Brief to the Office of Legislative Renewal from Women and Health Protection

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"The relationship between the regulator and the regulated… must never become one in which the regulator loses sight of the principle that it regulates only in the public interest and not in the interest of the regulated."
Krever Commission Report

Introduction

In 2000, the Women and Health Protection Working Group submitted to the Office of Legislative Renewal over 50 recommendations responding to a working draft of the proposal for a new Canada Health Protection Act. A sub-set of those recommendations specifically addressed the Health Protection Branch's draft "Decision-Making Framework for Identifying, Assessing and Managing Health Risks".

In various consultations that have taken place across the country since that time, and most recently over the past several months, Mario Simard – Health Canada's senior counsel to this process – has asked of this latest version of recommendations for a Health Protection Act (*Health and Safety First: A Proposal to Renew Federal Health Protection Legislation*), **"Did we hear you right?"** We respectfully submit that the short answer to that question is **"Not quite."** In the following pages we will outline those areas of greatest concern about health protection and suggest ways to deal with them.

Opening up the Food and Drugs Act

We understand, through the documentation circulated, that everything in the proposal is "open for debate". We trust that this includes the very decision to open up the Food and Drugs Act and put in its place a new Canada Health Protection Act.

Our organization, and many others across Canada who have been following this process closely, remains convinced that it is neither wise nor necessary to open up and dismantle the Food and Drugs Act. The Act has existed in its present form in part to restrict how those industries affected by it – pharmaceuticals, food – carry out their affairs, in order to protect the health and safety of citizens. It is our conviction that the Act is still capable of achieving this health protection mandate effectively, and that a series of regulatory amendments would allow the Act to be upheld and enforcement improved where it is most needed. We do not believe that it is necessary to dismantle one act and create an entirely new one for the "modernization" desired to take place. Indeed we worry that "modernization" may simply be a euphemism for "making regulation more palatable to industry".

Less than a decade ago, when the National Forum on Health was carrying out its investigation of ways to improve the health system and the health of Canadians, it asked if the Canada Health Act adequately met current needs or whether there were deficiencies that needed to be addressed. The conclusion of this review was clear: although the Act was imperfect, the risks of opening up the Act outweighed any potential benefits[1]. We are convinced that the same is true in this case.

[1] "The public does not want to see any significant changes which would alter the fundamental principles of our publicly administered health care system. They have an abiding sense of the values of fairness and equality and do not want to see a health system in which the rich are treated differently from the poor. The Forum supports this view and supports necessary changes to our health system only if we preserve the essence of medicare – universal coverage based on need, without financial barrier, portable across the country, to a comprehensive array of publicly administered health care services." National Forum on

While the proposal circulated outlines what is missing in the current legislation, and what "modernization" is needed to address various societal changes and recent tragedies, it does not sufficiently argue that these changes can take place only by dismantling the current Act and creating an entirely new one.

The Krever Commission Report is cited in the current proposal as a reason for needing to replace the existing Act. But while Justice Krever called for many changes in the current regulatory system, replacement of the existing Act with a new one was not specifically one of them. By contrast, what the current proposal does ***not*** note as a defence for entirely changing the Act is the enhancement of industrial competitiveness. This, we argue, is a far stronger motive for changes in this arena than the reasons that are cited.

Our concerns about opening the Act echo similar concerns about opening the Canada Health Act: that the wishes of industry will predominate and will trump public health concerns. **The current problems with Canada's health protection system have more to do with a lack of enforcement authority than with faults in the current legislation.**

The current Food and Drugs Act was written in an era when an ethic of public health and health protection – not industrial competitiveness – prevailed. Opening up the Act would create an enormous risk that those important principles will be seriously jeopardized. Through the proposals we offer below, we maintain the conviction that the authority to make these changes is already in the Act and that many of these changes can be brought about through regulatory amendments or enhanced enforcement. What is needed is the political will to exercise that authority.

Why a Concern about Women?

Although our concerns about the proposed legislative change apply to all Canadian citizens and residents, the response we present here reflects our organization's mandate to examine, in particular, the implications of these proposed changes for women:

1) Women use the health care system more extensively than men because of their biology, because they are more likely to engage in preventive and health maintenance behaviours, and because they are most often the caregivers of others.
2) Women are more likely than men to have natural life experiences framed as medical problems, with this being especially true in the areas of reproductive and mental health.
3) Women's lives have been affected by a number of health protection failures – DES, silicone breast implants, and more recently hormone replacement therapy.
4) Women's lives intersect regularly with the health protection system, as those most likely to report adverse drug reactions for themselves or family members, as the primary purchasers of foods and food supplements, and as targets of publicity for health care products and services.
5) Many drugs and devices are gender- and/or sex-specific (e.g., birth control, menopausal hormone therapy, breast implants). Others are prescribed more often

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Health. *Canada Health Action: Building on the Legacy. Volume II: Synthesis Reports and Issues Papers*. Ottawa, 1997.

for women than for men (e.g., anti-depressants, bisphosphonates) and companies have been known to target women in their efforts to expand the base of use (e.g., the recent efforts to find a "Viagra for women"; efforts only aborted in March 2004).

6) Safety standards for many medications have often been based on studies conducted exclusively or predominantly on men, without separate analysis of effects in women. For certain types of adverse drug reactions, for example dose-related ones, women may be more vulnerable due to smaller average body size. For others, such as specific cardiac rhythm anomalies like *torsades de pointes*, women are more vulnerable due to physiological differences. Canada has guidelines for the inclusion of women in clinical trials; at present adherence to these guidelines is poorly enforced.
7) Women predominate in one demographic group where prescription drug use is at its highest: the elderly.

In 1999, Health Minister Alan Rock introduced Health Canada's *Women's Health Strategy* in keeping with the *Plan for Gender Equality*, published by Status of Women Canada in 1995. At the time, Minister Rock noted, "As part of the Strategy, I have undertaken to fully integrate gender-based analysis in all of my Department's program and policy development work."

A key aim of Women and Health Protection is to assist Health Canada in the incorporation of this mandate in policy development, particularly in the area of health protection. **We are especially interested in ensuring that changes in Canada's drug regulation system safeguard the health and safety of women, with this always given precedence over commercial interests.** This involves both the identification of current inadequacies in the health protection system that need to be addressed, and ensuring that the direction of future policy development will contribute to better health for women, and not to an exacerbation of current gender inequalities or further limits on safeguards to health.

WHP responses to specific recommendations in the proposal

In this section, we have limited our comments to those areas that are of particular concern and interest to Women and Health Protection. We emphasize how concerns in these areas can be addressed appropriately and adequately without opening the Act.

A – GENERAL

A.1 - TITLE - Do you agree with what is being proposed (e.g. the consolidation of the four Acts identified into one piece of legislation?) It is not clear how we can judge whether it is appropriate to incorporate all the Acts into one, or even whether the Acts need updating, without a description of what is in each of the Acts. There is no justification given for why these four Acts were chosen; e.g., why is pesticide legislation left out?

As mentioned above, our key concerns are the lack of clear rationale for dismantling the Food and Drugs Act, and the potential for the new Canada Health Protection Act to lead to lower safeguards than those currently in existence.

A2 – POLICY DIRECTION – Summary of the purpose, the values, and the guiding principles of the proposed Act

It should be noted that policy direction can be added as a Preface to the existing Act. Basic principles and values can also be put into regulations as well as reflected (and enforced) by departmental policies.

- **"public scrutiny of government actions and public engagement in decision-making will be encouraged"** The term "encouraged" is open to a broad range of interpretations and does not instil confidence as stated. Without specific proposed changes to access to information and accountability of regulator procedures, such encouragement is likely to be interpreted by the public as an empty promise. Similarly, a much clearer definition of public engagement is required. As a minimum, a policy on public engagement must include: legislative protection for the "right to know**";** representation of women's and citizen interests on product review panels and expert advisory committees; separation of private sector interests from any decision-making that influences public safety; and enforcement of explicit conflict-of-interest guidelines.

- **"the concept of precaution will be applied"** Why is a vague notion such as "the concept of precaution" used when "the precautionary principle" is much more widely understood and well-defined? **The precautionary principle must operate as a guiding principle throughout the framework, and must prevail over other principles.**

Additionally, any discussion of policy direction with respect to drug regulation must have enshrined in it a gender-based analysis of the impact of any decisions.

A3.2 – "Health would not be defined in the proposed Act and would consequently be given its generally accepted meaning (general condition of body and mind)."
Why would the WHO definition not be used? It has garnered international acceptance and contains nuances and richness that are lost in this paraphrasing.

B- PRODUCTS
B3.1.2 – *"In some circumstances (e.g. innovative new products such as some new drugs) should the manufacturer be required to pursue long term research to confirm the safety and effectiveness of the product?"*
All therapeutic products should be required to have their licenses renewed on a five-year cycle – a move that was recently reaffirmed by the European Union - and the renewal should take into account new evidence of safety and effectiveness.

Renewal could also assist Health Canada to deal more effectively with post-market enforcement, specifically, for example, some of the difficulties encountered with enforcement of the prohibitions on direct-to-consumer advertising and off-label promotion of pharmaceuticals. Sanctions could include requirements for corrective actions, for example, as a precondition for renewal, or renewal could be refused in the case of repeated violations. Additionally, if new risks are identified in the post-market period, as often occurs, additional studies could be required and/or restrictions imposed.

B6 – DECEPTION
Would the proposal for this provision allow the government to delegate enforcement of the provision to the manufacturers? If so, what criteria would be used to establish if delegation is permitted? How would compliance be monitored? What would be the penalties for non-compliance?

Of specific concern is that the current definition of 'deception' in the Act has been limited in these documents to deception concerning only manufacturers' health claims. Currently, Health Canada has regulatory authority over the complete set of claims made in advertising and promotional material, including those that create an erroneous impression about the product's characteristics as well as health claims. The proposed shift – giving the Competition Bureau regulatory authority over claims related to product characteristics – would create enormous enforcement problems, with two government agencies sharing responsibility for specific promotional campaigns.

This cannot but lead to slower administrative procedures which, in turn, means that health professionals and/or the public would be exposed to misleading, deceptive and erroneous messages for a longer period of time before any action is taken. It is also possible that disagreements would arise between the two regulatory authorities over whether a claim relates to health or to a product characteristic, which could further slow procedures.

In the recently-held advertising consultations, Health Canada personnel have alluded to current difficulties with enforcement of advertising provisions. It is unclear how a sharing of regulatory responsibility for specific promotional campaigns would improve enforcement capabilities; it is much more likely to restrict them further.

B6.5 – "…the manufacturer must make available to the public a meaningful summary of the data in support of a claim that relates to the safety of the product or its effect on health to the extent reasonably possible and subject to protecting confidential information."

The caveat about making data available only "to the extent reasonably possible and subject to protecting confidential information", makes this phrase virtually meaningless, and provides no assurances of adequate public access to information. To this point to date, Health Canada has applied a very liberal reading to the term "confidential information"; it is important that any change allow for a more democratic access.

The phrasing of B6.5 also appears to suggest that manufacturers would no longer be required to restrict claims to approved product labelling, i.e., statements that are consistent with the Product Monograph.

Is Health Canada suggesting that claims for unapproved indications would be acceptable, as long as the manufacturer makes a meaningful summary of the supportive data available? This would provide perverse incentives to manufacturers not to carry out the types of studies required for approval of a new indication (as they could promote the product for that indication regardless) and calls into question the whole process of pre-market product approval.

We further question: Who would have access to these data and under what conditions? How would the data be provided? How would they be kept up to date? Would they be product or class specific? Would access apply retroactively to products that are already on the market? Does Health Canada intend to create a registry of all clinical trials, as has been suggested by our organization and others, wherein all data – negative or positive – would be accessible to the public?

B7.1.9 – "The rulings would have to be made public within sixty days after they are rendered, subject to protecting confidential information."

How is "confidential information" being defined? The current administrative definition is unacceptably broad. If a promotional campaign is declared illegal, the company should be required to remove the ads immediately; a 60-day grace period before the public is informed is much too long.

B7.2 – Food (Definition)

Would breast milk substitutes be included within this definition? It is notable that the Pharmaceutical Advertising Advisory Board does not regulate ads for breast milk substitutes because it considers them foods not drugs. Since they are promoted to doctors in the same way that drugs are, they should be treated as such.

B8 – Transparency of the review process –
We have concerns that two issues are not dealt with here – 1) releasing data about drugs that have been refused approval, and 2) making safety and efficacy information available while drugs are still in the review process. Additionally, we require the release of data about indications for drugs that were refused. As we know, there are many off-label uses for drugs. If companies have applied for approval for some of these off-label uses and been refused, this information should be publicly available so that the off-label uses do not continue.

B8.5.2.2 – "[The legislation would provide authority to] reassess a product after it has been approved for sale and determine whether the product should be allowed to stay on the market, in light of new evidence as to its safety and effectiveness;"
See previous comment – there should be an automatic review every five years to renew a license. Companies should be obligated to forward all new information on safety and effectiveness (published or unpublished). There should be a process that allows the public to petition for review before the automatic 5-year review process. We could consider here a requirement that companies also conduct comparative trials of new drugs either as part of the regulatory approval system or after the drugs have entered the market.

B8.5.2.3. – "[The legislation would provide authority to] enter into international harmonization agreements concerning the format or content of submissions for market authorization;"
These agreements must be the subject of open hearings and debate before they are adopted. They should also never result in the lowering of Canadian standards. (For more from WHP on international harmonization and concerns for women's health, see http://www.whp-apsf.ca/en/documents/who_benefits.html .)

B8.6.1 – Options for More Openness "They [NAFTA, TRIPS] provide that the government must protect the confidentiality of undisclosed test or other data provided by the applicant to determine whether the use of such products is safe and effective…"
This wording gives the impression that governments are *obligated* to protect clinical data on safety and efficacy but, as shown by the FDA in the United States, this is not the case. This is solely a convention created by the industry that regulators have chosento respect in this country (but not in U.S).

B8.6.2.2. "…summary of data presented by the manufacturer to demonstrate the safety of a new product…As a complement, should Health Canada set up a reading room where people could review all the data submitted by the manufacturer, but not transcribe or copy it, or otherwise make that data available to interested members of the public?"
First, why would there only be a summary of the data and not the complete data? Secondly, the notion of a reading room with such restrictions is, at best, absurd; it would require individuals to travel to – presumably – Ottawa to gain access to the material, and

make it impossible for health professionals and the public to record any data that would allow them to make independent assessments of drug safety and efficacy.

Data on product safety and efficacy should be freely available to the scientific community, health professionals and the public. The information should be available to the public via the Internet. It should not be considered a commercial secret. The current climate of secrecy leads to decisions about drug use and prescribing being made on the basis of incomplete information (as has been so dramatically highlighted recently with the use of SSRI and SNRI anti-depressants by children and adolescents).

The only data that should be protected are the identities of trial participants, because of privacy considerations. Data on production processes etc. are covered in patents and are therefore also outside the scope of commercial confidentiality.

B8.6.2.3 – "Should this information be made public whether the submission has been approved or rejected?"
The full assessment by Health Canada reviewers should be made publicly available on the Internet regardless of whether the product or indication was approved or rejected. For example, with a product such as Diane-35, which is already marketed for use as last-line acne medication, and is being used off-label for birth control, it would be very important for both prescribers and women and girls to know if a company's application for an official indication of the off-label use was rejected.

B8.6.2.4 – "reports of adverse effects to both safety and efficacy…Should any suspected cases be disclosed…?"
Health Canada should release all reports of suspected adverse drug reactions (ADRs)] once identifying information is removed. It should also release the rationale for its decision about whether the event was actually an ADR. Health Canada also needs to develop criteria – preferably through public consultation - about when it releases advisories about safety issues with drugs.

B8.6.3 – "Prior to approving a new product, should Health Canada provide a reasonable opportunity for the public to present written comments…What information would have to be provided to the public for that purpose?"
Providing an opportunity for the public to comment on a new drug submission should be routine. Health Canada should release the same level of information prior to a public consultation that the FDA releases. Provisions should also be made to create participatory decision-making structures that include representation of women's interests, privileging those groups that are independent of corporate interests and providing them with adequate ongoing funding to enable their participation. This is especially crucial when evaluating products, drugs and devices that will be used solely or mainly by women. Women must be involved in the discussion of how these will affect their lives, whether the product is necessary, and what areas of research should be encouraged.

B8.7 – Post-Market Review
Any proposed changes in post-market surveillance will only work with a considerable infusion of funds flowing to Health Canada's post-market surveillance program (Marketed Health Products Directorate). In addition, any requirements for companies to do Phase IV trials must be made public, along with details about the nature of these trials. Health Canada must follow up on whether these trials have been undertaken and make the results available to the public. Failure to conduct the trials should result in removal of the drug from the market.

B8.7.3.1 – "…the power to make regulations respecting matters such as …the tracking and reporting to Health Canada, by suppliers, of information related to the safety and effectiveness of their products at the post-market stage."
This should be mandatory, not optional, for all new chemical entities.

B8.7.3.2 – "…the power to make regulations respecting matters such as …the reporting of adverse health effects, by health professionals and other persons with privileged access to such information"
Reporting should not be limited to "health professionals and other persons with privileged access to such information". There must be a provision for the reporting of suspected ADRs by consumers. The BC-based organization, PharmaWatch, provides a model for such reporting and should be supported by Health Canada.

B10.2 – Prescription Status "…an administrative list of prescription products would be maintained (as opposed to a Schedule in the Act)…"
We do not support the elimination of Schedules in the Act if this would lead to allowing direct-to-consumer advertising (DTCA).

B10.3 – Advertising
Any new legislation should establish a separate drug safety agency, reporting directly to the Minister. Such an agency would be mandated to uphold the federal code on all matters pertaining to post-market provisions, including both regulations concerning advertising and promotion and monitoring of drug safety. It should maintain the highest standards of accountability and transparency and be part of the evolving public health structure within government. Members with any competing interests in the pharmaceutical and advertising industry should be excluded. While other models have been proposed (e.g., an arms length agency along the lines of the CRTC) and may work, providing they abide by the same rules of accountability and transparency, our consensus is to support an agency that reports directly to the Minister.

Options for Schedule A – As above, we do not support the elimination of Schedule A in the Act. There is a need for a clear set of criteria for determining which diseases should be listed for which advertising is not allowed. Such criteria exist in other jurisdictions.

Currently, the only options for Schedule A under discussion are restriction of the list (to only the most severe diseases among those listed) or elimination altogether. We support the existence of Schedule A as a means of protecting the seriously ill, and those who are

concerned about future illness, death and disability, from undue commercial influence. People need unbiased, independent information on the range of options available for disease prevention, treatment and cure. We do not believe that advertising is an effective mechanism to provide such information. It can take advantage of people's legitimate concerns about their health, and can lead to poorer health if a person substitutes less appropriate care for a serious disease. It can also lead to less cost-effective care. If a clear public health rationale exists in law for promotion of a specific product for disease prevention, such as condoms to prevent STD transmission, exceptions can easily be introduced through regulation.

We strongly oppose the 'clarification' of terms in the law such as 'prevention' to mean total or 100% prevention, leaving most prevention activities outside of the scope of the law as 'risk reduction'. This definition for prevention is not in keeping with either the spirit or the wording of the law. It is accepted for example that seat belts prevent automobile accident fatalities. It is generally understood to be an effective prevention measure although people do sometimes die in a car crash. Similarly, no product promoted for disease prevention has ever been found to prevent disease 100% of the time.

Direct to consumer advertising (DTCA) of health products – The "series of tools" referred to in this section of the proposal are listed in such a way as to give the reader the impression they are mutually exclusive, when they need not be. For example, DTCA ***can*** be prohibited – the option that we support – and there can also be a mandate to distribute government-approved consumer health product information.

It is inappropriate for the 'tool' concerning consumer information to have been listed in the section entitled direct-to-consumer advertising, as this 'tool' is unrelated to advertising and would require no change in advertising law. We strongly support increased access to independent, comparative information on the pros and cons of all available treatment options, as well as mandated, approved product information – written in plain language and in a user-friendly format – to accompany each dispensed prescription. These have nothing to do with direct-to-consumer advertising. They require no change in pharmaceutical advertising regulations.

Lack of adequate access to independent, accessible health information is a current gap in health service provision and should be addressed. However, it cannot be addressed through advertising, which by definition is biased in favour of the product it aims to sell. We strongly support the separation of policy development on independent information from proposals to change advertising regulations. These are two different policy directions, and they require separate consideration.

WHP's opposition to DTCA has been documented elsewhere (http://www.whp-apsf.ca/en/documents/doc_index2.html#dtca). This can be summarized around 3 key points:

- DTC advertising promotes the rapid widespread use of new medicines, when little is known about their safety, especially in the longer term. This is not in the best interests of health protection of the public.

- The "name, price and quantity" clause in the existing amended regulations (1978) has been re-interpreted by Health Canada in a way which does not respect the original intent of the law (i.e., allowance for a list consisting of the name of the product, the price per given quantity and any potential side effects in order to allow for comparative marketing by pharmacists). The law is not being adequately enforced by Health Canada and is leading to the proliferation of confusing advertising – "reminder ads" and "help-seeking messages" - to the public. The original intent of the clause should remain in force.
- **The Canadian public does not need product-specific prescription drug advertising. It needs accurate, up-to-date, comparative information on available treatment options, both drug and non-drug, and on the conditions they treat.** Production and distribution should be publicly financed as a necessary component of health care services, and should be fully independent of commercial interests. Such information should be clear, reliable, and adapted to the reading and comprehension level of the users. Cost information should be included.

Additional points on DTCA in the proposal:
The wording in section 10.3.1 makes it sound as if DTCA was endorsed at the multi-stakeholder consultations in 1996, 1998 and 1999, provided it conformed to the provisions listed in the proposal. DTCA ***was not*** endorsed at these consultations, even though certain groups were in favour of it. The distinction is an important one.

Additionally, those groups that favoured advertising tended to be the industries that stand to gain financially from expanded advertising (pharmaceutical, advertising and media) and organizations with direct financial links to those industries. Currently, the Canadian Medical Association, the Canadian Pharmacists' Association, and the Consumers' Association of Canada all oppose the introduction of DTCA.

B10.3.1.5 – "Should the proposed Act include provisions to control the promotion of products that takes place on the Internet?...What about the advertising which takes place on American television and is picked up in Canada?"
There should be provisions regarding the content of web sites originating in Canada. Web sites of Canadian subsidiaries should not include any links to promotional material on web sites outside of Canada. Those web sites that contain promotional material must be clearly labelled as being commercial in nature.

American ads for prescription products on television could be blocked by the cable provider and substituted with Canadian ads for other products, similar to what was done in the past when programs were simulcast on Canadian and American stations.

B10.3.3.2.1 – "Should "help seeking" messages inviting consumers to ask their doctors about new health products for a given condition (without emphasis on a specific product) be permitted?"
This could be allowed if carried out by independent groups, not the industries that stand to gain from specific promotion. Enforcement of the law concerning help seeking

messages is currently inadequate, and companies provide misleading and inaccurate information about disease risks. A recent example is Pfizer's toe-tag campaign to promote sales of Lipitor (atorvastatin), which does not mention the product name. This campaign provides an exaggerated impression of disease risks and the benefits of treatment.

Part of the problem with enforcement of advertising regulations concerning help-seeking promotion is the redefinition of 'advertising' in the 1996 Health Canada guidance on the difference between advertising and information. If the definition in the Food and Drugs Act is used – "any communication by any means aiming to stimulate sales"– then it would be possible to regulate help-seeking ads more effectively.

B10.3.3.2.3 – "Controlling the content of promotion"
Any controls on the content of DTCA will not negate the primary purpose of this advertising, which is to promote the sales of prescription-only drugs, through advertising aimed at the public.

The U.S. does a better job of controlling content than New Zealand, but U.S. ads remain highly problematic. The model being considered by Health Canada is very close to New Zealand's: direct industry self-regulation (or regulation by a non-governmental multi-stakeholder body with strong industry involvement), including pre-clearance. The existence of pre-clearance in New Zealand has not prevented misleading and erroneous information from reaching the public. Risk information is inadequate in U.S. ads – with techniques such as distracting visuals and speedier voice-over being the norm rather than the exception in television ads. In New Zealand, the same companies promote the same products to the public with even less risk information provided and frequently a more exaggerated impression of benefits. There is no evidence to suggest that a 'made-in-Canada' solution of industry self-regulation with pre-clearance would function any better than a 'made-in-New-Zealand' solution currently does.

Additionally, ads to health professionals in Canada remain highly problematic, without adequate risk information provided in the advertising copy and without any requirement for the labelling information detailing risks to be presented next to the ad or with adequate font size and organization for readability.

Health Canada is being naïve if it thinks it can adequately control the content of DTCA to ensure that the public receives accurate and balanced information concerning the products that are being advertised. We need only look at the content of DTCA in New Zealand and the United States, as well as the promotion to physicians in Canada, to see that this is not being done.

B10.3.3.2.4. – "Pre-clearance"
Pre-clearance is only as good as the regulations that govern what is allowed. To date, pre-clearance has not prevented grossly misleading advertising to physicians in Canada, or to the public in New Zealand (via the Therapeutic Advertising Pre-Vetting Service, or previously the Therapeutic Advertising Advisory Service). All New Zealand DTC ads are

pre-cleared. This does not prevent them from having an even lower standard of information than U.S. ads.

Currently, Health Canada has allowed reminder ads to run in Canada after pre-clearance by P.A.A.B. and/or A.S.C. These ads provide highly misleading messages about the effectiveness and safety of the products that are being advertised, and how they compare to other treatments that are available. They even include images that suggest off-label use, for example the woman with gorgeous, translucent skin in the Diane-35 (cyproterone/estradiol) billboard ads, who looks nothing like a woman with severe acne, resistant to previous treatment (i.e., highly likely to have scarring) and with signs of hormonal imbalance. This is a misleading image whether it is meant to be pre-treatment or post-treatment, for the approved indication.

Additionally the television ad for Viagra (sildenafil) does not distinguish use for impotence and recreational use. The toe-tag ad for Lipitor (atorvastatin) provides misleading information about the risks of a fatal first heart attack and the evidence concerning whether cholesterol-lowering drugs can prevent a fatal first heart attack. It also has a misleading overemphasis on the importance of cholesterol as a risk factor for heart disease versus for example smoking, a sedentary lifestyle, obesity and family history. This may lead to poor health choices.

Thus far, the track record in Canada in ensuring that DTCA provides accurate information to the public is very poor. Promotional campaigns that are not in keeping with the law are allowed to continue to run, even those that target adolescents (i.e., legal children). In order for there to be good regulations, the body developing them needs to be independent of commercial interests.

B10.3.4. – "Health Practitioner Oriented Promotion…is there a need for federal regulation in this area?"

Currently, health practitioner oriented promotion could be regulated by Health Canada under the 'deception' clause in the Food and Drugs Act. This has been delegated to industry self-regulation, mainly through Rx&D's Code of Marketing Practices Committee (the brand-name pharmaceutical industry) and through the Pharmaceutical Advertising Advisory Board (multi-stakeholder, with a strong pharmaceutical and advertising industry presence).

Experience in Canada has shown that voluntary self-regulation does not work. There is a need not only for federal regulation but also enforcement by a governmental or independent body established under legislation. There should be no involvement of pharmaceutical or advertising industries on this board, and it should report to the Minister and hence to Parliament.

H5 – Advisory Committees

Hearings of Advisory Committees, as a rule, should always be open and, if closed, the reasons for this should be publicly disclosed. Announcements of meetings and

comprehensive minutes from them should always be posted on the Health Canada web site. Regarding the issue of declaration of potential conflict of interest, there should be public hearings to help define what is meant by conflict of interest particularly in this context. An excellent model exists for declaration of conflict of interest in current provisions by the major medical journals, including the Canadian Medical Association Journal, for declarations by authors. This, and other statements, can serve as a starting base. However, declaration of conflict of interest is not adequate when it comes to regulatory decision-making. Those with declared conflicts concerning the manufacturer of a product or any of its competitors should not have any direct involvement in advice concerning regulatory decisions.

H6 - International Responsibilities – "Circumstances where the products manufactured in Canada for export would not be subject to Canadian standards"

Any therapeutic products manufactured in Canada for Canadian export must be subject to the same manufacturing standards applied in Canada. Drugs that have been withdrawn from the market or refused marketing approval in Canada must not be exported. All drugs exported to developing countries should be on the WHO Essential Drugs List or the essential drugs list of the recipient country. All exported drugs and devices must include approved product labelling and product information in a language that is appropriate for the recipient.

H8 - Cost Recovery

Paramount in any discussion of cost recovery must be emphasis on the need to minimize the direct influence of industry on the regulatory process. Indeed, concurrent to this review, we strongly recommend that government undertake a review of taxation policies with respect to limits on what industry can spend on advertising and other promotional activities and the percentage of such activities that they are allowed to claim.

Fees charged for licensing activities should go into general tax revenues and not be directly tied to financing the work of the Health Products and Foods Branch. Such monies earned should also be applied to enhance post-marketing surveillance. Money raised through cost recovery should be additional to and not a substitute for government allocations.

In addition to these points relating directly to items in the "Safety First" proposal, Women and Health Protection offers the following recommendations on related issues:

1. An efficacy and safety review be required of all drugs and devices currently marketed for disease prevention in healthy women (For more on this issue, see WHP's publication, "Preventing Disease: Are Pills the Answer?" by Sharon Batt at http://www.whp-apsf.ca/en/documents/pills_prevent.html .)

2. In light of the recent announcement by the Prime Minister of his intent to establish a Public Health Agency of Canada and to appoint a Chief Public Health Officer, the Canadian public should be informed of the role of the legislative renewal process in relation to this initiative.

3. Any legislation respecting health protection issues in Canada must provide 'whistle-blower protection' for individual Canadians who come forward with evidence that has been withheld from the debate.

4. Any legislation respecting health protection issues in Canada must override any legislation relating to genetic and reproductive technologies as well as to the area of biotechnology.

5. In order to put citizens on a level playing field with industry, budgets and resources must be allocated for citizen participation. Citizens must be able to participate from the beginning of the process, when standards are established.

6. Any safety assessment process must clearly impose the burden of proof upon the manufacturer.

7. Product safety assessment must include an evaluation of reproductive risk in women and men, including effects on sexual function, fertility, pregnancy outcomes and lactation.

8. The new legislation must include, as a required component of the industry fee system, a victim compensation fund for adverse drug reactions.

9. Safety assessment must take into account vulnerable populations (those living with chronic disease, the elderly, immigrants and refugees, children, those living in poverty or with low levels of education, among others).

10. All levels of health protection legislation in Canada (safety assessment, marketing, and post-market surveillance) must include a gender analysis.

11. Corrective action must be taken to redress the current inadequacy of resources for post-market surveillance of pharmaceuticals and medical devices, including provision of adequate resources for voluntary reporting by both the public and

health professionals, public awareness and educational campaigns, and the development of an active prospective post-market surveillance system for new drugs and devices with the Public Health Agency. The goal should be to develop a comprehensive surveillance system similar to that used for infectious disease monitoring and transportation safety. Given the evidence currently available that drug-induced injuries are a major cause of hospitalization and are estimated to be between the 4th and 6th leading cause of death, there is a pressing need for systematic monitoring and prevention, in order to enhance public safety.

Canada has the capacity to become a world leader in drug safety, with the appropriate allocation of re sources and expertise, and appropriate collaboration with other jurisdictions.

Individuals and Organizations endorsing the brief of Women and Health Protection

Breast Cancer Action Montreal
DES Action Canada, Montréal
Fédération du Québec pour le planning des naissances, Montréal
Inter Pares, Ottawa
Ontario Women's Health Network, Toronto
PharmaWatch, Vancouver
Prairie Women's Health Centre of Excellence, Winnipeg
Seniors Network BC
Women's Health Clinic, Winnipeg

Alan Cassels, drug policy researcher, University of Victoria
Marianne Cerilli, Winnipeg, environmental educator, former MLA, MB
Suzanne Elston, environmental educator, Courtice Ontario
Laurie Helgason, Advocate for Women with Disabilities and Healthy Living
Brewster Kneen, publisher, The Ram's Horn Newsletter, Sorrento BC
Cathleen Kneen, facilitator, BC Foods Systems Network
Carol Kushner, health policy analyst, Toronto
Kathleen O'Grady, Res. Associate, Simone de Beauvoir Institute, Concordia U.
Janine O'Leary Cobb, founder, A Friend Indeed, Montreal
Noralou P.Roos, PhD, Canada Research Chair in Population Health, U. of Manitoba
Dorothy Goldin Rosenberg, PhD, Cancer Prevention Interest Group, U.of Toronto
Karen Seabrooke, social justice advocate, Ottawa
Penny Van Esterik, PhD, Dept. of Anthropology, York University
Bilkis Vissandjee, PhD, Faculté des sciences infirmières, Université de Montréal
Susan White, M.A., Canadian Women's Health Network
Mary E. Wiktorowicz, PhD, School of Health Policy and Management, York University
Terence H. Young, Chair, Drug Safety Canada

International Endorsements:
Leonore Tiefer, PhD, Campaign for a New View of Women's Sexual Problems, New York
Dr. Peter Mansfield, Healthy Skepticism, Adelaide, Australia