco: Breast Cancer Action, February 1996. Accessed December 11, 2003 at: <http://www.bcaction.org/Pages/SearchablePages/1996Newsletters/Newsletter034B.html>.
- ⁶⁶ For example, Elliot, Carl, Pharma Buys a Conscience. *The American Prospect*. September 24, 2001. Online at: <http://www.prospect.org/print/V12/17/elliott-c.html>; Carl Elliott. Six Problems with Pharma-Funded Bioethics. *Studies in History and Philosophy of Biological and Biomedical Sciences*. 23(2004):125-129.
- ⁶⁷ Elliott, Carl. Pharma Goes to the Laundry: Public Relations in the Pharmaceutical Industry. Public address to the Health Law Institute, Dalhousie University, Halifax. January 14, 2005.