Tales from the Other Drug Wars

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Foreword

Pharmaceutical research can claim many significant breakthroughs in the treatment of human disease and disability. It has produced, in the words of an Astra Zeneca official, “revolutionary medical advances worldwide”. And the achievements of the past pale when set against the promise of new and more effective treatments in the future. The seemingly unending development opportunities are a magnet to researchers, who hope to make a lasting contribution to their area of scientific investigation. The public has an interest in the development of new, effective ways of dealing with often devastating illnesses and in seeing those developments available as actual treatments as quickly as possible. Drug manufacturers are also interested in the quick introduction of new therapeutic agents, since every day gained is a day of patent protection during which profits, rather than costs, accrue. The incentives of patients, researchers, and manufacturers are aligned. Or are they?

Lurking beneath this rosy external picture of an industrial sector working feverishly to combat the ills that beset mankind is a darker interior. Much less well-known to the public, although common knowledge within the research community, is that breakthrough products are the exception rather than the rule. Most of the “research” enterprise is concentrated on the development and promotion of disease management models in which drugs with minor therapeutic advantage for a few people are built into major, often population-wide marketing strategies to manage drug-industry defined clinical ‘conditions’. The marketing strategies include raising public awareness of and fear regarding the condition, promoting untested screening programs, sponsoring biased continuing medical education programs, and direct-to-consumer advertisement of drug therapy. In keeping with these strategies, the drug industry saturates the market with a seemingly endless number of “me-too” products, new forms, new doses, and new delivery mechanisms. The introduction of these disease management models and ‘me too drugs’ will have little to no impact on the health of the population, but may have a large effect on the fortunes of particular pharmaceutical manufacturers.

The papers in this volume are a selection of the presentations at the Centre for Health Services and Policy Research’s 1999 Annual Health Policy Conference, “Competing Interests, Competing Evidence: The Uses and Barriers to Use of Research Evidence.” They provide views through a variety of windows that are obscured for much of the research community, and for the most part entirely inaccessible and therefore unknown to the general public. Those who do get periodic looks through these windows see a rather more gloomy landscape than that painted by the Rx&D (formerly PMAC, or the Pharmaceutical Manufacturers’ Association of Canada), the pharmaceutical industry’s ‘communications’ arm.

Robert Evans sets the stage with a chilling portrayal both of the infiltration and takeover of the country’s clinical research enterprise by pharmaceutical money and agendas, and of the tactics used by the pharmaceutical industry to ensure that results favourable to their interests emerge into full public view while findings threatening to sales and profits are suppressed. The extensive and growing support by the pharmaceutical industry of research in this country often comes at a steep price, and with a rather sinister implied threat—“do things our way, or you may end up not doing them at all”. To some observers, this looks a whole lot like “legal thuggery”, assault (though not battery) carried out through the mechanisms and with the assistance of our ‘legal’ system. Evans makes the particularly interesting observation that the corporate legal harassment of uncooperative researchers comes at no cost to the manufacturers—they win if they win; and they win if they lose. The same cannot be said for the researchers, who lose if they win, and lose big if they lose. He suggests that the only way to begin to combat these tactics is to be far more careful and honest with ourselves as members of the research community in the choices we make about our mandate, our obligations, and the conditions attached to our sources of support. Individually, we are easy pickings for the pharmaceutical industry; collectively, we may be able to develop enduring ethical guidelines that provide us with both protection and comfort.

Central to Evans’ case is the fact that the objectives of the pharmaceutical industry are quite different than those of (most of) the research community. Industry has a fiduciary duty to
drug dependency or, from the perspective of the pharmaceutical companies, committed life-time customers. In both cases, potential new ‘patients’ are identified through screening—cholesterol, bone density, the particular ‘illness’ for which the screening is encouraged is not important. What is important is that once a ‘marker’ is found, there is a pharmaceutical white knight, that will control—not cure—the ‘illness’, ready for the patient’s life-long consumption. The long term effects, and side effects, are often poorly understood because the trials on which approval was based did not follow patients for long enough to establish these outcomes with any confidence.

As with cholesterol, those with an economic stake in the drug peddling trade also have key economic interests in the screening technology. And so, in situations like this, we find unholy alliances between the manufacturers of the screening technology and the makers of the pharmaceutical ‘magic bullets’. The fact that...as the absence of a link between cholesterol-lowering drugs and heart disease seems to have been mysteriously forgotten.

Both Savoie and Bassett suggest that the key to preventing the proliferation and promotion of opportunities like cholesterol screening and bone densitometry rests with a more...political machinery in Ottawa) has lost sight of the fact that its first and foremost responsibility is to the citizens of Canada, not to the shareholders of Rx&D members. The drug regulatory approval apparatus seems increasingly to be a...and those interested in encouraging international trade and investment and de-regulation, whatever the consequences.

Indeed, Brill-Edwards suggests that we are in the...of a protracted process of dismantling the regulatory structures with which drug approval has been governed in this country. That process, involving three separate but related tracks (de-regulation,
de-professionalization, and de-construction) appears to be inexorably emasculating the Health Protection Branch, at least for many key public-protecting intents and purposes. The objectives of the drug manufacturers are to remove as many regulatory roadblocks as possible, and to minimize the time it takes to get a new product to market. Brill-Edwards suggests that the changes to the regulatory oversight processes at Health Canada are making these objectives increasingly easy to achieve. It may be no accident that we are already beginning to see the emergence of more new product-related health ‘events’ such as those associated with the high-profile Olivieri case.

But that is not the whole story. In addition to having successfully lobbied for a more favourable approval and regulatory process, the industry has also increasingly taken over the process of developing and providing the ‘independent’ evidence on which that process rests. An increasing number of drug trials are now designed, managed, and reported by the companies which developed the products in question or by private research consortia with which the companies contract. Even when trials are apparently conducted by ‘independent’ research organizations, including academics at universities across Canada, the drug companies still commonly control the question (with what products and what doses, and for what patients and conditions, is the new drug compared), they control the patients in the trials, they control how drop-outs and side-effects are handled and reported, and they control what information makes its way into peer-reviewed publications. No one else (with the possible exception of the Health Protection Branch) ever sees the entire picture. Researchers and physicians providing patients are, more often than not, simply pawns in this shell game, and the general public has no hope of ever having access to the information that would allow understanding of the intricacies of this drug research take-over.

Not surprisingly, Brill-Edwards suggests that there is now an acute need to revitalize the public presence in the process of evaluation and approval of new drugs, whatever happens to the Health Protection Branch of Health Canada. She also suggests an independent agency for “failure analysis,” akin to the role the U.S. Aviation Safety Board has vis-à-vis the Federal Aviation Administration. At the moment, the Health Protection Branch is not subject to any independent audit or oversight. When problems arise, there is an internal investigation. We have all seen that movie before.

Of course the enduring key to market success in this sector is getting physicians to prescribe your product. In addition to the time-tested approach of drug detailing directly to physicians, the pharmaceutical manufacturers spend significant sums of money advertising in media that physicians read. Barbara Mintzes describes the process in Canada through which this drug advertising is regulated. She makes clear that, in addition to increasing control over research and researchers, and over the regulatory approval processes, the pharmaceutical manufacturers are also, for all intents and purposes, permitted to self-regulate their members’ advertising. While the regulation of drug promotion has an unequivocal legal base in the Food and Drug Act, authority has been ceded to two organizations that are dominated by industry interests. Not only does the process have few teeth, but the penalties are so small as to be simply a minor irritation, part of doing business. It is largely complaint-driven, and the costs to the industry of non-compliance (as for example through advertising a product for non-approved uses, or for failing to note risks or side-effects) are tiny relative to the expected benefits through increased sales. The only wonder here is that there are not more egregious examples of false claims. Indeed, we might expect this as new forms of drug promotion, which are becoming increasingly common, take root. Sponsorship of patient/disease groups, and disease-oriented advertising in non-professional media (e.g. daily newspapers), fall completely outside of Canada’s regulatory codes. In addition, there is growing pressure to make direct-to-consumer advertising legal in Canada. Given the intended audience, this is likely to require more, rather than fewer, regulatory teeth. Yet as Brill-Edwards points out, the trend in the regulatory ‘centre’ appears to be in the reverse direction.

Clyde Hertzman’s paper closes this collection by asking why it is that the claims of health improvement that presumably underpin all of the drug promotion and use described elsewhere in the volume, are not more systematically evaluated. This may be a case of shoring up the dike after the fields are already flooded, but even this sort of activity is conspicuous by its absence. We have no systematized process of post-marketing surveillance which would not only identify serious problems post-trial, but which would also provide an ongoing ‘report card’ on the performance of new products. Drugs, once approved and marketed are, like health care professionals, ‘licensed’
for life unless they become implicated in extreme ‘health events’ that draw the notice of the public and the media (at which point the regulatory bodies have little choice but to get involved).

Were such evaluation to be possible, however, it seems unlikely that the new products that are the subject of the papers in this volume would show “population health” effects of a magnitude anywhere close to the effects implicit in, for example, morbidity and mortality differences across the hierarchy of social position, or income. This observation leads Hertzman to suggest that, in addition to an Aviation Safety Board analogue, there might be value in an overarching oversight/accountability mechanism such as a population health auditor-general, operating at arm’s length from the health care system and from its regulatory structures. Its objectives would be to evaluate new innovations within the health care system against other innovations with health impacts, outside that system, and it would have the authority to expose wasteful new ‘innovations’ for what they are.

At the end of the day, we find ourselves wedged firmly between a rock and a hard place. On the one hand, we look with anticipation to the pharmaceutical research industry to assist in the alleviation or elimination of the effects of some of the most devastating and debilitating human diseases. On the other hand, as the papers of this volume have made so abundantly clear, all that glitters is not gold. Indeed, nuggets in this game are far less common than in the mining exploration business. The industry, however, has perfected the creation and sale of fools’ gold.

The challenges for the research community (and not just physician researchers but, increasingly, economists, health services researchers and others) in the face of these realities are daunting, and exceedingly important. Are we to be taken over, to become pawns in a shell game of unprecedented magnitude, with implications for human health that we are only beginning to understand? Or can we maintain the principles of scientific integrity and the interests in enquiry for the sake of discovery that drew most of us to that enterprise in the first place? A great deal rests on how each of us chooses to answer those questions.

Morris L. Barer
Kimberlyn M. McGrail
August 2000
dedicated professionals in the industry and together we are Astra-Zeneca and we’re well worth a closer look.1

They are right, they are absolutely right—they are well worth a closer look!

Consider a quote from an article in the Globe & Mail. This is from a letter sent to Dr. Anne Holbrook, a physician and pharmacist at St. Joseph’s Hospital in Hamilton, asking her to refrain from distributing guidelines developed by a committee she chaired. “In the event you proceed notwithstanding this warning you should assume that our client will take appropriate steps including the commencement of appropriate legal proceedings in order to protect its interests and to obtain compliance with the law.”2 This sort of letter could put a chill into anyone’s day. As Slartibartfast says in The Hitchhiker’s Guide to the Galaxy, “if you don’t hurry, you’ll be late, as in the late Arthur Dent. That’s a threat. I hear they’re terribly effective.”

This threat was made to Anne Holbrook personally, telling her she was not to release the report which the committee that she chaired for the provincial government had developed on the relative effectiveness of different ulcer medications. It was a threat issued on the letterhead of a Toronto law firm with the name of Smart & Biggar. The objective of this threat was very clear. It was intended, first and foremost to “protect [its client’s] interests” by suppressing the information that the committee had developed. The business about “compliance with the law” was just pure window dressing. It was, let us say, an idiosyncratic interpretation of the Food & Drugs Act.

The point is that if I go up to someone and say, “Look, if you make any more noise in here I’m going to punch you in the nose,” that constitutes a common assault in my understanding of the law. We often think of assault as being something physical. It is not. Assault is a threat which may, as in this case, be intended to secure compliance. If I then proceed to try to hit the individual in the nose and succeed, that is a battery. And that is why we talk about assault and battery. Common assault consists simply of uttering threats. The letter from Smart and Biggar to Anne Holbrook is a form of

1 Quoted from a recruitment advertisement circulated in the fall of 1999.

2 Shuchman M (1999). Drug firm threatens suit over MD’s product review, Globe and Mail, Wednesday 17 November.

legal assault. It is a direct threat with the intent of ensuring compliance in the interests of the client of Smart & Biggar. The client happens to be Astra-Zeneca.

This situation is not unique. A few years ago, Bristol-Myers Squibb attempted to suppress a report on statins prepared by CCOHTA (the Canadian Coordinating Office for Health Technology Assessment). The Oliwieri case involving Apotex is perhaps better known, but yet another example of similar behaviour. And a recent article in the New England Journal of Medicine by Richard Deyo and his associates3 provides a series of case studies of efforts by commercially interested organizations in the US to make personal attacks on researchers. Attacks there have gone all the way to Congress, in attempts to have the budgets of organizations that funded the research eliminated. (The equivalent of this is harder to do in Canada, but see Ken Bassett’s paper elsewhere in this collection for an example of an attack with similar intent, taken up at the level of a University faculty.)

This is a multi-pronged strategy and it is a strategy which is broadening out and becoming more common, despite the fact that Bristol-Myers Squibb was rapped on the knuckles by both the trial judge and the appeal judge and was the subject of a very critical editorial in the Journal of the American Medical Association.4 The judgements and editorial did not deter Astra-Zeneca from issuing its legal threats. This pattern of behaviour is becoming systematic, and as our friend Ted Marmor reminds us at any opportunity, “Nothing that is regular is stupid”. The attacks are not only of the legal sort, as with the case of Holbrook, but are also attempts to use the mechanisms of the scientific community itself. In other words, these attacks have been based on charges of scientific misconduct.

A charge of scientific misconduct has the interesting feature of making the accused guilty until proven innocent; it is up to the person charged to prove that (s)he was not engaged in scientific misconduct. It does not take much of an imagination to envision the impact on a program of research of responding to such allegations.


The number one imperative is to respond to a charge of that sort; if nothing else, this will slow to a crawl, if not bring to a standstill, the research that is the target of the accusations. And even if the charge is eventually dismissed, as it will likely be, some considerable damage will have been done. The fact of a charge of scientific misconduct remains on record.

Thus, this type of attack is successful even when the company loses the case, because the threats disrupt people’s lives, they slow research, they create a climate of intimidation, and responding costs money. In the CCOHTA case, Bristol-Myers Squibb preserved its market position for a year by delaying the release of a CCOHTA report they perceived as threatening to that position. They may have lost in the eyes of the legal system, but they actually came out ahead commercially (the same cannot be said for CCOHTA, the very existence of which was under assault). This was true even after considering the costs of bringing the legal action. Bristol-Myers Squibb made a sound commercial decision. They generated shareholder value by their actions. It was not just a mistake—and it was not stupid.

Bristol-Myers Squibb did suffer a public relations black eye for a little while, but they were able to send a very strong message to the research community. The gist of the message was: “Do you really want to get into this? Even if you win, you will lose money and you will lose research time. The next time you come up to a competition for grants, you will not have been doing as much research as your competitors because you have been busy fighting a legal case. Pity.” So it is possible to assault one to teach a thousand, and probably the tactic will work.

Some have argued that this type of attack represents a short-sighted approach providing short-term gains at considerable long-term cost to the industry. I am not convinced by this argument. It appears to reflect a fundamental misunderstanding of the workings of public outrage, media attention, and corporate motivation. Issues like this create “sound-bite outrage”. That these terrible things happen is news for a moment, or if things get really hot, for a few weeks. Then things settle down, and we are off hearing about Chechnya or Somalia, or another market meltdown. The limited space in the media and public attention span gets quickly filled with something else. And if profit-oriented corporations are increasingly engaging in these types of actions, their judgment is that whatever the short-term image fall-out, it will have a net positive effect on retained earnings and shareholder equity.

This set of observations provides guidance to the party being assaulted—the research community. You are invited to regard the process described above as legal thuggery. Would Astra-Zeneca, if they thought it would work, hire someone to go out and smash Anne Holbrook’s kneecaps? Probably not, but not because it would be wrong, but rather because it would be unprofitable. It will not be profitable because it is unlawful and all kinds of bad things could happen. But should we as a research community not now regard and treat the people who work for Bristol-Myers Squibb or the people who work for Astra-Zeneca as if they were members of the Mafia, as if they were people who hire thugs to intimidate members of our community in their own interests? To date, we do not and have not. But why not? Is it because they simply have too many resources at their disposal?

Going back to Astra-Zeneca’s recruitment notice, the company would have us believe that it is one of ten companies supporting an institute at a public university. This independent, not-for-profit Institute has a mission of delivering outstanding, not just regular, research on health economics, health outcomes, and health policy, as well as providing related services to government and health care providers. Some of the words in the official advertising have such a nice ring: “to deliver health policy research services to governments”. They conjure up images of a public-spirited Institute based at a prestigious public institution, producing and delivering high quality research and advice to governments; a little white truck will be delivering gold-plated advice to your MP’s office any day now. To some observers, this is recognized as lobbying; to others it is simply trying to create a positive environment for products. Do the people behind this public-spirited initiative have any connection whatsoever with thuggery and intimidation? Heavens no!

Astra-Zeneca and their ilk are actually engaged in two kinds of research. Neil Postman uses a distinction between practices and processes which he attributes to Michael Oakeshott. Processes are the things that go on in nature; they are the objects of scientific investigation. Research on processes tends to be cumulative over time. We learn things about the natural world. Physicists collect up the body
of knowledge they call physics and they keep adding to it and every now and then something turns out to be wrong and they correct it, but generally it is progressive. Chemists do likewise, as do biologists and so on. The ‘real’ sciences study processes which are immutable. The laws of physics, we believe, do not change. They certainly can be manipulated; you can do wonderful things with a better understanding of natural processes by manipulating them in a variety of interesting ways. But you do not change the processes themselves.

The study of policy, and research in all the misnamed social sciences, is the study of practices, human practices at that. We study the practices of human communities, for example. And those can be changed.5 Within fairly wide bounds there are a number of different ways of organizing human communities and a wide range of policy choices that would affect how the members of those communities interact. Therefore, policy is amenable to a variety of types of research lenses. Not only can one examine the underlying structures and processes (where did a policy come from? how does it get embodied in activities? what apparent effects does it have?), but policies can also be evaluated (is this policy better or more effective or cost-effective than that one) which takes us into the whole normative realm. The policy process itself may or may not take advantage of such evaluative research.

Which brings us to the subject of many of the other papers in this conference monograph. How do we as researchers overcome barriers to the uptake of our work into the policy realm? In other words, how do we get human practices to change in response to the information that we think we have generated and that we believe ought to affect policy change? If we frame our enterprise in that way, then what we are focusing on is how to modify behaviour, human practices, in response to research evidence. If this is so, how are we different from the drug and medical device industries? Is that not what they are doing?

In fact, that is precisely the rationale for supporting the University of Alberta fellowships. Even to the muddle-headed, it should be crystal clear that the corporate offices of partners in this enterprise are not funding health economics fellowships because of a fascination with the intricacies of discount rates or opportunity costs; nor are their executive branches much interested in the notion of adding to human knowledge. They are responsible, legally and economically, to their shareholders for the creation of shareholder value, which could be called profit if that were not politically incorrect (“creating shareholder value” sounds so much nicer and more technical, but it is plain and simple profit). It is their legal responsibility, and if they are choosing to spend some of the corporation’s revenue on this kind of activity, then they believe that the research and policy advice that they deliver to governments will improve the environment for the profitability of their corporations.

The way that this might work is fairly straightforward. Processes are studied to develop products, and practices are studied to make those products profitable. Products become profitable by shaping and guiding and restricting information. If there is information out there that tends to threaten the profitability of your products, you must suppress it. If you cannot suppress it, then attempt to suppress the individual who produced it. Suppress the people who financed it, send out threats; in short, do what the pharmaceutical manufacturers are doing. Make very sure that the information that threatens profitability does not get out. Restrict competition.

There has been an amazing transformation over the last fifteen years. George Orwell, in both his essay on the politics of the English language and in 1984, attached extraordinary importance to the way in which rephrasing things changes the way we think about them. Until about fifteen years ago, patents were clearly recognized by everyone in the legal and the economic community as the means by which the state conferred a monopoly on a private group or individual, not as a reward for past performance, but as an incentive to future performance. That was quite explicit in any number of sources. The more recently evolved concept of ‘intellectual property’ (wonderful phrase!), reverses that. Now it is the past that matters; it is the property you have accumulated by virtue of your investment in research or in another company that produced research. One way or another you have purchased a piece of intellectual property and the state

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5 They are, to a degree, arbitrary although there are presumably practices like murdering all your children which tend to be somewhat self-limiting. Eating each other has turned out to have certain downsides as well, since you may wind up getting kuru, or something of the sort, in the same way as feeding meat to your cattle can turn out not to be good for your brain. Actually, anyone who is going to feed meat to their cattle in the first place has got something wrong with his or her brain, but I think that is what the econometricians call sample selection bias.
is not conferring a privilege on you, the state is, in fact, obligated to protect your property the same way it would protect my house if it caught fire or was being burgled.

This idea of intellectual property assumes that the state is not making a concession to you. It is not engaged in a balancing of the disadvantages of monopoly against the advantages of providing incentives for future innovation. It is obligated to protect what is just another piece of property. The issue is how to define that property, how many years to protect it, how restrictive to make the protections, and so on. In practice, the world standard for patent protection is however the Americans want to define it. That is hegemony by another name.

There is, thus, an uncomfortable parallel between what is exercising the research community, which is how do we get people to change their behaviour in response to our research?; and the primary thrust of Astra-Zeneca, which is how do we get people to change their behaviour in response to our research? We talk about research uptake, but this means the same thing; somebody takes up our research and does something different as a result. When we worry about research uptake, it is not solely that we want to justify our existence by making sure people know we have lived. We also think the world would be a better place if people paid attention to our research. We might get a nasty shock if they ever did, but that is, for most of us, a prime motivation.

We may experience a little discomfort when we realize that this is no different from what motivates the drug companies. The only difference would appear to be the criteria for judging whether the research has made the world a better place. For the drug companies all that is necessary is that the research increases shareholders’ equity. Remember Vince Lombardi’s comment that winning is not the most important thing, it’s the only thing. For a for-profit corporation, profit is not the most important thing, it’s the only thing. The rest is only window dressing to gull the rubes.

It works pretty well; there are a lot of rubes out there and they believe the kinds of lies promulgated by representatives of organizations like Rx&D (formerly the Pharmaceutical Manufacturers Association of Canada) who claim that pharmaceutical company advertising budgets are actually education budgets. Of course, they have redefined education to mean convincing you to believe what they want you to believe. But we public-spirited and publicly supported university professors think education means more than our students believing what we want them to believe, right? Yes, well, this begins to get a bit awkward. What’s good for the goose….

We have bought into a long-run objective of healthier populations and effective health care. It is an even better world if the health care that is effective is produced efficiently. But that endless search for more efficient solutions means doing research, the results of which will often threaten others’ jobs. For example, recent research released by the Manitoba Centre for Health Policy and Evaluation demonstrated that downsizing the hospital industry in that province has not had negative effects on patient outcomes. It appears to be sound, solid, evidence-based research of more than passing interest to policy-makers in that province and beyond. I might feel differently about that research were I a member of the Manitoba Nurses’ Union.

A question to address is whose interests, or what kinds of interests, should take precedence in the game of attempting to change behaviour, of influencing the health care policy process? An individual, for example, may have an interest in providing labour to an industry that is overutilized, as hospitals have been through most of Canada’s history. We have implicitly, and without reflection, adopted a social objective that says that interest is of secondary importance. We might qualify this by suggesting a labour adjustment process to buy people out or deal with downsizing by attrition. This might be desirable for political reasons, because we hope it will be less uncomfortable. Of course (and this gets us very much into the realm of amateur policy evaluation) the result of BC’s adopting a labour adjustment strategy while Alberta adopted a bloody-minded axe-man’s approach to downsizing the hospital sector is that the Alberta government is deeply unpopular and likely

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6 Increasing proportions of university-based researchers rely on drug or device manufacturer research lifelines. If those direct i.v. drips are a little too obvious, well then we’ll cook up a ‘partnership’ between MRC and Rx&D so that it becomes more difficult to ascertain whether any given piece of research is being supported publicly or by private interests (but who is (or was) driving MRC policy should be relatively obvious by the nature of the partnership). What would make the world a better place begins to lose focus...

Once we get into the research uptake business, we are really opening up a can of worms. If we take this task seriously, we ought to go back and ask ourselves what basis there is for the kinds of implicit value judgments that underlie the recommendations we make. These will be a threat to the profits of the drug industry, and they will react to that threat. This is the essence of the challenge and response model. Human empires also strike back. The recommendations of BCOHTA (see Bassett paper elsewhere in this monograph) are a natural response to the growth of evidence-based medicine.

An expansion of research activities to develop better evidence will be a threat to some interests, and those interests will then try to suppress that information, and create or support their own research engines (“my evidence is better than yours...”). This is, in generic terms, not much different than the pharmaceutical industry’s response to pharmaceutical benefits management companies (PBMs) in the US. These companies were developed as a means by which costs of pharmaceuticals might be lowered within a highly competitive managed care environment. But while they made sense for managed care companies, they had obvious effects on the bottom lines of the pharmaceutical manufacturers. In response, the pharmaceutical industry (a) began buying out the PBMs, and (b) ratcheted up the amount and forms of direct-to-consumer advertising. Anything—in this case research evidence—that is effective in making the environment for profit less good, will generate a whole suite of responses to try to suppress, undercut, blunt, and attack upstream either the generation or the use of that research.

As researchers, we face two challenges. First we need to try to figure out what the nature and the source of our mandate really is. As one of my students asked some time ago, “[a]re you just basically a kind of a systems boy scout running around trying to do a good turn here, there and everywhere?” Or as King Edward’s commissioners in the Middle Ages said, the commission known as Quo Warranto—“By what right do you do these things, on whose

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9 DTCA has been so successful in the US (if not, the manufacturers would not continue to pour obscene amounts of money into it), that the pharmaceutical manufacturers have stepped up the lobby in Canada. See, for example, Mintzes in this volume.
Over the past few decades, public health strategies have relied on individual-level health promotion initiatives in order to attempt to improve the health of the population. It is debatable, however, whether this movement toward consumer education and involvement has resulted in better utilization of health care resources or better health outcomes. In the area of heart disease, for example, attempts at educating consumers around the use of tests and drugs has led to an increased use of inappropriate interventions. We suggest that the forces seeking to increase the use of tests and drugs are so sustained and powerful that consumer education measures are put at a severe information disadvantage rendering them unable to compete.

The prevention and management of heart disease, and in particular the promotion and use of cholesterol-lowering drugs in women, provide a particularly compelling illustration of the challenges facing researchers, administrators and practitioners who seek to improve the health of populations through evidence-based decision-making.

This paper will discuss three of the key elements that have shaped the landscape of heart disease in BC, Canada, and in much of the world. These are the Framingham Heart Study, the National Cholesterol Education Program’s guidelines on cholesterol testing and treatment, and the women’s health movement. We will then discuss how we can learn from these elements and develop an approach which could be effective in ensuring an evidence-based use of tests and drugs.

The Framingham Study
Cholesterol has been implicated as a risk factor for heart disease since the late 1940s. At that time, pathologists performing autopsies on war casualties found that nearly 80% of the victims had gross, visible lesions in their coronary arteries. These were mostly men in their early 20s without symptoms of heart disease.
The presence of the lesions in the arteries of asymptomatic individuals raised the question of how to identify individuals at risk for heart disease when arterial damage begins to appear so long before symptoms emerge.

The Framingham study was a large, longitudinal cohort study designed and funded to answer that question. In 1948, it recruited about 5,000 men and women between the ages of 30 and 62 from Framingham, Massachusetts, a small industrial town near Boston. Every two years, the study subjects were asked to complete a questionnaire about their lifestyle and diet, and to undergo an ECG test, a treadmill test and other lab tests.

The main contribution of this study has been the identification of potential risk factors for coronary heart disease. One of these factors is high cholesterol level. To put this finding in perspective, to date, over 240 other risk factors for coronary heart disease have been identified. These risk factors include male baldness, short stature, and (for men) being married to women in white-collar jobs. However, very few of these risk factors have received as much attention as cholesterol.

One of the most important outcomes of the Framingham study, however, remains the massive media dissemination and diffusion of the presumed importance of cholesterol in coronary heart disease in men, women and the elderly, and the (also presumed) importance of diet as a preventive measure. By the early 1980s, nearly two-thirds of the American population was aware of the reported role of dietary cholesterol in coronary heart disease and of the reported importance of reducing dietary fat intake as a means of controlling cholesterol.

The National Cholesterol Education Program

Many of the findings of the Framingham study were later formalized in a series of guidelines produced from 1985 onward by the National Cholesterol Education Program (NCEP). The NCEP was established by the National Heart, Lung & Blood Institute (NHLBI), which had been funding trials to determine whether the risk factors identified by Framingham could, in fact, through early identification and modification, lead to the prevention of heart disease. The NCEP recommendations represented the beginning of a large and intense public health campaign around cholesterol, a campaign that is still ongoing. In both American and Canadian media, ads promoting the importance for individuals to be tested for cholesterol can regularly be seen. Messages like “Live healthier, live longer, cholesterol counts and counts for everyone, whether you want to prevent heart disease or whether you have heart disease” can been seen across North America. An advertisement from the Canadian Heart & Stroke Foundation used to promote better heart health in Canadians reads: “Know your [cholesterol] numbers, ask your doctor if your levels are normal.”

The NCEP recommendations, therefore, went one critical step beyond the media messages that arose from the Framingham study. In the NCEP recommendations, the emphasis no longer was on the importance of diet and healthy lifestyles. Now, through the NCEP recommendations, everyone was given the additional responsibility of having their blood cholesterol levels tested and, for a large proportion of individuals tested, of adhering to life-long treatment with cholesterol lowering drugs. The NCEP recommendations therefore represent a not-so-subtle shift in emphasis from the importance of diet to the importance of testing and drug treatment. By the late 1980s, almost 30% of Americans and between 20% and 25% of Canadians had been prescribed a lipid-lowering drug.

Women’s Advocacy

The third key element in shaping the landscape of heart disease has been the women’s advocacy or the women’s health movement. The goals of the women’s health movement were to encourage the ‘de-medicalization’ of health issues, to enable women to regain control over their own bodies and health, and to ensure that women’s voices were heard when the care, the needs and the wants of women were discussed.

An additional goal of particular relevance in this context, was to encourage women to gain equal access to health care services. Through the women’s advocacy movement, women became recognized as consumers, and as health consumers increasingly sophisticated in their demands. In the case of heart disease, this sophistication resulted in an increased demand for the latest tests and drugs. The obvious contradiction with the ‘de-medicalization’ goal of the women’s health movement appears to have been missed.
The resulting landscape: in the interest of the population’s health?

The combination of these three elements—the Framingham study which identified dietary cholesterol as a risk factor for coronary heart disease, the NCEP recommendations which institutionalized a focus on cholesterol tests and treatment as a positive health measure, and the women’s health movement which encouraged women to demand the latest drugs and tests—has been instrumental in leading to an increased use of tests and drugs.

The case of cholesterol illustrates well how the demands for testing and drugs interact: testing leads to increased utilization of cholesterol lowering drugs, which in turn leads to even more testing, which in turn leads to more drug utilization. In developing health policies, it is therefore essential to consider policies on testing procedures together with policies on pharmaceutical interventions.

One question remains: has the resulting landscape led to better population health? Are the public health strategies derived from the Framingham and NCEP guidelines based on valid research evidence of effectiveness or are they a facade for other interests?

A critical examination of the Framingham study produces the following findings. The study actually found an association between blood cholesterol and coronary heart disease in young and middle-aged men only. No corresponding association was found in women or in the elderly, and it is in the latter group that most of the cases of heart disease occur. The study also found no association between dietary cholesterol and the risk of coronary heart disease, even in young and middle-aged men. Dietary saturated fats were not associated with heart disease even after adjusting for other risk factors. Buried deep in the massive number of reports produced from the study is a quote from the investigators saying “...there is, in short, no suggestion of any relationship between diet and the subsequent development of coronary heart disease in the study group.” This evidence is very different from the public health messages disseminated from the study.

The trials paid for by the NHLBI, and on which the NCEP recommendations were based, in reality found no improvement in morbidity or mortality from either cholesterol testing or cholesterol lowering drug treatment. Georges Mann noted that “[t]he NCEP failed to acknowledge what the diet trial is saying firmly and loudly: No, the diet you use is not an effective way to manage cholesterolemia or prevent heart disease, and the drug you so generously tested for a pharmaceutical house doesn’t work either.”

The NHLBI spent over $300 million on the trials referred to here. This is relevant as it emphasizes the pressure the NHLBI was under to develop recommendations which could be used as a basis for a health promotion strategy.

In addition, the individuals who wrote the NCEP recommendations were essentially the same individuals who conducted the trials and who directed the lipid clinics where the testing and the follow-up for these trials took place. The funding for these clinics came from the NHLBI and from the pharmaceutical industry. The NHLBI also has ties to the drug industry as it conducts drug trials free of charge to the industry and then endorses them.

There were other powerful interests behind the NCEP recommendations. The American Medical Association, Merck Sharpe & Dohme pharmaceuticals, Kellogg and Pam also combined forces to promote the idea that cholesterol is the enemy. These parties were consequently creating a need for their respective products offering “the” solution in the fight against cholesterol.

Moore noted that “…the NHLBI’s eager partners in promoting cholesterol consciousness are the drug companies which are understandably very excited that the government is creating their largest new market in decades.” He went on to observe that “…a program that may have truly begun in sincere but somewhat misguided zeal for the public good, became very quickly intertwined with greed. The world was learning how much money could actually be made scaring people about cholesterol.”

Crowds of other agencies and companies have joined in the sustained reinforcement of the importance of cholesterol through


the advertisement of their respective products. One can hardly open
a magazine or browse the internet without seeing offerings of the
latest anti-cholesterol miracle drug, new low-cholesterol wonder
diet, new life-saving cholesterol treating device or health-conscious
cholesterol-lowering food product.

The voice of evidence questioning the value of directing so
many public resources towards cholesterol control was and is still
being lost amongst the thousands of advertising messages directed
at the public. Not only are private companies investing money in
direct advertising to the public, they are also investing in marketing
and advertising research in an effort to improve the effectiveness
of their advertising campaigns.

The women's advocacy movement is and has also been used
by private industry as a channel to promote the use of tests and
drugs. The message being delivered to women about cholesterol,
for example, is that if men are getting cholesterol-lowering drugs,
women should get them too. The discourse ignores the issue of
whether these tests and drugs are effective in women. In fact, to
date, no study has shown benefits from cholesterol-lowering drugs
in women. When an increased risk of breast cancer was identified
in one of the cholesterol trials, the result was quickly dismissed,
even by women's groups, as a chance finding, or as a 'plot' to
deny women equal access to health care services and health care
resources. The promotion of cholesterol lowering in women has
been such that in BC in 1997, 46% of people prescribed cholesterol
lowering drugs were women.

Given the current landscape, is it therefore possible to
intervene so that an evidence-based use of drugs and tests is
achieved? If yes, how could this be achieved?

The cholesterol experience suggests that it would be inefficient,
and most likely ineffective, for governments to try and compete
with the intense and well-financed advertising campaign often
disguised as consumer 'education'. Private interest spending on drug
advertising could only be matched by governments (that is, the
public) with difficulty and could result in the diversion of resources
away from the promotion and use of effective interventions. To
sell its products, industry can more easily simply increase its own
spending, and in the resulting advertising spending race, the public
would be the most foreseeable loser.

Another approach would be to control the amount of information
from the private industry allowed to reach the consumer. As Mintzes shows in this volume, however, there has been little willingness in Canada to enforce the existing legislation against direct-to
consumer advertising. In addition, this would not control the many
subtle ways in which the industry advertises its products.

Many have suggested that clinical practice guidelines would
be an effective tool to ensure evidence-based practice. As shown by the NCEP guidelines, however, even guidelines endorsed by
medical associations cannot be guaranteed to be evidence-based. Past appraisal of clinical practice guidelines have shown that the
failure of CPGs to lead to evidence-based practice is not only an
issue of adherence but also of internal validity of the guidelines
themselves.

In short, it seems difficult to control the diffusion of drugs and
tests once they become available to physicians and the public. It is not without reason that the drug industry has been so vocal in
Canada against reference-based pricing and has brought so much
pressure over the years to reduce the influence of organizations like
the Health Protection Branch of Health Canada. The reference-
based pricing system in British Columbia controls which drugs
become listed on the provincial formulary and hence available
through public funding. The Health Protection Branch is mandated
by the Federal government to approve drugs, tests and devices for
market in Canada.

For these reasons, a more effective approach may be to bring
evidence 'upstream'—to support an evidence-based decision process
by those individuals and agencies determining whether or not a
test or drug should become available to physicians and consumers
in the first place. As compared with 'downstream' measures which
seek to guide individual patients or physicians, 'upstream' strategies
focussing on the processes which determine availability of drugs and
tests may be more likely to be effective in reducing inappropriate
utilization.

There have been a number of local success stories using such
an approach. For example, the Capital Health Region Technology
Assessment Committee has established an evidence-based decision-
making process. The results of their appraisals are used by the
regional body in making funding decisions.
On Trying to Stop the Measurement of Bone Density to Sell Drugs: A Tribute to a Friend

Ken Bassett

In May of 1996, the Medical Services Commission of British Columbia slapped a moratorium on public funding of bone mineral density (BMD) testing in new facilities in the province. BMD testing is an x-ray technique used to assess bone strength and to predict future fracture risk. Low bone density is increasingly used to justify drug therapy.

Unlike the FDA process, examination of the research evidence by individuals and agencies making decisions about availability needs to take place within a structure and process which ensures the accountability of participants, applies clearly-stated rules of evidence, and protects the broad interest of society in the best possible health outcomes.

In light of weak evidence, interested parties’ strategy may be to argue even more loudly. While difficult, we believe it is possible to ensure that decisions are made based on valid research evidence such that the private interests promoting the un-evidence-based use of drugs and tests can be effectively counteracted. It is a matter of will.

Linking researchers with policy makers, while necessary, is not sufficient in itself. For example in the United States, the FDA, the federal agency determining drug availability, approved Lovastatin, one of the cholesterol-lowering drugs. The growth in the use of Lovastatin was the fastest ever for a drug approved by the FDA. Approval was based on two studies of less than seven months follow-up which did not examine either morbidity or mortality; despite the fact that statins had been found to be carcinogenic in animals.

In May of 1996, the Medical Services Commission of British Columbia slapped a moratorium on public funding of bone mineral density (BMD) testing in new facilities in the province. BMD testing is an x-ray technique used to assess bone strength and to predict future fracture risk. Low bone density is increasingly used to justify drug therapy.

The moratorium, and the process of review leading up to it, effectively stopped the diffusion of BMD technology in publicly-funded facilities in the province for three years. The moratorium occurred because a Medical Consultant with the BC Ministry of Health took a stand based on the best available scientific evidence at the time. As he explained, “I was convinced that there was no scientific evidence that BMD testing led to improved patient outcome. In my opinion, we had better things to spend our money on.”

As of late 1999, the Medical Consultant had left the Ministry; his contract had not been renewed. The BMD moratorium ended. And in 1999, the number of publicly funded facilities with BMD-testing capability doubled. Commercial interests were promoting BMD testing in most large and medium-sized communities in the province.

Despite the ‘final’ outcome, the story of the BMD moratorium should be told. It provides an opportunity to acknowledge the tireless and committed work of someone who had the courage to
make an influential, evidence-based policy decision. Its outcome reminds us, as does the cholesterol testing story of Isabelle Savoie’s paper (see Savoie, this volume), about the power and persistence of the private interests whose well-being depends on selling tests and drugs, whatever the evidence might indicate, and of the daunting challenge of attempting to forestall the diffusion of technology that has gained a foothold. This story also emphasizes the importance of critically evaluating diagnostic imaging devices such as BMD. The potential impact of BMD extends far beyond the availability and use of densitometers, the testing instrument. In this case, and in many others, the testing technology (BMD) is used, in part, to diagnose ‘diseases’ that then ‘need’ to be treated with pharmaceuticals. As with cholesterol testing, the testing technology is, in effect, a marketing tool.

The Beginning

Funding for the more than $1.5 billion allocated to diagnostic and treatment services in BC is the responsibility of the Medical Services Commission. One of the mandates of the Commission is to provide “reasonable access to quality diagnostic facility services for BC residents.” The Advisory Committee for Diagnostic Facilities (ACDF) was established to provide the Commission with advice regarding the availability and distribution of diagnostic tests and facilities. It assesses whether a test such as BMD is available in existing facilities (public or private), and whether the available services are adequate to meet demand.

The ACDF consisted of five doctors (a pathologist, a radiologist and three general practitioners) and one public representative. Two of the general practitioners worked for, and therefore represented, the Ministry of Health. One of these two was the Medical Consultant, and it was his position as chair of the committee that made the moratorium on BMD possible.

The ACDF was not mandated to advise the Medical Services Commission on issues of medical necessity. This leads to two questions: 1) Why was the Chair of this committee assessing medical necessity instead of service distribution? His short answer was that “no one else and nowhere else in the Ministry were issues of medical necessity of BMD being raised”; and 2) How was he able to raise the issue of medical necessity in this context? In response to this there was another, equally short, answer: “I didn’t. Instead, I used several procedural issues to stall requests for more BMD facilities.”

The medical consultant describes the ACDF in the period immediately prior to the moratorium:

Back in 1995, we were suddenly getting all these applications from all over the province asking to add BMD [testing capacity] to facilities. Hospital administrators and radiologists were insisting that people living in their regions deserve access to BMD equal to people living in Vancouver and Victoria, areas already supplied with BMD technology. At the ACDF we were also made aware of the lengthening waiting lists for BMD testing at these existing facilities.

The growth in demand is evident from the data in Figure 1. Between 1990 and 1995, expenditures on BMD testing paid for by the Medical Services Plan nearly quadrupled.

13 These figures are unadjusted for changes in the fee schedule, but these changes were relatively minor over this time period.
normal or above normal BMD levels, at every age;
2) age is so dominant a risk factor that prevention strategies should be prioritized from oldest to youngest regardless of BMD; and
3) the clinical care strategies proven to reduce fractures do not involve testing with, or treatment based on, BMD.

Furthermore, BMD has not been linked to any improvement in health outcome. Women are being tested at age 50 and based on those results are being asked to take medications to prevent fractures predicted to occur 20-30 years later. In the absence of proven benefit, women are being asked to take estrogen, a medication known to have significant long term health risks particularly in relation to breast and ovarian cancer, for several decades.

This fueled the Medical Consultant’s concerns about medical necessity. He asked about the utility of a BMD test to guide therapy and to improve patient outcome. As far as he could tell, as a practicing GP, he should be telling all women, regardless of their BMD measurements, to eat better and exercise more. As an employee of the Ministry of Health, the Medical Consultant saw himself as representing the last possible opportunity to control diffusion of BMD technology in the province. BMD testing had already passed the major hurdle of acceptance in radiology departments of several tertiary care teaching hospitals. Device manufacturers often struggle for years to get their device into these institutions.

BMD testing also already had a fee code within the Medical Services Plan benefit guide. Establishing a fee code and payment conditions can take several years because, under a capped global expenditure budget, fee codes are fought out in a very competitive environment within the BC Medical Association. Having the fee code—even though it was an old one originally used for an isotope as opposed to x-ray technique—was a major boost to diffusion of BMD measurement into clinical care across the province.

Despite this situation, the Medical Consultant held out some hope of controlling BMD measurement in hospitals. I did not share his optimism. Only one hospital group in the province, the Greater Victoria Hospital Society, had a process in place to consider medical necessity of new technology. Yet BMD testing is one of the dark moments in the history of the Technology Assessment Committee at the Greater Victoria Hospital Society. The committee could
not bring itself to consider BMD testing because it was such an important potential source of desperately needed funds. Hospitals in BC are able to bill for BMD measurement, and other diagnostic services, provided to outpatients; these services provide funds that augment the global budget.

Consequences of Diffusion

The ‘osteoporosis disease management model’ favoured by several large drug and device manufacturers is a masterfully crafted means to promote the medical management of bones and ‘bone health’ across the life-span. It brings together BMD measurements with specific drug therapy designed to alter those measurements. The ultimate goal is to create a direct relationship between BMD measurement and drug prescription. Since the early 1990s, the osteoporosis disease management model has been vigorously promoted for all women at or beyond menopause.

This model draws attention away from problems of diet, exercise, lifestyle, poverty, and unsafe walking and shopping environments, and toward a specific, measurable, alterable component of bone structure. Not only is it alterable, but pharmaceutical products exist for the job (the fact that weight-bearing exercise could also alter BMD, as well as conferring other life-course benefits, is conveniently ignored). In their absence, it seems a virtual certainty that the pressure for BMD testing facilities would not have developed. The problem for our HTA office, and the concern shared by the Medical Consultant, was that there was no proven connection between measurement and treatment based on the osteoporosis disease management model on the one hand, and the probability of future fracture, on the other.

With BMD in mainstream hospitals, an established provincial fee code, and no possibility of internal hospital regulation, it looked like nothing could stand in the way of massive expansion of BMD testing. The Medical Consultant explained what he did next:

The big step was deciding that widespread BMD testing was not a medical necessity, and therefore that funding BMD was not in the public interest. ...I was concerned about just stalling on making ACDF recommendations regarding new facilities. I could have stalled by asking for more information, but that would not have been wise. The applications would have remained pending and new applications would have piled on top. Too many applications sitting for too long makes the Ministry look bad. I needed a way to influence the proceedings. You convinced me of the state of the evidence; but evidence did not matter in this decision beyond my own resolve. No, I had to move to convince the ACDF committee and the Commission that a decision was unwise at this point because of several uncertainties. I argued that decisions regarding further BMD funding should not be made until three issues were settled:

1) the fee for BMD is adjusted downward to reflect the use of newer x-ray rather than older, more costly, nuclear medicine techniques;
2) a BCOHTA report is completed;
3) a BMD Protocol is published. [emphasis added]

The Medical Consultant judged that whether the Medical Services Commission believed in the medical necessity of BMD or not, the procedural concerns were sufficient for the Commission to establish the moratorium. After all, the Medical Services Commission had already initiated the development of a protocol in one of its other subcommittees. What the Medical Services Commission did not know was how long the BMD protocol would take to produce or the problems it would create for both proponents and critics of BMD testing.

The Medical Consultant acted in the only way he saw possible, which was to influence whether BMD became available to clinical care, rather than how it was used in clinical care. He feared that once diagnostic imaging technology such as BMD became widely available, the game would already be lost (recall the cholesterol testing story related by Savoie in this volume). No publicly-funded groups, no regulatory efforts such as clinical guidelines or protocols, have been able to counter the commercial forces rolling out the BMD-centred osteoporosis disease management model anywhere in the developed world.

The Moratorium Years:
Limiting Public/Growing Private Payment

Two of the justifications for maintaining the May 1996 moratorium were met relatively quickly. First, in fiscal 1996/97 the provincial fee paid for BMD was rolled back for single site measurements
I will respect the Medical Consultant’s request not to repeat any of his comments on the use of scientific evidence during these protocol meetings; it is safe to say that the development of the BMD protocol was a very miserable experience. The protocol went through 17 drafts before being published in 1999. The final product was less than satisfactory to everyone involved. Several radiologists on the committee considered the protocol ‘too discretionary’. For example, one condition for payment allowed physicians to order a BMD measurement whenever it would assist them in making a diagnostic or treatment decision:

Bone density [measurement] should only be performed when the results are likely to alter patient care. It may be appropriate for the following indications:

• other situations where information on bone density is considered essential to decisions about therapy.

During the process, several of the radiologists on the Working Group became our ‘friends’, including one department head who, based on our earlier BCOHTA report, had written to the Dean of Medicine requesting that the Office’s funding be terminated and the office removed from the university. This individual began using our report and our critical position on BMD measurement to justify a restrictive protocol on public BMD funding. ... the moratorium was lifted in 1999. Within a few months, six new sites became eligible to bill the Medical Services Plan.

Lessons

The BMD moratorium taught BCOHTA important lessons:

1) avoid CPG and protocol processes like swampland—they are! If BCOHTA has learned nothing else in a decade of providing evidence on new and emerging technologies (including drugs) to health care policy-makers, it is that CPGs and anything like them can be co-opted and corrupted. Even if they are not, they are unlikely to be a major source of influence on clinical care;

2) move upstream to provide evidence, preferably in person, to individuals involved in decisions about what becomes available to clinical medicine;

from $125 to $57, and restrictions were placed on concurrent testing at a second body site. Second, the BCOHTA, led by Carolyn Green, published an HTA report that summarized the findings from fourteen major systematic review groups around the world.\textsuperscript{14} The conclusion of all of these groups was that BMD testing does not result in a reduction in fractures.

The third condition, producing a funding protocol, moved much more slowly, and is a story on its own. It illustrates that if you are convinced that a medical device is not medically necessary, a limit on diffusion through a moratorium is far more effective than trying to influence clinical care more directly through protocols or guidelines.

To understand what went on, it is necessary to know that the BMD moratorium only restricted public payment for BMD. Private clinics were free to offer BMD, and charge patients directly, once they were accredited and licensed by the Diagnostic Accreditation Program. Once the possibility of private BMD clinics became known, they began to appear. The light went on, and individuals who had been pushing for more BMD testing capacity in public facilities turned 180° and began to favour—at least privately—BCOHTA’s critical position towards BMD evidence, and the moratorium on public funding. Publicly, however, they continued to denounce BCOHTA and the government for restrictions on BMD access, and argued in favour of routine BMD testing.

At the same time, the Medical Services Commission established a Protocol Steering Committee and Protocol Working Groups that consisted mainly of service providers. The Working Group developing the provincial BMD protocol consisted primarily of radiologists, at least one of whom was widely known to have a financial interest in one of the private BMD clinics. Similarly, the Working Groups developing funding protocols for laboratory tests consisted mainly of pathologists, many of whom may have had financial interests in private facilities. The protocol process, while potentially a place to consider medical necessity, was not actually structured for that type of input. BCOHTA participation was explicitly excluded from committee proceedings. The Medical Consultant acting as Chair of the ACDF represented the Ministry on all of these protocol committees.

\textsuperscript{14}Green CJ, Bassett K, Foerster V, Kazanjian A (1997). Bone mineral density testing: Does the evidence support its selective use in well women?, BCOHTA 97:2T.
3) the stronger the industry-promulgates the “Disease Management Model”, the further one has to move ’upstream’ to address the health care system pressures to approve funding of the testing and treatment options that comprise the “Disease Management Model”. The issue is not only the test and treatment itself, but also increased use of that test and treatment beyond what scientific evidence will support.

The epilogue belongs to the Medical Consultant:

I wasn’t interested in just distributing BMD or any other technology equitably around the province. I thought my job was to spend public funds wisely. I believed I was supposed to ask what was medically necessary, not to make sure everyone got a BMD [measurement] because their neighbour had one. It still bothers me that no one else in any of those committees asked about medical necessity. …Look, I’m no hero, I’m just a GP who happened to have no vested interest in promoting BMD technology. You know about Whistle Blowers. I’m sort of like that. I didn’t blow the whistle on anyone (I’m not like Olivieri); but I’m in the same boat. I didn’t play the game, so I lost. … Yes, it bothers me that I lost, not the people who were going along with distributing BMD. Thanks for telling my story.

Canada’s Health Protection Branch: Whose Health, What Protection?

Michele Brill-Edwards

There are laws in Canada that set out the rules of the game for how evidence about the effects and effectiveness of drugs is to be weighed in the process of their getting to market. Other sectors of health care have to rely on generally accepted practice conventions that may or may not be evidence-based. In this respect, the pharmaceutical sector is unique. Regulatory activity in this sector draws its legitimacy from the Food and Drugs Act. This Act has been the focus of considerable debate over many years and has seen some dramatic changes in the 1990s. The nature of some of the recent changes has very important downstream consequences for the consuming public, as well as for everyone engaged in the weighing of evidence regarding the safety, efficacy, effectiveness, and cost-effectiveness of drug products.

The intent of the Food and Drugs Act is found in the Foreword to the older editions. There we find a very simple, yet eloquent, statement of purpose: “to protect the public from health hazards and fraud in the sale and use of foods, drugs, cosmetics and medical devices.” Yet that very simple statement speaks volumes about the hundred-year history that supports the need to have legislation to constrain manufacturers with respect to what products they can sell and what they can say about those products.

There has been a tendency over the last few years to think of regulation in negative terms. This general perception is often fed by the business press. In fact, regulation is a public good. It is the legal intervention by government into the marketplace to constrain the behaviour of private interests where those private
The thirty-year history of deregulation illustrates that the process is quite deliberate. More importantly, we are already seeing damage from deregulation and no one is paying any attention to it. The train is still moving toward full deregulation despite sobering evidence that should be getting considerable public attention and debate. Consider that the mad cow debacle in Britain was, in fact, a de-regulatory mega-disaster, not simply an accident. In the 1970s when it was decided that feeding sheep offal to cows would be an advisable thing, the regulatory climate in England permitted it, despite the fact that it flew in the face of thousands of years of precautionary action by farmers and feed producers not to take that components of the agency, and the emasculation of the laws that govern the regulatory process. The Bureau of Drug Research, for example, has been dismantled, so there are no more public drug research labs. On the food side, half the labs were destroyed (including the smashing of beakers, willful destruction of reference samples and that kind of thing). That process was half-over before there was any kind of public reaction. The labs that still exist are in limbo at the moment, but the clear intent remains to disassemble the Health Protection Branch over the next few years, thereby dismantling the structure with the legal authority to enforce the Food and Drugs Act.

The laws that created the authority for the Health Protection Branch (HPB) function are also in a state of tremendous change. The Food and Drugs Act is being cleaved into two pieces. A new Food Safety Act was proposed in the previous Parliament and is due to be introduced in the 1999/2000 Parliament. The remaining parts of the Food and Drugs Act will then be put into what is called the Therapeutic Products Act, a new drugs act. This may sound like housekeeping, but subtle changes are being introduced in these legislative moves. The standards for both drug approval and food safety are being lowered in the new pieces of legislation. But the ways in which these standards are being lowered are not likely to be noticed by the average professional, and will be completely invisible to the average member of the public. For example, the new Food Safety Act says an injurious food cannot be sold. This means that there must be causal proof that the food is injurious before it is taken off the market—an inversion of the previous, and heretofore standard, burden of proof.

We are now in the final phase of a three-phase Canadian process of deregulation in the pharmaceutical industry, which is perhaps one of the best-kept secrets around. The first phase, lasting until the early 1980s, involved the discrediting of regulation—the creation of a picture of regulation in the public mind as nothing more than bumbling bureaucrats wasting taxpayer dollars and interfering with an otherwise efficient marketplace in the production, distribution, and utilization of drugs. Then in the mid to late-1980s, we went through a second phase of de-professionalization, during which the regulatory agencies responsible for this sector were stripped of capable professionals—physicians, scientists, chemists—who could intelligently evaluate data and had the professional capacity to defend their decisions.

The final, and current, phase of deregulation is the dismantling of the structures of the regulatory agency, the physical

risk. The result was that Britain lost its beef industry for the better part of a decade. And of course it was the farmers who paid the price, not those who made the regulatory mistakes. More recently, the U.K. lost its plasma industry as a secondary result of the mad cow disease. The infective agent of mad cow disease was shown to be transmissible from human to human via blood plasma. Could similar things happen in Canada? Well, in fact, they have. We dodged the bullet on mad cow disease, but we certainly got it right in the forehead on blood.

It took a long time for the Canadian public and health care professionals to understand that, had blood been regulated as required under the Food and Drugs Act, we would not have had a Canadian blood scandal. Blood and blood products are ‘drugs’ as defined under the Act; therefore they ought to have been regulated under that Act. The failure to uphold a statutory duty—a failure that may constitute criminal negligence—is the reason we have a criminal investigation involving the highest levels of the federal government.

The Food and Drugs Act is part of criminal law in Canada primarily because a breach of the Act can place human life at risk. Furthermore, misleading people about the merits of a food or a drug is fraud, another criminal act. So why are we not paying attention to the dismantling of a system that is so vital to us when very serious harm to the public has already resulted from the dismantling to date? Does no one care? Who is representing the Canadian public in Ottawa these days?

The elements of deregulation that apply specifically to drugs are a speeding up of the approval process for both the assessment and approval of clinical trials developed to test drugs, and the assessment of drugs prior to their market availability in Canada. Expert advisory committees and independent experts are increasingly substituting for, rather than complementing, the work of the HPB. This increases the potential for conflicts of interest. It has also reduced the expertise available in-house, consistent with a policy shift toward viewing the pharmaceutical industry rather than the public as the client of Health Canada. Since the pharmaceutical industry has plenty of expertise, why duplicate internally? The question of conflict of interest seems rarely to be raised. This policy shift has been denied by Health Canada in hearings before the Senate, but even the Senate wrote in an interim report that “while the Department denies that industry is their client, the entire body of documentation produced by the internal staff under oath, plus produced by external interested parties, demonstrates that, in fact, the industry is the client of the Department”. They would not be the first public body to forget who the public is.

The drug development and regulation process begins with clinical trials usually undertaken in academic settings or under the supervision of evidence developed by the company must be sufficient to justify the nature and size of trial proposed. Over time, this pre-trial review process has been accelerated. For many years there was no time limit on this review, and the number of patients needed to be established in advance of clinical trials is being distorted at best, and eliminated at worst.

When the sixty-day policy was first brought in, deaths during trials began to follow almost immediately. For example, a death in the Volmax trial became a coroner’s case and a coroner said that, in fact, they had no duty to assess these trials. This was untrue, but somehow it escaped cross-examination.

The HPB has also failed to exercise its authority during the conduct of a trial. The Olivieri story, the story of LO1, deferiprone is an example of such a failure. Dr. Olivieri went to the HPB when she began to see her data going sour and realized that the patients in her trial were at increased risk and the company was not going to heed her concerns. She was told that this was not a matter on which the Health Protection Branch would intervene. This response was not consistent with the mandate of the HPB, with its...

16This may seem hard to believe, but so few people, including lawyers, understand the role and duties of Health Canada that a self-serving denial of duty usually succeeds. The attitude is that if Health Canada says something is not their duty, it must be so. It was an uphill battle at the Krever inquiry to establish the duty of Health Canada to regulate blood.
duty to protect the public and to protect the safety of participants in clinical trials. It appeared to be simply one more bit of evidence that the HPB considered Apotex, rather than the patients in the trial, its ‘client’. But again, if a government authority simply stops meeting the terms of its mandate, who is going to recognize that or do much about it? The beneficiaries of this new disregard are concentrated and powerful; the victims, unorganized, unfunded, and unaware of processes that might provide relief.

Another phase of the drug regulatory process involves new drug submissions which involves an evaluation of the entire body of data, including the clinical trials outcomes, on a drug prior to approval. The difference between this process and what might be done by an academic group like the Therapeutics Initiative at UBC is that the HPB has the legal power to compel companies to produce all of their evidence. Failure to do so can theoretically result in a jail sentence, although that is never done. There is, in fact, more data available to HPB reviewers than to any external reviewer, but these data remain secret. As a result, reviews done by non-governmental groups may produce different results than those produced by the HPB. This happens because companies may choose to forego publication of results in a peer reviewed journal if the results are not consistent with their sales intent. If the HPB sees industry rather than the public as their client, by what mechanism will negative information that arises post-approval be brought to light?

The final phase of regulation starts when a drug gets to market. This is the phase of post-marketing surveillance and promotion. Again the Food and Drugs Act is very clear about what can and cannot be said by a company about its products, but as noted in other papers in this volume (see papers by Evans and Mintzes), there are many ways around the law. Overall, we are dealing with relentless acceleration intended to compress the time to market for potential new drug products. Not only are pre-existing deficiencies in the approval process being exposed, but now we have actually begun to lower the standards. This can only create additional weak spots in the regulatory armament.

In the last year we have seen the quiet introduction of the policy of ‘Notice of Compliance with Conditions’. This permits a company to market a drug in Canada without prior evidence of efficacy; in essence, then, the drug can be marketed even if there is no evidence that it works. All that is required is evidence that the Department describes as ‘promising’, which is left undefined. The only condition on such marketing is that the company commits to carrying out more research. But there is no stipulation of what would constitute acceptable, or sufficient, additional confirmatory research, and there is no legal mechanism with which to compel the company to make good on the promise and actually undertake the research.

The Food and Drugs Act and regulations are clear that ‘substantial evidence’ is required to get a drug to market, so this new policy pretty clearly violates the current law. To paraphrase the new policy, ‘We will let drugs go to market in cases where there is no substantial evidence so long as whatever evidence there is shows promise, and so long as the manufacturer commits to continued research, which we know they will because they’re all good, public-spirited corporate citizens’. What we have here is this country’s drug regulatory authority violating the very regulations that it has a statutory duty to uphold. But no one seems to have caught on. This is a system where dramatic changes are being made, where drugs are coming to market without manufacturers having provided the evidence required under current law, and the agency responsible is not only not meeting its regulatory obligations to the public, it is aiding and abetting.

Even if the regulatory process were functioning well, there are still means by which companies can influence drug development and drug regulation, the most important of which is the design, conduct and interpretation of drug trials. AIDS patients in the late 1980s got a sudden education in drug development and put their collective finger on a very serious problem. They reminded the HPB, the regulators, that they were dealing with product testing, not medical research. They pointed out that, in general, academic clinical researchers do not design and implement drug trials in an environment free of influence by the manufacturer of the product being studied. Data collection, interpretation, analysis and publication are generally in the hands of the company, and the physician investigators are very often just along for the ride because they are the people with access to patients. The patients have figured this out, the industry has figured this out, and the regulators have figured this out. The only group that has not
There are many ways to prevent the disclosure of negative, or it. This was matched by failure to disclose (under-publishing) of data which were not so favourable in terms of drug promotion. These times. This is an abuse of the scientific process, however you look at it. Among a collection of thirty-one studies, ten were published twice, another ten were published three times and one was published five times. The analysis of conflict of interest concerns with righteous indignation and say ‘How dare you suggest that that trip to Greece had anything to do with my opinion about the drug!’, ... fools of ourselves. Others understand that to get at motivations and incentives, one simply has to ‘follow the money’.

Finally, companies have direct influence over publication of data. An article in the November 1999 issue of the Journal of the American Medical Association demonstrated the production of multiple publications from one data set (over-publishing).

The conduct of trials can also be influenced through the timing of the start and stop dates. If early trouble develops in a study it can be stopped prematurely. The fact that the stop actually occurred ahead of schedule does not become public, except perhaps in the context of court cases.

The deferiprone experience provides a good example. The early promise of this iron chelator ran into trouble with failing efficacy becoming apparent half way through the major pivotal randomized controlled trial. When the principal investigator, Dr. Nancy Olivieri, decided to inform her patients in the trial and the medical community of this possibility, the company abruptly stopped the trial. This precluded evolution of data to confirm the loss of efficacy. No news precludes bad news. The Olivieri data were then withheld from the European, Canadian and other regulators on the basis of being “sloppy data” not worth reviewing. In Europe the drug was approved with no scrutiny of these data. This is under challenge by Olivieri in the European Court of Justice.

It is vitally important to bear in mind who is interpreting the results of a trial. The potential biases are perhaps most obvious when it is the company that is interpreting and reporting on its own data. But more subtle forms of bias are, if anything, more rampant. Even when data are evaluated by ‘outside parties’, those external researchers will often have received support from the company promoting the product. A recent study of the impact of conflict of interest is very pertinent here, as it provided hard evidence that the receipt of funds and other benefits from industry biases the manner in which data are interpreted.17

Funding and other benefits from companies have covert and insidious, not overt, influences on our decisions, and we are being foolish as physicians if we insist on burrying that uncomfortable fact. When we respond to conflict of interest concerns with righteous indignation and say ‘How dare you suggest that that trip to Greece had anything to do with my opinion about the drug!’, we have to understand that nobody believes us, indeed, that we are making fools of ourselves. Others understand that to get at motivations and incentives, one simply has to ‘follow the money’.

Finally, companies have direct influence over publication of data. An article in the November 1999 issue of the Journal of the American Medical Association demonstrated the production of multiple publications from one data set (over-publishing). The analysis looked at non-steroidal anti-inflammatory drugs and showed that among a collection of thirty-one studies, ten were published twice, another ten were published three times and one was published five times. This is an abuse of the scientific process, however you look at it. This was matched by failure to disclose (under-publishing) of data which were not so favourable in terms of drug promotion.

There are many ways to prevent the disclosure of negative, or

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Beyond influence through drug trials, companies can attempt to manage the regulatory process through influencing bureaucrats, politicians, professionals and the media. Companies hire lobbyists to make their case with government directly through ministers and ministerial assistants. In Canada there are no regulations governing funding provided to politicians between elections. There is a lot of focus on contributions to election campaigns, but as citizens we are kept in the dark about what goes on between campaigns. It is also not unusual for companies to phone reviewers of drug submissions directly and ask ‘Why is this drug not being put through; it’s on the market in England, why isn’t it on the market here?’ It is even more common for them to press the senior officers of the HPB to intercede on their behalf even though what happens to individual drugs should not be a matter for the attention of officers in these senior positions.

When a senior officer who has been contacted by a company sends a message down to the ‘worker bee’ level, the staff get worried. A staff reviewer might have twelve submissions on their desk at any given time and suddenly the Director-General is interested in one. As the senior physician in charge, I would at times have staff come to me and say ‘Why is he interested in Drug X?’ and I would ask myself ‘Indeed, why is he interested in Drug X?’ and I would then know what was going on at the lobbying level. It is unfortunate that this goes on, but it is even more unfortunate that it goes on behind closed doors where there is no way to deal with it. The people who sense the pressure at the lower echelons of the Department do not have any recourse. They know that they have limited ability to fix the internal system when drug approvals are rushing through without the proper checks and balances. They know that the influence is coming from higher up in the Department and outside the Department, and they know that influence is illegal and that if it ever comes to light they are going to be implicated in it. They are caught in a classic power squeeze, where the benefits of attempting to expose this wrongdoing are not obvious, but the personal costs certainly are.

The public’s view of particular drugs is influenced largely through their contact with physicians in this country (at least to
this point in time). Increasing numbers of those physicians are, in turn, being influenced directly by detailing, and by money from the manufacturers, and indirectly through their professional societies. There is hardly a professional medical society in Canada that is not funded by industry and there are many, many horror stories to demonstrate that professional societies will inevitably defend either industry decisions or, more commonly, industry-friendly government decisions, even though the facts may point in the opposite direction. Again, these societies do not need to harness very many of their collective neurons to figure out the consequences of cutting their own financial umbilical cord. One recent example is the Canadian Medical Association setting up a rather bizarre committee that concluded that breast implants were safe, when in fact they were on the market illegally because no evidence of safety had been developed as required by Canadian law.

Industry also routinely influences the context of decision-making by ‘working’ and ‘feeding’ the media. Health beat reporters are under constant pressure to produce riveting copy, and if companies are willing to put out quick press releases that provide all the background data, then the reporter’s job is that much easier. There is then no need for time-consuming background work or chasing down hard-to-find independent academic researchers for interviews. There is much for the rest of us to learn about interaction with the media, and no better teacher than the pharmaceutical industry. If the public interest is going to be served, there must be voices in the media who reflect the public interest; right now that is rarely the case.

The industry’s reach extends beyond national borders, since it is multinational in structure. For example, it is no accident, and very common now, that when a drug issue gets sticky we suddenly find the World Health Organization or some equivalent body weighing in with suitably lulling commentary. Despite the aura of independence, international agencies are beholden to their member countries, largely the governments of the developed world, and industry influences these governments’ positions in those agencies. When you scratch the surface to look at the roots of the decision-making, you come right back to the major countries and their industrial sponsors.

In Canada, the road to policy influence travels not through Health Canada, but through Treasury Board, Industry Canada and the Privy Council Office. For example, the entire deregulation movement was spawned in, and directed from, those areas. Key cabinet committees such as the Priorities and Planning Committee might be composed of ministers who know virtually nothing about a particular issue because they have completely unrelated portfolios—Defense, Industry, Transport. Who better to educate them than the corporate lobbyists? There is no countervailing process of a public interest input, so that lobbyists end up making the ‘public’ case. Again, we are drawn back to the question about why there are no alarm bells ringing. In short, you cannot be alarmed about matters about which you know nothing.

Secrecy and privacy pervade the entire regulatory process. The manner in which an ever-increasing amount of the country’s medical research gets funded is a major barrier to any open discourse on this problem is the deeply engrained culture of deception that pervades behaviour in large institutions, both private companies and public institutions. People will believe it until someone says ‘Excuse me, there’s a Food and Drugs Act’ or until you get twenty lawyers involved and they realize ‘Oh, yeah, there is a Food and Drugs Act’.

As the effectiveness of denial begins to wear thin, it is time to replace it with a more powerful drug, delay. Once the jig is up and the average citizen is starting to understand that there is a problem, a committee is set up to study the issue. Or, more research is called for that will take at least two or three years to complete. In the case of calcium channel blockers the line was, ‘We need more data and the study is underway, but it won’t be ready until the year 2002’.
Coincidentally, by then the patents for key calcium channel blockers will have expired, and the question will be moot. A delay tactic is an almost foolproof way of getting a hot issue back off the public’s radar. ‘Oh, yeah, that’s being dealt with, we don’t need to worry about it any more.’

While the public may snooze off during the delay phase, the interested parties are wide awake and active. Their strategy is to harness the final two Ds: divide and discredit. They identify among the opposition the ‘softies’ who can be seduced to go along with the company or government perspective. The ‘middle-grounders’ can be relied upon to fold soon after and follow the softies, which leaves the hard liners to be discredited. There are endless ways of discrediting people. Dr. Olivieri became ‘difficult’. Dr. Abenschein, who spoke up about dexfenfluramine long before it was even put on the market, let alone taken off the market, was considered ‘unreliable’ by the Canadian regulators. This is the phase when white collar thuggery, as Bob Evans put it, really gets up a head of steam.

Meanwhile, if the media cannot be sold on the discrediting, and the hot issue continues to resonate with the public, the news coverage itself can be discredited by being described as hysterical. This was true around the reporting of food safety issues recently. As media coverage of the safety questions surrounding genetically modified bovine growth hormone grew steadily, the news itself was dismissed as “media hype” by Monsanto executives and government apologists. Government scientists who spoke out about the factual scientific evidence supporting the safety doubts were sanctioned as disloyal public servants. This is a powerful discrediting tool. The federal court has now handed down a landmark ruling in the case challenging the government’s authority to sanction the two scientists for speaking to the media. The court ruled in favour of the scientists’ duty to speak publicly about safety concerns when all internal means to ring the alarm bells have failed. Unhappily, we have no formal mechanism to permit such crucial disclosure.

If we agree that the public interest is best served by reliable, accurate, complete information about drugs, served up in a way that communicates effectively with potential and actual patients and their physicians, then we must accomplish at least two things. First, we have to acknowledge publicly that the increasingly dependent relationship between government and industry is not serving the public good, that it is not acceptable for the Health Protection Branch to be so heavily under the influence of the pharmaceutical industry. We have to state publicly that that influence is distorting our ability to get accurate information and to use it to keep patients alive and to reduce suffering.

Secondly, we have to ask ourselves if we are not going to have a Health Protection Branch, what do we put in its place? We need a system that is open, informed, independent and accountable, not just another regulatory process. The impetus will have to come from citizens, hopefully with the help of non-captive health care professionals.

We also have to stop trusting government processes carried out in an atmosphere of secrecy, behind closed doors. We have to demand openness, to reverse the secrecy. In other words, instead of saying everything is secret unless you can get at it through a freedom of information request, we need to move closer to ‘everything is open unless there is a good reason to keep it under wraps’. We need legislation protecting whistle-blowers, because currently people within the system who might want to bring information to the public have no route to do it other than to be willing to give up their careers and have their reputations assaulted. We have to restore public resources in the form of independent expertise, by recreating jobs that scientists can take pride in, whether the process is occurring within government or within independent agencies in university settings. We cannot have people without expertise telling us which drugs are safe to go to market.

Above all, it appears that we need to reinvent a new and separate agency that can take on some of the responsibilities long ago abandoned by the HPB, irrespective of whether the HPB in some form continues to undertake routine drug evaluation. The notion of a separate agency for failure analysis would seem to warrant some serious consideration. This idea was put forward in an editorial in 1998 borrowing from the model of air travel.19 The Federal Aviation

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Administration governs ordinary air travel, but when there is a crash and the cause of the crash needs to be determined, the task is given to a separate body, the Aviation Safety Board. This split is intentional because the Federal Aviation Authority might have erred, might not have regulated properly, and cannot be expected to investigate itself. This only makes sense, but in Canada and in the US, the HPB and the FDA are never subject to independent investigation. At the moment whenever there is a drug ‘crash’, often with attendant loss of life, the government response is highly predictable: ‘Guess what, folks? There wasn’t a crash and we didn’t do it.’ Yet drug crashes pose a much more serious threat in terms of numbers of lives affected than plane crashes.

The current system is not working, patients are suffering unnecessary harm as a result, money is being wasted, and we are allowing the perpetration of deception on a massive scale. It is time to commit to building a new system that is open and accountable; a system that serves the public good, and puts safety above profits, as the law requires.

The Truth, the Half Truth, and Nothing like the Truth.  
Regulation of Drug Promotion in Canada

Barbara Mintzes

An estimated one to two billion dollars are spent every year in Canada by the pharmaceutical industry to promote prescription drugs. The World Health Organization defines drug promotion as:

all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs

This paper examines the regulation of drug promotion in Canada, with a particular focus on its effectiveness in ensuring that promotional claims are evidence-based, and so contribute to the use of drugs that maximize health outcomes and minimize harm.

In 1957, major medical journals in North America ran an advertisement for diethylstilbestrol (DES) promoting its use for the prevention of miscarriage and premature labour. The advertisement quoted an impressive case series of 1,200 women and a 96% successful pregnancy completion rate. What the advertisement neglected to report is that four years earlier, in 1953, the results of the first large, well-designed randomized controlled trial of DES against placebo had been published, showing that DES did not actually prevent miscarriage or premature labour. Results of a poorly designed uncontrolled study were presented in the advertisement because they favoured the

Taken from Andrew Herxheimer, the UK Cochrane Collaboration.
manufacturers’ claims; results of methodologically rigorous studies were ignored because they found DES to be ineffective.

The drug was banned for use in pregnancy in 1971, when it was found to cause a rare form of vaginal cancer in women who had been exposed before birth. Most of the more than 200,000 Canadian women and the millions of other women worldwide who were prescribed the drug during pregnancy received their prescription after 1953. There were certainly other reasons that prescriptions of DES were provided to women, but the 1957 advertisement illustrates that misleading messages about ‘evidence’ of a drug’s effectiveness have the potential to cause harm.

The DES story happened a long time ago, before the thalidomide era and before our modern system of drug regulation. We could hope that things have improved. In 1999, medical, nursing and pharmacy journals in Canada featured an advertisement for Evista (raloxifene), a drug that is indicated for prevention of osteoporosis. Like the DES advertisement, this ad promotes a drug for use by a healthy population. The advertisement headline is “a woman’s choice for protecting her health after menopause”. This is a vague claim implying that all post-menopausal women would improve their health by taking the drug. The advertisement promotes Evista for two unapproved indications: prevention of breast cancer and cardiovascular disease. It exaggerates potential benefits and does not mention the risk of deep venous thrombosis and pulmonary embolism, although these potentially fatal blood-clotting disorders were associated with the drug in pre-marketing clinical trials. Like DES, it is a drug for which there is animal evidence of carcinogenicity, but there is no documentation of this information anywhere in the advertising text or the fine print labeling that goes with it.

Bob Nakagawa, then Director of BC’s Pharmacare program, James Wright, Director of the UBC-based Therapeutics Initiative, and I submitted a written complaint about the advertisement in 1999 (see below on the monitoring and complaint mechanisms under Canada’s current self-regulating regime). Five months later, the advertisement was pulled from journals, which is probably about when it would have been pulled even in the absence of the complaint. The company was not subjected to any fines, nor was it required to run ads to inform doctors, pharmacists or nurses that they had been misinformed. Under such circumstances, there are huge potential benefits to the company and no costs other than the actual costs of running the advertisements. As Bob Evans pointed out in his paper, there is no mystery as to how and why these decisions get made.

In fact, the Evista advertisement was pre-screened and deemed acceptable in spite of the unbalanced presentation of benefit and risk information and the promotion of uses that are not approved in Canada. This is but one example exposing the inadequacies of the current system of regulation of drug promotion in this country.

Hopefully Evista will not turn into another drug disaster like DES, but the aim of regulation should be to take us beyond having to rely on hope. The objective of regulation is to create safeguards to prevent drug promotion from providing misleading information about the expected benefits and risks of medicines. Regulation of drug promotion in Canada is covered in Section 9.1 of the Food and Drugs Act, which states that advertising should not include any information that is false, misleading, deceptive or likely to create an erroneous impression. Information in promotion must also comply with approved product labeling. The other two points in the Food and Drugs Act relevant to regulation of drug promotion are a prohibition against advertising prescription-only drugs to the public, except for name, price and quantity, and a list of serious health conditions for which neither prescription nor non-prescription drugs should be advertised to the public.

The complaint process for the Evista ad, described above, highlights the three key elements of regulation of drug promotion: the standards on which regulations are based, the systems in place for monitoring, and enforcement procedures. With respect to enforcement, there is a need for sufficiently punitive sanctions that will deter future offenses and for a mechanism to correct misinformation.

Although the regulation of drug promotion in Canada is covered by the Food and Drugs Act, in practice we have ceded enforcement to the pharmaceutical industry, in effect allowing self-regulation through two avenues. First, the brand name industry association, Rx&D, which was formerly called the Pharmaceutical Manufacturers’ Association of Canada or PMAC, regulates most forms of prescription drug promotion through its Code of Practices Committee. Second, the Pharmaceutical Advertising Advisory Board (PAAB) was set up in 1976 as a semi-autonomous organization when then federal Minister
of Health, Marc Lalonde, threatened to implement direct government regulation of promotion if the industry did not clean up its act. The PAAB is responsible for pre-clearing published advertisements of all kinds. This includes audio-visual as well as print advertisements, printed materials used by sales representatives and advertisements in medical journals. The Board consists of representatives from the pharmaceutical industry (both generic and brand name), the advertising industry, the Canadian Medical Association, Canadian Pharmaceutical Association and also the Consumers Association of Canada. It is set up on a pluralistic model, but the majority of the members of the Board are representatives from the pharmaceutical and advertising industries.

The PAAB asks manufacturers to submit all published advertisements for voluntary pre-clearance. The Board also does some random monitoring and responds to complaints. Most of these complaints come from competing companies, and the response to complaints involves a model in which the company and complainant are first asked to attempt to directly resolve their differences. Eventually, at a second stage, PAAB steps in. This process can be time-consuming, and meanwhile an advertising campaign runs its course, as in the Evista example above. Until an ad has been shown to contravene PAAB’s code, it is allowed to run. There is no option for an injunction while the case is being considered. If a complaint is upheld, the company is usually required to withdraw or revise an advertisement. Only very rarely, in what are considered serious cases, will PAAB ask for corrections to be published. PAAB’s activities are self-financed through fees charged for each advertisement submitted for pre-clearance. Companies making unsuccessful complaints are also required to pay a fee to PAAB, presumably in an attempt to reduce frivolous claims.

Rx&D’s Code of Practices Committee is responsible for overseeing most forms of drug promotion. This is an industry committee, with one additional representative from the Canadian Medical Association. It covers the activities of sales representatives (drug detailers), the distribution of free samples, continuing medical education, market displays, gifts and other types of special promotions, and also post-marketing research. The committee uses a passive monitoring system based entirely on responding to complaints, most of which are made by competing pharmaceutical companies. If the committee finds that a company violated the Code of Marketing Practices, the company is fined. For the first violation in a year, a company is fined $1000, with fines for subsequent violations following a sliding scale up to a maximum of $15,000 within a year. At the end of each year, the company gets a clean slate and begins again at the $1000 mark. In comparison to the amount of revenue that can be generated through sales in an aggressive promotional campaign, even the maximum fine of $15,000 is a bad joke. The Code of Practices Committee’s activities are financed through companies’ association membership fees.

Sales representatives, or drug detailers, who make individual visits to doctors are by far the largest ticket item in a company’s promotional budget. Last year in the United States, the budget for drug detailing to doctors was Canadian $6.9 billion, which was 80% of the budget for promotion aimed at health care professionals. The marketing code states that sales representatives must present full and factual information to a physician, that the information must be scientific, and that it must be in keeping with current medical opinion. What is missing is any requirement for specific types of information to be provided, including information on risks, contraindications, or warnings. Sales representatives are not required to provide physicians with a copy of the approved labeling for the product or the official product monograph. Companies are allowed to pay drug detailers commissions tied to sales volumes. These provide a financial incentive to detailers to market products aggressively. Most disturbingly, there is no process in place for monitoring what a sales representative is actually saying to a doctor. As a result, this form of promotion is, in practice, completely unregulated.

The only country where there is any kind of on-going monitoring of sales representatives is France. A non-profit organization of physicians and pharmacists called the Association for Better Prescribing formed an anonymous network in 1991 to monitor sales representatives’ activities. This is a network of doctors who complete a brief questionnaire after each visit by a sales representative. The results are compiled and published annually, and individual cases are published in a monthly column in a bulletin for doctors and pharmacists, La Revue Prescrire, as well as being passed on to the French Medicines Agency. Even in this more transparent environment, from 1991 to the present, in 75% to 80% of sales presentations no mention was made of adverse effects, contraindications, warnings or precautions. Most sales pitches were entirely devoid of risk information. This was fairly
consistent over the entire period of monitoring. The Association also reported that, in about 25% of cases, either unapproved indications were promoted or indications were widened beyond the approved product labeling. Promotion of drugs to Canadian doctors is unlikely to be more accurate or balanced, especially as no one is watching.

With respect to pre-screened advertisements, the main standard governing the information in advertisements is that the ads must comply with the product monograph and approved product labeling, which are in turn based on the company’s pre-marketing submission to Health Canada. PAAB’s Code also includes specific language stating that there should be no unqualified use of the word “safe”, for instance, or use of language that might engender fear. In this particular respect, Canada has higher standards than the US. However, Canada’s requirements for the presentation of risk information are weaker. In Canada, unlike the US, there is no requirement for a balanced presentation of risk and benefit information within all parts of an ad, including the advertising copy. Also, PAAB’s code states that the references provided must be consistent with current medical opinion, rather than needing to be consistent with current scientific evidence.

The most recent systematic evaluations of how well published advertisements complied with PAAB standards were carried out in 1990 and 1991. A 1990 review of 111 advertisements found that 36% did not comply although they had all been pre-screened by PAAB. Another review in 1991 found that nearly half of the advertisements included no risk information in the advertising copy. Little appears to have changed since 1991. For example, a 1999 advertisement for an estrogen patch did not mention the risk of endometrial cancer if estrogen is used alone, or the need to combine use of the estrogen patch with progesterone if a woman has not had a hysterectomy. In very small print, the advertisement notes only that the estrogen patch has risks similar to other estrogens. Similarly, an advertisement promoting azithromycin for the treatment of children’s ear infections in the February 9, 1999 issue of the Medical Post conveniently (but predictably) failed to note either that the majority of children’s ear infections will resolve without drug treatment, or that if an antibiotic is needed, azithromycin is not considered to be the first choice in current practice guidelines. Even if the information in advertising complies with approved product labeling, it does not necessarily follow that it is consistent with health policies more generally. In this instance, the same issue of the Medical Post ran advertisements impelling doctors not to over-prescribe antibiotics.

Despite its flaws, a structure for pre-clearance of published advertising is a positive feature of the Canadian system which stands in marked contrast to most other national regulatory systems. With appropriate standards and enforcement, pre-clearance of advertisement should mean that misinformation could be short-circuited before it goes out. It is inexpensive for a company to change its advertising copy before it goes for publication, so there are few economic barriers to ensuring a high standard of information. Another positive aspect of the Canadian system is that regulation of advertising and other forms of promotion is enshrined in the Food and Drugs Act within a framework, as Michele Brill-Edwards notes, of health protection (see Brill-Edwards, this volume). It is also within this framework that prescription drug advertising to the public is currently prohibited.

In Canada, the cost of regulating drug promotion is left to the industry. This is the original rationale for delegating regulation of advertising to the industry. Additionally, pre-clearance of advertisements is financed through fees for each submission, and is therefore directly related to volume. As taxpayers, we are paying very little for the regulation of pharmaceutical promotion in Canada. However, we are also getting very little out of the process. The standards for evidence in advertising are inadequate. There is no monitoring of most forms of drug promotion, which means, in effect, we have non-regulation. The sanctions are either entirely absent, or inadequate as deterrents, and there is generally no requirement to correct misinformation. There is also inadequate reporting to the public of the basis for regulatory decisions concerning advertising violations, which echoes a theme that Brill-Edwards raised in terms of accountability in regulation. And within this spotty regulatory environment, advertising aimed at the public is completely unregulated, whether it is cross-border advertising from the US, or any of a variety of activities originating in Canada aiming to stimulate prescription drug sales.

Direct-to-consumer advertising (DTCA) is especially significant because Canada is situated next to one of the two industrialized countries which allows it (the other is New Zealand).

21 Although that prohibition is currently under assault.
Nolvadex (tamoxifen), a drug that has been approved for the indication of "temporary reduction in the incidence of breast cancer." This is very odd wording for an indication, a questionable compromise agreed to by the FDA because whether this drug actually prevents breast cancer or simply delays diagnosis, is simply not clear from current evidence. Nor is there any evidence that the drug’s use for prevention has any effect on breast cancer deaths. The ads convey quite a different story. The drug is being promoted very heavily for breast cancer prevention. The advertisement promises women that they can now predict their chances of breast cancer and act on it. The visual image radiates anxiety; the implied promise is one of anxiety eliminated. This example is also relevant to screening, as the impression of accurate prediction through risk factor screening implied in this ad is unlikely to reflect reality.

Another US direct-to-consumer advertisement promotes paroxetine (Paxil), an antidepressant, for ‘social anxiety disorder’—a disorder with symptoms that might easily be mistaken for what used to be called shyness. Yet another advertisement, for an arthritis drug, states: “What will you do on the day that you discover Celebrex?” This is a non-steroidal anti-inflammatory drug (NSAID) being promoted as safer than other NSAIDs. The evidence base for these claims is thin at best. The ad’s headline, however, implies that a patient can suddenly begin to be active in a new way after taking Celebrex. This is in essence a claim of superior effectiveness as an arthritis treatment, which is completely misleading. In late 1999, the British Columbia Therapeutics Initiative published a bulletin for BC doctors highlighting the difficulty in judging the relative merits of this drug. At the time, although the drug was approved in the United States and Canada, not a single randomized controlled trial had been published. These are but a few examples of the unregulated excesses associated with DTCA south of the border. There is nothing in the Canadian regulatory structure that provides much hope for more honesty in advertising on this side of the border. When one reflects on the amount of inappropriate prescribing in an environment where only physicians are being assailed by the drug promoters, it is difficult not to cringe at the thought of that promotion juggernaut being loosed on an unassuming public. If doctors can not tell a real breakthrough from yet another “me-too” anti-inflammatory drug, similar to a dozen others except perhaps for its higher price, how
will people without any training in therapeutics sift through the promotional claims to make this distinction?

In conclusion, drug promotion aimed at health professionals is currently poorly regulated in Canada. Drug promotion aimed at the public, both in the form of cross-border advertising from the United States and in many indirect forms originating in Canada, is also poorly regulated. In such circumstances, should the first priority be to consider further deregulation? The problem is not in the wording of the clause governing drug promotion in the Food and Drugs Act. It is as clear and applicable today as in 1953, when the Act was passed: advertising should not include any information that is false, misleading, deceptive or likely to create an erroneous impression. The problems lie with inadequate information standards, inadequate rules governing the way scientific evidence is presented, inadequate monitoring, inadequate enforcement, inadequate requirements for corrective actions and inadequate sanctions to deter future offenses.

Although Brill-Edwards was pessimistic about the current regulatory climate, she also recommended that we take advantage of the current legislative renewal process to press for needed regulatory changes, improvements both in the standards for drug approval and in public accountability and access to information on which decisions are based. The same could be said for the regulation of drug promotion. Instead of deregulating further, in an environment where the appearance of regulation is already a misleading indicator of the reality, we need to look at more effective mechanisms to ensure that the messages in prescription drug promotion accurately reflect the best available evidence about a medicine’s effectiveness, safety and appropriate conditions for use. As a first step, this will require an unequivocal shift away from industry self-regulation. As Bob Evans noted so eloquently (see opening paper in this monograph), the industry has become quite adept at suppressing undesirable information when sales are at stake. An ad which accurately represents the best available evidence about a drug’s risks and benefits and the limited patient population for which it may be helpful might stimulate some sales. An ad which exaggerates benefits, minimizes risks and expands the target patient population is likely to stimulate many more. Without effective regulation, is it any wonder that marketing needs outweigh health priorities?

Concluding Comments

Clyde Hertzman

A key organizing theme during the planning of the conference from which the papers in this volume have been taken was the idea of ‘windows of opportunity’ in the policy world and, in particular, the notion that certain policies will gain acceptance only if a variety of circumstances are in alignment (the open window). In other words, even if the landscape outside the policy window is accommodating, the window still has to open. But after a day of presentations on the use, abuse, and neglect of research evidence in policy decisions that affect our health care system, we might, in retrospect, have been better off calling this conference “When the Policy Window Opens, It Opens onto a Swamp”. Perhaps it does not matter whether the window opens or not, if the landscape on the other side is uninhabitable.

If we reflect on the detailed and at times disturbing information provided in the papers in this volume, it is striking how little the health status of populations, and the role of the health care system in supporting or enhancing that health status actually feature in the discussion of policy. It was mentioned, but it got pretty limited coverage. That is a statement about the way in which the game that we came to discuss is mostly played. The other thing that is overwhelmingly clear and consistent is the fact that population health status matters little because it does not factor into the decision calculus of the dominant interests in this game. And those dominant interests have become immutable forces. They are huge, have seemingly infinite financial resources, are all around us, are relentless, and they win when they win, and they even seem to win when they lose.

Those forces operate at one level even below what has been described here. The famous Framingham study is the study that, in a sense, has given rise to the lipid measuring and intervention industry. It is a long-standing, longitudinal study of an adult population. As Isabelle Savoie pointed out (see Savoie, this volume), that study collected very little information on other factors that
might have had an effect on heart disease – there was some passing mention of differences between white- and blue-collar workers, for example, but this was very much an afterthought. By and large, the data set was never organized or focused using that lens and, as a result, it has not generated a lot of usable information in terms of competing determinants of health that could affect heart disease.

At the same time, another large study, the Whitehall study, was also looking at heart disease in Britain. That study not only did a pretty thorough job of looking at cholesterol and other individual risk factors, but it also looked very profoundly at work hierarchies and psycho-social working conditions in relation to heart disease and a bunch of other outcomes. Lo and behold, it found that those other things were much more important than cholesterol. Funny, then, that this conference makes no mention of all the regulatory attempts to stop the world from packaging and marketing changed psycho-social working conditions. Whitehall, unlike Framingham, did not generate a multi-billion dollar industry of intervention, largely because the forms of intervention that are implied by the findings are difficult to concentrate into a specific package and to sell as an individual client service. In other words, it is very, very difficult to concentrate an industrial interest around the notion of changing psycho-social working conditions, or reducing the effects of work-place or broader social hierarchies.

Bob Evans (see Evans, this volume) described the idea of a Rawlsian citizen, a citizen who in a sense embodied what would be a public interest, and he suggested that people like that seem to be pretty rare. As a familiarly Canadian example, think about who it is that members of Royal Commissions hear from, and hear from, and hear from... There is no shortage of interest groups coming forward. But if there are people out there who are sitting back saying, “I wonder how we can best purchase health status for the population?” they are conspicuous by their absence. If they do exist, they are diffuse and unorganized, and therefore they are not heard. Even if there are a lot of them, there are no obvious ways for them to get organized, raise funds (from which private interests???) and make their pitch.

There are a number of problems in trying to think about the health care system actually being there to improve the health of the population. Nowhere is there systematic measurement of the contribution of the health care system as a determinant of health. There is no information that parallels other information we have on things like cigarette smoking or socio-economic factors, and so on. Nor is there any information that systematically evaluates the effects on populations of the introduction of regulatory or other public policy changes, or of new technologies for the health care system.

This is not all that hard to demystify. There are basically four ways that the health care system, at the margin, could contribute to population health status. First, it could improve the health status of defined groups of patients through new treatments or better delivery of existing treatments. This is the classic mechanism that would come to mind. Second, the health care system could deliver a given level of health status at a lower cost, theoretically freeing up resources for other health status improving activities. Third, it could spread or give access to effective treatments or technologies more widely, that is, improve the distribution of available and effective resources. And fourth, it could reduce harm at the level of iatrogenic disease, and in terms of the burden of morbidity carried by health care workers themselves.

The methodologies to measure those four potential impacts are actually quite simple. All that is required is the addition of a basic measure of mortality to a multi-attribute health status index such as the SF-36, the McMaster index, or something similar. There are several measures around that have good international reputations (in other words, that are valid and reliable), that are multi-dimensional, and that have known sensitivities to the objectives of the health care system. We may need to design a ‘short form’ version of the SF-36 that could be administered quickly and painlessly once every six months, or whenever an individual comes in contact with his/her primary care provider if less often than six months. An occasional Centre faculty, David Hadorn, was working on an idea along these lines some years ago. These measures of health status and functional capacity can then be built into linked databases such as the one that has been developed in BC, which would then provide the means of looking at relationships between health care problems, health care use, and health outcomes/status. There are lots of problems that you can imagine, but the point is that it is, in principle, feasible to develop some sort of system monitoring capability. It is not hard to imagine it could work, and yet we do not do it.
Much of what is covered in other papers in this volume concerns the evaluation of new ‘technologies’—drugs, devices, other services—before they enter the system. That is very important. But, by definition, system change will affect the health of the population, if it does at all, only after new ‘technologies’ are introduced. Asking questions about whether the system and changes in the system are affecting the health status of the population requires emphasis on evaluating the effects of those changes. This means coming up with ways to measure health status and functional capacity on a regular basis, so that we can track changes that might be attributable, in particular individuals, to particular changes in available technologies.

If we reflect on many of the specific technologies described in this volume, most of them do not look like things that could improve the health status of the population. For example, cholesterol and bone mineral density testing are proposed as screening tests, meaning they would be applied widely in the population. The key principle in thinking about the population effects of such new screening tests is that every time you bring along a new test, you basically create new disease. That is to say, you go to the population, a bunch of people who thought they were fine, you measure “X”, and lo and behold, by definition, 5% of the population have to be in the bottom 5% of the distribution of “X”. Those people are told they have hypo-Xemia. Some groundbreaking work on hypertension at McMaster University, now 20 years old, showed what happens when this sort of labeling occurs. A certain proportion of people, once they have the label, go downhill, even if there is effective treatment available. They start taking more sick days, they have downward occupational mobility, their self-perceived health status drops, and so on. So we know that if you bring in a screening technology which is not associated with an overwhelmingly effective intervention the likely effect is to reduce the health status of the population through that minority who will respond to labeling in that well-studied and predictable way.

This is an important consideration because the biggest new frontier we are facing is genetic testing. It is very difficult now to get through a week without reading about the gene for Alzheimer’s, the gene for breast cancer, the gene for aggression, the gene for buying a ’56 Chevy, putting US mags on it, hanging fuzzy dice and driving it off a cliff. There is a gene for everything now. We all have a huge number of genes, so it is a statistical certainty that every one of us is carrying at least one really, really bad gene. As it stands now, if you want to buy into this, each of us is only one blood test away from a latent diagnosis based on some gene. This cannot be taken lightly. The last time I was in Toronto, I was told that the notion is circulating through that city’s Jewish community that Jewish women are at particularly high risk for breast cancer, that it runs in their families. There are now cases of women going across the border, presenting their family history, having their genes read, being told that they have the ‘bad genes’ and having both of their breasts and both of their ovaries taken out pre-emptively. And there is no shortage of surgeons or facilities south of the border able, willing, and delighted to participate in this unnecessary mutilation. The potential for reducing the health status of the population as a consequence of that is huge.

That brings me back to where Bob Evans (see Evans, this volume) left off, which is, “Who is the agent for health improvement in the system; should there be an agent, and if so, can such an agent be created?” It is very clear that this is all about contending forces. It is not primarily about the marshalling of rational arguments, or evidence, although the rational arguments may paint a landscape (drain part of the swamp) which may be there when the window opens, if you are lucky. But by and large, if the overarching objective of continuous health improvement is going to get institutionalized, there has to be some sort of regulatory oversight with teeth. Bob raised the question of where the mandate would come from. One could argue, based on what goes on day to day in the politics and the practice of health care in Canada, that there is no mandate. But I think there is.

Is there an interest, albeit diffuse, within the population in improved health status? Judging by personal behaviours and choices, there seems little doubt. And there is evidence for this. For example, the Federal/Provincial/Territorial Advisory Committee on Population Health added some questions about what people understood about the determinants of health to a health monitoring survey. What came back was a fairly accurate list. By and large, people understood that cigarette smoking, and factors in the social
and physical environments, for example, were probably a lot more important than access to specific health care services. There were distorted ideas about how important ionizing radiation may be to the average Canadian, but in general respondents showed a remarkably accurate understanding of current evidence on some of the big picture effects on a population’s overall health. Does this prove that there is an interest in improving population health? Not directly, but the fact that so many respondents were aware of health-related issues suggests the presence of a diffuse but widespread interest. Were there no interest, we would expect to find far less awareness and understanding.

How might this diffuse interest be concentrated? It seems depressingly clear from other papers in this volume that we cannot generally look to Ministries of Health, either federal or provincial, as the ‘vessels’ of concentration. Nor are we likely to find the answer in agencies that are designed to regulate the introduction of new technologies, which tend to be far too narrowly focussed, and on factors that, in general, have not yet had an impact on the health of a population. On the other hand, I would suggest, and perhaps I am being naive, one way to concentrate the interest is through ongoing interest that taxpayers have in the waste of their tax dollars. For instance, in this province lately, public opinion has been galvanized by the notion that the fast ferries were a big waste of money, that unimaginable amounts of taxpayers’ money have simply been flushed down the collective toilet on a project with suspect objectives from the outset. If you think about what the potential marginal benefit of the fast ferries might have been had they worked (cutting 10 minutes off a one and a half hour one-way ferry ride), that is not dissimilar to the sorts of likely marginal benefits from many of the new drugs and devices that are in various pipelines at the moment, or that have been recent additions to the medical care arsenal. The marginal benefits they offer are often quite trivial, and many have potentially serious and costly side effects.

Building on this notion of widespread discontent with the squandering of tax dollars, one possible oversight/accountability mechanism might be a population health auditor-general. This office or organization would operate at arm’s length from the health care system, would have a mandate to compare within system vs. ‘extra-system’ investments with a view to their relative population health impacts, and would require the development of information systems that could support it in this function. This would, of necessity, include the development of instruments with which to measure and monitor population health status, evaluate the outcomes of new investments, and compare different regions. It would have carte blanche to expose wasteful new innovations for what they are. The headlines would write themselves: “$2 Billion of $8 Billion in Health Care Spending in BC Wasted.”

There is great potential for an audit organization to look over the shoulders of the provincial government, the health regions and the colleges, particularly in terms of their role in defining what appropriate practice should be. In suggesting this, I am borrowing Michele Brill-Edwards’ idea (see Brill-Edwards, this volume) about the distinction between the FAA and the National Transportation Safety Board in the United States. We are talking here about the period after things are introduced, and about monitoring and evaluating how and whether they change the system and how they affect patients and potential patients. The airplanes are in the air already, we have approved them, and if they crash then we have a different agency that looks at how they crashed, and has the right to make comments about the work of the various agencies that put the plane into the air to begin with, as well as about the crew of that plane.

But perhaps we have come adrift a bit from the original question. Even with an audit function in place, windows are not necessarily going to be flung open for good, evidence-based new policy ideas, and closed in the face of bad ones. Recent newspaper coverage suggests that Ralph Klein saw the window opening (indeed it seems quite possible that he worked hard to paint a landscape that had people begging him to open the window), and then threw a private hospital through it in a time-honored, zombiesque tradition. This was immediately taken up by the business press in this country as the greatest thing since white bread. Ontario answered with the idea of the private university. Clearly some people do perceive windows opening for radical changes in the institutional structure of Canada. I do not think folks like us are seeing those kinds of windows ajar very often (indeed, we seem to spend an inordinate amount of our time trying to get open windows closed again), but I think that we have to imagine the possibility. We have to get our ducks in a row
because it is possible that some windows will open, and if they do we will not have the luxury of mounting long and costly research projects at that point. We need to be prepared.

As an example, the National Longitudinal Survey of Children and Youth started several years ago and has generated a fair amount of information about the determinants of healthy child development. Based on this, we have constructed ‘goalposts’ or population-based success indicators such as community-based readiness to learn measuring and monitoring. This work was all done prior to the announcement in the Speech from the Throne about government interest in promoting a ‘children’s agenda’. We actually had the potential to measure population-based outcomes when the call came, and this put us in a highly leveraged position. In other words, when the window opened, it opened on an opportunity, and we were ready to respond. This requires anticipation, foresight, and determination, but in the face of the forces sketched out in the papers of this volume, we should take comfort from small victories, and build upon them. This is a war that will never be fully and truly won, there will always be another battle over the next hill, and we are likely to remain out-manned and out-financed for the foreseeable future. But if we want decisions about investments in the health care system to be guided by potential improvements in a population’s health rather than by potential improvements in the bottom lines of private interests lined up around the public sector trough, this is a war we cannot, and should not want to, avoid.

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