



HOUSE OF COMMONS  
CANADA

**OPENING THE MEDICINE CABINET:  
FIRST REPORT ON HEALTH ASPECTS  
OF PRESCRIPTION DRUGS**

**REPORT OF THE STANDING COMMITTEE ON HEALTH**

**Bonnie Brown, M.P.  
Chair**

**April 2004**

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DURING THE 2ND SESSION OF THE 37TH PARLIAMENT**

José Cadorette

# **THE STANDING COMMITTEE ON HEALTH**

has the honour to present its

## **FIRST REPORT**

In accordance with its mandate under Standing Order 108(2), your Committee has conducted a study on Prescription Drugs, and presents a first report on its findings and recommendations.





## CHAIR'S FOREWORD

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Prescription drugs have an important role in our current health care system. When used appropriately, they have tremendous potential to save or improve the lives of Canadians. However, in addition to their beneficial effects, they also represent substantial risks and significant costs.

When members of the Standing Committee on Health embarked on this study, we were motivated by our collective knowledge of key events related to prescription drugs. The inquest into the death of Vanessa Young pointed to inadequacies in the drug safety system. Reports about health care expenditures indicated that drugs were the fastest growing segment of the system. *Fortune* magazine highlighted the higher than average return on investment experienced by the pharmaceutical industry. The Romanow report called for more recognition of the role of prescription drugs in Canada's health care system, including a review of patent laws.

As witnesses across the country openly shared their experiences, we learned more about the multifaceted nature of prescription drugs and their use. To date, our examination of the health-related aspects of prescription drugs has looked at the role of many players including governments, pharmaceutical companies, health professionals, consumers and others. We have also sought a consensus among multiple and sometimes conflicting opinions across a range of scientific, social and political issues.

The Committee recognizes the complexities of this subject. We acknowledge the need for a long-term approach and are not yet finished with our work. However, many thoughtful individuals identified particular concerns warranting immediate attention from the federal government. This first report presents our observations and views on some of the issues raised by Canadians.

On behalf of the members of the Committee, I would like to thank the witnesses who shared so generously their time and expertise. As always, we appreciate the professional guidance provided by the researchers from the Library of Parliament, Nancy Miller Chenier and Sonya Norris, the clerks of the Committee, José Cadorette and Carmen DePape, and the administrative support provided by Lise Tierney and Monique Pronovost. In addition, we are grateful for the continuing support of the editors, interpreters, console operators and others whose hard work and team effort have made this report possible.

I would also like to thank the individual members of the Committee who have participated in this study to date and have shared their wisdom and concern about this important issue.



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# **OPENING THE MEDICINE CABINET: FIRST REPORT ON HEALTH ASPECTS OF PRESCRIPTION DRUGS**

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## **COMMITTEE APPROACH**

In June 2003, the House of Commons Standing Committee on Health agreed to a study on prescription drugs (patented and generic) in Canada. Through a primary focus on the health aspects, it undertook to examine costs; price controls; drug approvals; adverse drug reactions; prescribing practices; marketing to and lobbying of prescribers and dispensers; direct-to-consumer advertising; access to drugs; and, misuse, abuse and addiction within the general population.

Over two months in the fall of 2003, the Health Committee held extensive hearings on the health-related aspects of prescription drugs. In addition to frequent meetings in Ottawa, the Committee travelled to western and eastern destinations to listen to the views of Canadians. This work produced a rich body of evidence and revealed multiple issues of shared concern.

This first report addresses three key issues relevant to prescription drugs in Canada: clinical trials, post-market surveillance and direct-to-consumer advertising. Building on information provided by witnesses, the report focuses on the federal responsibility in each area. The Committee intends to produce a second report on other areas of concern identified during our meetings across Canada.

Key to the work of this committee is its understanding that drugs are an integral part of the Canadian health care system and that the appropriate use of prescription drugs continues to benefit individuals across the country. However, it also recognizes the challenges of ensuring equitable access to safe, effective, quality drugs while managing costs. This report is the initial step in the work of assessing the health-related aspects of many issues related to prescriptions drugs. One objective is to increase public access to information about the realm of prescription drugs.

## **KEY ISSUES FOR CANADIANS**

### **Clinical Trials**

#### **What We Heard**

In the process of drug development, clinical trial research is essential to provide scientific data on a drug's safety, efficacy and optimal dosage. Clinical trials involve direct observation of human subjects. Health Canada then uses the data to evaluate a company's application for marketing a product for human use.

In Canada, regulatory requirements for clinical trials on drugs were developed in the 1960s. In 2001, changes to the regulations included an emphasis on the importance of research ethics boards and the establishment of a new inspection program. In general, a drug sponsor applies to Health Canada for authorization to conduct a clinical trial. The application must contain documents, including a copy of the protocol and a copy of the statement, to be set out in each informed consent form, about potential risks and anticipated benefits. Prior approval by a research ethics board is not required when making an application. However, prior to the commencement of a trial, the sponsor must identify the research ethics board and obtain research ethic board approval for the clinical trial protocol and for the informed consent form. After the clinical trial is initiated, inspections by Health Canada verify compliance with the regulatory requirements.

When approved, clinical trials are normally carried out in three phases. Phase 1 trials assess drug safety and involve a small number of adult volunteers. Phase 2 trials assess drug efficacy and recruit several hundred individuals randomly divided into a treatment group and a control group. Phase 3 trials assess drug efficacy, benefits and adverse reactions and require a very large group, possibly thousands of individuals, organized to be randomized, blinded, and long-term. Some witnesses called for federal regulatory requirements for a fourth phase or a phase 4 trial for additional assessment after the drug is available on the market.

Witnesses pointed to uneven standards and inconsistent operations among research ethics boards across the country. Currently, research ethics boards are not subject to federal regulations. Witnesses expressed concern about the lack of a standard accreditation system or regular audits for research ethics boards. Presently, the Canadian Institutes of Health Research expects funding recipients to adhere to the Tri-Council Policy Statement on ethical conduct for research involving humans. In addition, the National Council on Ethics in Human Research, a voluntary body made up of representatives from key organizations in clinical research and from the public, assists research ethics boards in interpreting and implementing guidelines for the ethics of research involving human subjects.

However, there is no single national body mandated to provide oversight for the ethical conduct of human research in either the public or private sector.

Witnesses had strong views about the lack of transparency associated with clinical trials. Overall, the concerns focused on the fact that, although the data generated from the various phases may be viewed by Health Canada and is sometimes included in published scientific and clinical reports, most of it remains confidential and unavailable to the individuals using the products. The drug companies argue that confidentiality is essential to limit the acquisition of knowledge by their competitors. To ensure this, the companies may require researchers, coordinators and others involved in clinical trials to sign confidentiality agreements. Several witnesses suggested that the confidentiality requirements meant that questionable activities went unreported due to fears about retaliation. They urged Health Canada to enhance its inspection process and to consider ways of legally protecting clinical trial researchers and other staff if they reported information deemed confidential. Witnesses pointed out that the confidentiality requirement left no avenue for Canadians to assess the completeness of the data used by the regulator, the reliability of the submitted information or the decision-making process leading to product availability. Individuals who use the resulting drug and who may suffer adverse effects as well as the prescribing physicians have difficulty accessing relevant data from the clinical trials.

Witnesses also questioned the increased reliance on partnerships between the pharmaceutical industry and university research centres and the lack of independence for individual researchers. Some witnesses expressed concerns about the trend to commercially oriented research organizations outside of academic centres. It was pointed out that companies developing a product and funding trials not only have the dominant role in designing protocols and choosing investigators, but they also play a major role in selecting volunteers as well as collating and interpreting the data. In addition to these areas where there is a strong potential for conflict of interest, companies have final approval over publication and usually seek positive reports published in established medical journals to raise awareness of their products and to promote their use.

The Health Products and Food Branch Inspectorate recently conducted inspections to validate data collected in the conduct of clinical trials as well as to increase the protection of enrolled subjects. A July 2003 report titled *Summary Report of the Inspections of Clinical Trials Conducted Under the Voluntary Phase* observed a number of deficiencies in areas related to records, to accuracy, to completeness and maintenance of source data, to systems and procedures for processes, and to informed consent forms for subjects enrolled in clinical trials.



## What We Think

The Health Committee believes that the health and safety of individuals who participate in clinical trials must be paramount. While it supports the current regulatory framework, it wants further measures to ensure that Canadians are not exposed to any undue risks during clinical drug trials. It calls for more rigorous scrutiny of clinical trial applications and an increase in the number of inspections.

The Committee does not support a clinical trial system that discourages openness in order to protect commercial interests. It feels that individual Canadians may be harmed by the lack of scrutiny and by a dearth of independently assessed information. It calls for increased transparency for Canadians and more accountability by Health Canada. To this end, it supports the development of mechanisms to enable public disclosure of information about clinical trials without jeopardizing either the intellectual property rights of drug companies or the privacy of individuals involved in the clinical trials.

The Committee strongly supports the development of accreditation and oversight for research ethics boards responsible for assessing clinical trials. It also wants a full and open public discussion about confidentiality agreements that currently prevent disclosure concerning negative outcomes in clinical trials. In particular, it feels that information on all serious adverse drug reactions observed during clinical trials and reported to Health Canada should be made publicly available.

The Committee therefore recommends that:

### **RECOMMENDATION 1**

- **Health Canada significantly increase the number of inspections conducted annually for all phases of all current clinical trials for prescription drugs involving human subjects and produce public annual reports of the findings;**
- **Health Canada introduce measures to ensure public confidence in the clinical trial process, starting with a public database that provides information on trials in progress, trials abandoned and trials completed;**
- **Health Canada develop standards that establish an accreditation process for research ethics boards assessing clinical trials;**

- **Health Canada conduct consultations aimed at discouraging or at least minimizing the use of confidentiality agreements when conducting clinical trials.**

## **Post-Market Surveillance**

### **What we heard**

The Marketed Health Products Directorate of the Health Products and Food Branch is responsible for post-market assessment and surveillance of therapeutic health products (pharmaceutical drugs and medical devices). Post-market surveillance involves a complex set of activities with the objective of identifying or further clarifying risks and therapeutic effectiveness of the products once they are in the Canadian marketplace. These post-market surveillance activities are a shared responsibility of manufacturers, health professionals, researchers, and regulators and require ongoing consultation and collaboration among the various stakeholders.

Currently, Health Canada relies on voluntary reporting of adverse drug reactions from physicians, pharmacists or patients and mandatory reporting from drug manufacturers. The Department administers five adverse reaction regional centres (situated in British Columbia, Saskatchewan, Ontario, Quebec, Nova Scotia) as well as a national centre in Ottawa. The national centre has eight Adverse Reaction Information specialists and each regional centre has one professional coordinator. In 2002, the Department received more than 8,500 domestic adverse reaction reports and more than 106,600 foreign adverse reaction reports. There were 169 recalls of drugs for human use for the same year. Health Canada estimated that **half of newly approved therapeutic health products have serious side effects** identified only after approval and marketing due to exposure within the larger population.

To facilitate surveillance and reporting of adverse drug reactions, Health Canada maintains a Canadian Adverse Drug Reaction Monitoring Program (CADRMP). The CADRMP database contains information from individual reports based on suspicion, opinion or observation. The Department also publishes and distributes a quarterly *Canadian Adverse Reaction Newsletter*. In addition, it provides access to a toll-free telephone and fax line and to Web site information on adverse reactions. Other departmental measures to provide access to health professionals range from broad-based education using guideline development and conference presentations to individualized computer-based information access.

Despite Health Canada's efforts, witnesses called for more effective post-market surveillance in Canada. Health professionals indicated that they rarely take time to fill out the reports and that the forms themselves are difficult to find

and to use. Many consumers were unaware of the toll-free number and of their capability to report adverse drug reactions. Generally, consumers suggested that their role is to identify their adverse drug reaction to a healthcare professional, physician or pharmacist.

In the absence of an adequate reporting system, some consumers have established their own databases to record personal experiences with prescription medicines. Some health professionals have set up mechanisms in hospitals to identify and investigate adverse drug reactions. Witnesses provided various estimates of the extent of the problem. It was suggested that up to 50% of hospital patients have an adverse drug reaction, either contributing to their hospitalization or during their hospital stay. One study calculated as many as 10,000 deaths yearly related to in-hospital adverse drug reactions in Canada. Reported adverse reactions could include not only those associated with a particular suspected drug but also negative outcomes associated with inappropriate drug dosages, underlying medical conditions, faulty dispensing and simultaneous use of other medications. Many witnesses argued that adverse drug reactions lead to increased physician and emergency room visits and more hospital stays, with a significant effect on overall health care costs in Canada.

Both health professionals and consumers called on Health Canada for increased monitoring of submitted adverse reaction reports, collation of the resulting data, and information dissemination. Many witnesses stated that the current monitoring of adverse drug reactions by Health Canada, by health professionals and by manufacturers is inadequate. Some witnesses pointed to the need for Health Canada to improve its communications strategy to better inform health care providers of the least complex way to submit the adverse reaction reports. They wanted simpler electronic means of transmitting information between the Department and health professionals and urged Health Canada to work collaboratively with the Canadian Medical Association and the Canadian Pharmacists Association to achieve this goal. Several witnesses emphasized the need for Health Canada to be more proactive in providing public reports about adverse drug reactions.

Other witnesses called for more fundamental changes. They argued that complete reporting of adverse drug reactions would only take place if it were made mandatory for physicians and pharmacists. They insisted that the pharmaceutical industry should have more extensive mandatory reporting requirements and be required to invest in the post-marketing and adverse reaction reporting process. They suggested the establishment of an independent agency, like the Aviation Safety Board, to investigate drug safety.

## What we think

The Committee feels that the current system for post-market surveillance of prescription drugs needs major changes to be effective. It acknowledges that Health Canada is making efforts to facilitate reporting options and to improve its communications and public relations with regard to post-market surveillance. However, additional measures must be taken to make certain that health professionals have ready access to an adverse reaction reporting system that assists rather than discourages their efforts. The Committee is very concerned about the lack of staff resources within the Department to address adverse drug reaction reports and calls for additional resources to assess the reports and to reflect the findings back to health professionals and consumers.

The Committee wants to ensure that the observations made by consumers about adverse drug reactions are taken seriously; that they are reported, recorded, reviewed and made publicly available. **The Committee agrees that the current system of voluntary reporting by health professionals and consumers as well as the mandatory reporting by drug manufacturers is unsatisfactory.** It sees a need for more comprehensive mandatory reporting by manufacturers and for an extension of mandatory reporting to health professionals. It believes that the number of Canadians affected by adverse reactions to drugs would be reduced if both manufacturers and health professionals were required to forward information to Health Canada on all serious adverse drug reactions within 48 hours of their recognition.

As a further measure to monitor adverse reactions, the Committee seeks heightened surveillance following product licensing. It sees a need for a probationary period for the drug after it initially is approved and put on the market. This measure could provide outcomes similar to a phase four clinical trial.

The Committee recommends that:

### **RECOMMENDATION 2**

- **Health Canada make licensing of new drugs probationary to ensure that post-market surveillance of adverse drug reactions is carried out diligently during a specified period after the drug is approved for marketing;**
- **Health Canada increase resources for post-market surveillance so that the infrastructure has the capacity to receive, analyze and respond to consumer and health professional reports and complaints about adverse drug reactions;**

- **Health Canada increase resources dedicated to public disclosure of adverse drug reaction reports;**
- **Health Canada facilitate reporting by health care professionals using simple formats and integrated computer technologies that permit health providers to submit adverse drug reaction reports online;**
- **Health Canada facilitate adverse drug reaction reporting by consumers, including recognition of anecdotal evidence; and,**
- **Health Canada initiate work with its provincial and territorial counterparts to implement an effective mandatory reporting system for health care professionals.**

## **Direct-to-consumer advertising**

### **What we heard**

Within Health Canada, the Health Products and Food Branch administers the current regulatory framework that governs all health product advertising. The *Food and Drugs Act* and its regulations specify that direct-to-consumer advertising is substantially prohibited. However, advertising directed at health care professionals is permitted.

The prohibition on advertising directed at consumers applies to those drugs covered by Schedule A and Schedule F of the regulations. Schedule A lists 40 conditions and disorders for which treatments, preventions or cures cannot be advertised to the general public, while Schedule F includes chemical entities or classes of drugs which are required by regulation to be sold under prescription.

According to Health Canada, a complete prohibition against direct-to-consumer advertising of prescription drugs was inserted into the regulations in 1949 to protect the purchasing consumer against injury to health and against deception. In 1978, an amendment intended to accommodate price comparisons for consumers permitted prescription drug information for the public to include name, price and quantity.

Witnesses referred to two types of prescription drug messages considered permissible for public dissemination to consumers: *reminder ads* and *help-seeking messages*. Reminder ads may contain the name, price, and quantity of a particular

drug but may not mention the disease or ailment that the drug is intended to treat. In practice, reminder ads tend to limit themselves to the name of the drug with some kind of lifestyle image, but price and quantity can be mentioned. Help-seeking messages describe ailments or conditions and encourage consumers to talk to their doctor or their health care professionals about the different available treatments. Help-seeking messages cannot contain the name of the drug that the advertiser would like the doctor to recommend. Therefore, only reminder ads contain information about a specific prescription drug.

Witnesses cited research indicating that public exposure to direct-to-consumer advertising resulted in an increase in the use of prescription drugs and a greater tendency for doctors to prescribe what the patient requests. In addition, witnesses suggested that the advertising emphasis on newer expensive drugs leads to increased health care costs. They pointed out that health information and drug information must not be confused with advertising information aimed at selling a product. They acknowledged that the Canadian public can use accurate, up-to-date, comparative information on available treatment options, both drug and non-drug, for various conditions. However, they emphasized that the information should be publicly financed, produced and distributed because Canadians want assurances that the information is prepared independently of commercial interests.

At present, Health Canada is responsible for enforcing the regulations and addressing any complaints about prescription drug advertising and information intended for the Canadian consumer. Two voluntary organizations also have been endorsed by Health Canada to play a role in reviewing other advertising material on drugs. The Pharmaceutical Advertising Advisory Board oversees prescription drug advertisements permitted for health professionals and Advertising Standards Canada oversees the advertisement of non-prescription drugs to the general public. Although Health Canada provides a toll-free line and other mechanisms, both these non-governmental organizations occasionally receive complaints about prescription drug advertising directed at consumers. When complaints were forwarded to Health Canada, witnesses reported that they received no feedback from the Department on actions taken.

With respect to enforcement of the current regulations and policies on direct-to-consumer advertising, Health Canada indicated that its efforts range from education and voluntary compliance to warning letters and prosecution that could result in fines, injunctions or imprisonment. When the Health Products and Food Branch Inspectorate investigates complaints against advertisements, it does not proceed unless it can demonstrate that the ad is deceptive or poses significant risk to the health of Canadians. Witnesses suggested that no penalties have been imposed since 1978.

## **What we think**

The Health Committee is concerned about the rising cost of health care in Canada and about the role of drug expenditures as a significant factor. It is convinced by research evidence suggesting that direct-to-consumer advertising of prescription drugs contributes to these costs.

The Committee heard that Health Canada, as part of its review of health protection legislation, is currently discussing the possibility of legislative changes to allow wider public advertising of prescription drugs. It agrees that the Canadian public can use high-quality, balanced information to assist in making informed decisions about prescription drug use. However, it wants the information to be provided by sources that do not benefit from product sales. In addition to governmental sources, such information could be prepared by various health organizations. The Committee feels strongly that, for all information on prescription drugs designated for the general public, Health Canada needs to take an active role in pre-clearance, surveillance and enforcement.

The Committee agrees with the original rationale for the prohibition against direct-to-consumer advertising of prescription drugs as protection against injury to health. It is of the opinion that drug advertisements could endanger rather than empower consumers by minimizing risk information and exaggerating benefits. The Committee contends that any direct-to-consumer advertising, including reminder ads, could contribute to increased or inappropriate drug consumption. Further, the Committee feels that the rationale for the 1978 amendment to the prohibition is no longer valid. Price comparison is no longer a significant issue for consumers as the majority of Canadians belong to some form of drug plan, whether publicly funded or through work or private insurance.

The Committee is concerned that the voluntary approach to pre-clearance of prescription drug advertisements with the burden for submitting complaints placed on the consumer is a feeble mechanism. Finally, the Committee is very dissatisfied with Health Canada's passive stance on the enforcement of the current regulations about direct-to-consumer advertising. It feels that Health Canada has abrogated its clear responsibility to enforce the existing rules.

The Committee has multiple concerns about direct-to-consumer advertising of prescription drugs. It feels that such advertising contributes to increased health care costs; does not provide balanced and unbiased information; is potentially harmful to consumers; and has no ongoing scrutiny. The Committee therefore seeks strict measures to ensure that the existing prohibition is actively enforced.

The Committee recommends that:

### **RECOMMENDATION 3**

- **Health Canada immediately enforce the current prohibition of all industry-sponsored advertisements on prescription drugs to the public;**
- **Health Canada ensure the provision of independent, unbiased and publicly financed information on prescription drugs to Canadians;**
- **Health Canada dedicate specific resources to the Health Products and Food Branch Inspectorate for vigorous enforcement of the direct-to-consumer advertising regulations on prescription drugs, including active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports;**
- **Health Canada ensure that all direct-to-consumer advertising complaints about prescription drugs received by Advertising Standards Canada or the Pharmaceutical Advertising Advisory Board are forwarded to Health Canada for investigation and action.**





# **LIST OF RECOMMENDATIONS**

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## **RECOMMENDATION 1**

- **Health Canada significantly increase the number of inspections conducted annually for all phases of all current clinical trials for prescription drugs involving human subjects and produce public annual reports of the findings;**
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## APPENDIX A LIST OF WITNESSES

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Department of Health</b>	16/09/2003	43
Robert Peterson, Director General, Therapeutic Products Directorate, Health Products and Food Branch		
<b>Department of Health</b>	18/09/2003	44
Carole Bouchard, Director, Office of Controlled Substances, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch		
Diane Gorman, Assistant Deputy Minister, Health Products and Food Branch		
Beth Pieterston, Director General, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch		
Christopher Turner, Director General, Marketed Health Products Directorate, Health Products and Food Branch		
<b>Department of Health</b>	23/09/2003	45
Wayne Lepine, Manager, Pharmaceutical Policy, Quality Care, Technology and Pharmaceuticals Division, Health Care Policy Directorate, Health Policy and Communications Branch		
Barbara Ouellet, Director, Quality Care, Technology and Pharmaceuticals Division, Health Care Policy Directorate, Health Policy and Communications Branch		
<b>Patented Medicine Prices Review Board</b>		
Wayne Critchley, Executive Director		
Robert Elgie, Chairperson		
Réal Sureau, Vice-Chairperson		
<b>Department of Health</b>	24/09/2003	46
Carole Bouchard, Director, Office of Controlled Substances, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch		
Danièle Dionne, Associate Director General, Health Products and Food Branch Inspectorate		
Brian Gillespie, Director, Senior Medical Advisor Bureau, Therapeutic Products Directorate, Health Products and Food Branch		
Beth Pieterston, Director General, Drug Strategy and Controlled Substances Programme, Healthy Environments and Consumer Safety Branch		
Christopher Turner, Director General, Marketed Health Products Directorate, Health Products and Food Branch		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<p><b>Department of Health</b></p> <p>Susan Fletcher, Associate Assistant Deputy Minister, First Nations and Inuit Health Branch</p> <p>Felix Li, Director, Chronic Disease Control and Management Division, Office of Public Security, Centre for Emergency Preparedness and Response, Population and Public Health Branch</p> <p>Leslie MacLean, Acting Director General, Non-Insured Health Benefits Program, First Nations and Inuit Health Branch</p> <p>Louise Plouffe, Manager, Knowledge Development, Division of Aging and Seniors</p> <p>Claude Rocan, Director General, Centre for Healthy Human Development, Population and Public Health Branch</p>	25/09/2003	47
<p><b>Better Pharmacare Coalition</b></p> <p>Brian Battison, Coordinator</p>	29/09/2003	49
<p><b>British Columbia Health Coalition</b></p> <p>Terrie Hendrickson, Coordinator</p> <p>Patt Shuttleworth, Registered Nurse</p>		
<p><b>British Columbia Persons With AIDS Society</b></p> <p>Ross Harvey, Executive Director</p> <p>Malsah, Vice-Chair of the Board of Directors</p>		
<p><b>Centre for Health Services &amp; Policy Research, University of British Columbia</b></p> <p>Barbara Mintzes, Post Doctoral Fellow</p>		
<p><b>Council of Senior Citizens Organizations of British Columbia</b></p> <p>Sylvia MacLeay, Second Vice-President and Chairperson of the Health Committee</p>		
<p><b>Downtown Eastside HIV/IDU Consumers' Board</b></p> <p>John Cameron, Chairperson, HIV/AIDS</p>		
<p><b>Market Media International Corp.</b></p> <p>John Constible</p> <p>Joan Gadsby</p>		
<p><b>Society for Diabetic Rights</b></p> <p>Colleen Fuller, President</p>		
<p><b>The Fraser Institute</b></p> <p>John Graham, Director, Health and Pharmaceutical Policy Research</p>		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Vancouver Coastal Health Research Institute</b> Bernie Bressler, Director	29/09/2003	49
<b>Vancouver Native Health Authority</b> Steve Adilman, Clinic Coordinator		
<b>British Columbia Pharmacy Association</b> Derek Desrosiers, Vice-President Marnie Mitchell, Chief Executive Officer	29/09/2003	50
<b>Canadian Centre for Policy Alternatives</b> Carol Cole		
<b>Canadian Nurses Association</b> Rob Calnan, President		
<b>Centre for Health Services and Policy Research, University of British Columbia</b> Steven Morgan, Assistant Professor, Medicine, Health Care and Epidemiology		
<b>Faculty of Pharmaceutical Sciences, University of British Columbia</b> Robert D. Sindelar, Professor and Dean		
<b>Pharmawatch</b> Warren Bell		
<b>University of British Columbia Therapeutics Initiative</b> Thomas L. Perry James M. Wright		
<b>Alberta College of Pharmacists</b> Greg Eberhart, Registrar	30/09/2003	51
<b>Alberta Health and Wellness</b> David Bougher, Director, Pharmaceutical Policy and Programs		
<b>Canadian Association of Chain Drug Stores</b> Jeffrey May, Director, Government & Regulatory Affairs Lori Turik, Vice-President, Public Policy		
<b>North West Territories Health and Social Services</b> André Corriveau, Chief Medical Officer		
<b>Canadian Union of Public Employees, Alberta Division</b> Bruce McLeod, President	30/09/2003	52

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<p><b>Consumer's Association of Canada — Alberta</b>  Wendy Armstrong, Volunteer Board Member  Larry Phillips, President</p> <p><b>Council of Canadians</b>  Dale Watson, Red Deer Chapter</p> <p><b>Health Law Institute, University of Alberta</b>  Tracey Bailey, Executive Director</p> <p><b>Institute of Health Economics</b>  Devidas Menon, Executive Director and Chief Executive Officer</p> <p><b>Native Council of Canada (Alberta)</b>  Richard Long, Executive Director  Doris Ronnenberg, President  Glen Stashko</p> <p><b>Seniors' Action and Liaison Team</b>  Brian Staples, Chair</p>	30/09/2003	52
<p><b>All Nations Hope AIDS Network</b>  Margaret Akan, Manager</p> <p><b>Canadian Arthritis Patient Alliance</b>  Anne Dooley, Vice-President</p> <p><b>Community Health Services (Saskatoon) Association</b>  Patrick Lapointe, Administrator  Kathleen Storrie, President</p> <p><b>Government of Saskatchewan</b>  John Nilson, Minister of Health  Heather Nord, Senior Ministerial Assistant  Kevin Wilson, Executive Director, Drug Plan and Extended Benefits</p> <p><b>Saskatchewan Health Coalition</b>  Dale Holmberg, President</p> <p><b>The Arthritis Society (Saskatchewan Division)</b>  Sherry McKinnon, Executive Director</p> <p><b>As an Individual</b>  John McConnell</p>	01/10/2003	53

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Representative Board of Saskatchewan Pharmacists</b> Brett Filson, Executive Director Guy Nobert, Vice-Chair	01/10/2003	54
<b>Saskatchewan College of Pharmacists</b> Ray Joubert, Registrar Randy Wisner, President		
<b>Saskatchewan Drug Research Institute</b> Marianne Greer, Director		
<b>Saskatchewan Union of Nurses</b> Rosalee Longmoore, President		
<b>As an Individual</b> John Bury		
<b>Addictions Foundation of Manitoba</b> Deb Kostyk, Seniors and Addictions Prevention Education Consultant	02/10/2003	55
<b>Coalition for Manitoba Pharmacy</b> Lothar Dueck, President Michele Fontaine, Vice-President Greg Skura, Secretary		
<b>Department of Family Medicine and Manitoba Centre for Health Policy, University of Manitoba</b> Alan Katz, Associate Professor and Associate Department Head		
<b>Manitoba Centre for Health Policy</b> Anita Kozyrskyj, Assistant Professor, University of Manitoba Noralou Roos, Director and Senior Researcher		
<b>Manitoba Pharmaceutical Association</b> Ronald Guse, Registrar		
<b>Manitoba Society of Pharmacists</b> Marian Kremers, President Scott Ransome, Executive Director		
<b>National Steering Committee on Patient Safety</b> John Wade, Former Chair		



<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Government of Manitoba</b> Dave Chomiak, Minister of Health Jack Rosentreter, Executive Director, Pharmaceutical Drug Programs Milton Sussman, Deputy Minister, Department of Health Marcia Thomson, ADM Health Programs, Health Programs Ulrich Wendt, Federal/Provincial Advisor	02/10/2003	56
<b>Indian Council of First Nations of Manitoba</b> Andrew Kirkness Tom Kirkness, Secretary Treasurer Glenn McIvor		
<b>Women's Health Clinic</b> Madeline Boscoe		
<b>As an Individual</b> Kay Schwartzman		
<b>Best Medicines Coalition</b> Denis Morrice, Co-Chair	07/10/2003	57
<b>Canadian Labour Congress</b> Barb Byers, Executive Vice-President Cindy Wiggins, Senior Researcher	09/10/2003	58
<b>Canadian Union of Public Employees</b> Stan Marshall, Senior Research Officer		
<b>Congress of Union Retirees of Canada</b> Ronald Lang, Eastern Ontario Representative Larry Wagg, First Vice-President		
<b>Council of Canadians</b> Guy Caron, Health Care Campaigner		
<b>National Union of Public and General Employees</b> James Clancy, National President		
<b>Brogan Inc.</b> Tom Brogan, President Joan Fearnley, Senior Economist	22/10/2003	60
<b>Canadian Institute for Health Information</b> Louise Ogilvie, Director, Health Resources Information		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Palmer D'Angelo Consulting Inc.</b> Janice D'Angelo, Principal Consultant Susan Neale, Senior Policy Analyst W. Neil Palmer, Principal Consultant	22/10/2003	60
<b>Assembly of First Nations</b> Bill Erasmus, Regional Chief, Northwest Territories Elaine Johnston, Director, Health Secretariat	23/10/2003	61
<b>Canadian Coordinating Office for Health Technology Assessment</b> Barb Shea, Director, Common Drug Review Vijay Shukla, Pharmacist, Common Drug Review		
<b>Canadian Health Coalition</b> Michael McBane, National Co-ordinator		
<b>University of Ottawa</b> Michele Brill-Edwards, Department of Pediatrics		
<b>Atlantic Institute for Market Studies</b> Don McIver, Director of Research	27/10/2003	62
<b>Canadian Cancer Society — Nova Scotia Division</b> Meg McCallum, Director of Programs Maureen Summers, Executive Director		
<b>Canadian Mental Health Association</b> Claudette Gaudet, Consumer Carol Tooton, Executive Director, Nova Scotia Division		
<b>Centre for Emotions and Health, Dalhousie University</b> Allan Abbass, Director of Education, Department of Psychiatry		
<b>Dalhousie University</b> David Zitner, Director, Medical Informatics, Faculty of Medicine		
<b>New Brunswick Pharmacists' Association</b> Peter Hogan, President		
<b>Nova Scotia Citizens Health Care Network</b> Peggy Brown, Disabled Individuals Alliance Representative Ian Johnson, Vice-Chairperson Sheila Richardson, Valley Chapter, Council of Canadians and Member of Health Network		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<p><b>P.E.I. Health Coalition and MacKillop Centre for Social Justice</b></p> <p>Mary Boyd, Chair, P.E.I. Health Coalition; Director, MacKillop Centre for Social Justice</p>	27/10/2003	62
<p><b>University of New Brunswick, Faculty of Nursing</b></p> <p>Margaret Dykeman, Associate Professor and Nurse Manager Community Health Clinic</p>		
<p><b>New Brunswick Department of Health and Wellness</b></p> <p>Leanne Jardine, Acting Director, New Brunswick Prescription Drug Program</p>	27/10/2003	63
<p><b>Nova Scotia Department of Health</b></p> <p>Emily Somers, Acting Director, Pharmaceutical Services Thomas Ward, Deputy Minister of Health</p>		
<p><b>Atlantic Centre of Excellence for Women's Health</b></p> <p>Martha Paynter, Research Assistant</p>	28/10/2003	64
<p><b>Coalition of Physicians for Social Justice</b></p> <p>Paul Saba, President</p>		
<p><b>Committee of People Living with HIV of Quebec</b></p> <p>Luc Gagnon, Executive Director Marc Lapierre, President José Sousa, Member of the Board of Directors, CPAVIH</p>		
<p><b>Fédération des infirmières et infirmiers du Québec</b></p> <p>Sylvie Boulanger, First Vice-President Lucie Mercier, Consultant</p>		
<p><b>Kerbapharm Inc.</b></p> <p>Joseph Kerba, Chairman</p>		
<p><b>Le Groupe Jean Coutu (PJC) Inc.</b></p> <p>Richard Mayrand, Vice-President, Professional Activities</p>		
<p><b>Montreal International</b></p> <p>Michel Leblanc, Vice-President, Life Sciences</p>		
<p><b>Ordre des pharmaciens du Québec</b></p> <p>Jean-Yves Julien, President Marc Parent, Administrator</p>		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Union des consommateurs</b> France Latreille, Acting Coordinator Thérèse Richer, President Charles Tanguay, Communications Officer	28/10/2003	64
<b>University of Quebec in Montreal</b> Marc Hasbani, Researcher, Socio-economic Research Chair		
<b>Biogen Canada</b> Rob Hamilton, President Robert Kulik, Manager, Reimbursement and Government Affairs	29/10/2003	65
<b>Canada's Association for the Fifty-Plus</b> Lillian Morgenthau, President and Founder		
<b>Canadian Auto Workers Union</b> Len Harrison, Retired Worker Executive Dean Lindsay, National Coordinator, Retirees		
<b>Canadian Pensioners Concerned Inc.</b> Barbara Black, Past President Gerda Kaegi, President		
<b>Genzyme Canada Inc.</b> Peter Brenders, Health Affairs Executive Paul Drohan, Managing Director		
<b>Pharmex Direct Inc.</b> Thomas Holloway, President		
<b>Women and Health Protection</b> Anne Rochon Ford, Coordinator		
<b>Canadian International Pharmacy Association</b> John Myers, Secretary and General Counsel Andy Troszok, Vice-President, Standards	29/10/2003	66
<b>Canadian Pharmacists Association</b> Jeff Poston, Executive Director		
<b>Drug Safety Canada</b> Terence Young, Chair		
<b>Multiple Sclerosis Society of Canada</b> Deanna Groetzinger, Vice-President, Communications Kris McDonald, Volunteer and Member		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<p><b>Ontario College of Pharmacists</b></p> <p>Della Croteau, Deputy Registrar, Director of Programs</p> <p>Greg Ujiye, Manager, Pharmacy Practice Programs</p> <p><b>Ontario Ministry of Health and Long-Term Care</b></p> <p>David McCutcheon, Assistant Deputy Minister, Health Services Division</p> <p>Susan Paetkau, Director, Drug Programs Branch</p> <p><b>Ontario Pharmacists' Association</b></p> <p>Ruth Mallon, Vice-President, Pharmacy Services</p> <p>David Thomson, Chief Executive Officer</p> <p><b>Pharmaceutical Advertising Advisory Board</b></p> <p>Gloria Bowes, Vice-Chair</p> <p>Ray Chepesiuk, Commissioner</p>	29/10/2003	66
<p><b>Alliance of Seniors to Protect Canada's Social Programs</b></p> <p>Al Gorlick, Chair</p> <p><b>Anemia Institute for Research and Education</b></p> <p>Durhane Wong-Rieger, President and Chief Executive Officer</p> <p><b>Canadian Arthritis Network</b></p> <p>Edward Keystone, Associate Clinical Director</p> <p><b>Canadian Cystic Fibrosis Foundation</b></p> <p>Josée Chiarot, Director, Medical, Scientific and Community Programs</p> <p>Gord Thow, Past President</p> <p><b>Canadian Diabetes Association</b></p> <p>Donna Lillie, Vice-President, Research and Professional Education</p> <p>Alexis Mantell, Senior Manager, Strategic Communications</p> <p><b>Canadian Network for Asthma Care</b></p> <p>Kenneth Chapman, President</p> <p><b>Canadian Treatment Action Council</b></p> <p>Louise Binder, Chair</p> <p><b>Consumers' Association of Canada</b></p> <p>Mel Fruitman, President</p> <p>Joan Sayer, Provincial Liaison, National Health Council</p>	30/10/2003	67

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<p><b>Osteoporosis Society of Canada</b></p> <p>Joyce Gordon, President and Chief Executive Officer</p> <p>Gail Lemieux, Founding Member, Canadian Osteoporosis Patient Network</p>	30/10/2003	67
<p><b>United Steelworkers of America</b></p> <p>Rod Bezo, Canadian Coordinator, Steelworkers Organization of Active Retirees</p> <p>Jorge Garcia-Orgales, Researcher</p>		
<p><b>Alliance for Access to Medical Information</b></p> <p>Sandra Graham, Senior Vice-President, Public Affairs of the Canadian Association of Broadcasters</p> <p>Anne Kothawala, President and Chief Executive Officer, Canadian Newspapers Association</p>	30/10/2003	68
<p><b>ESI Canada</b></p> <p>Jean Joubert, President</p> <p>Steven Semelman, Vice-President, Health Management Operations</p>		
<p><b>Green Shield Canada</b></p> <p>Vernon Chiles, Vice-Chair of the Board</p>		
<p><b>Medical Reform Group</b></p> <p>Joel Lexchin, Associate Professor, York University School of Health Policy and Management</p> <p>Brad Macintosh, Member of the Steering Committee</p> <p>Rosanna Pellizzari, Member of the Steering Committee</p>		
<p><b>As an Individual</b></p> <p>Michael Rachlis, Private consultant in health policy</p>		
<p><b>BIOTECanada</b></p> <p>Suzanne Cadden, Vice-President of Clinical and Regulatory Affairs, Lorus Therapeutics</p> <p>Janet Lambert, President</p>	04/11/2003	69
<p><b>Canadian Generic Pharmaceutical Association</b></p> <p>Jim Keon, President</p> <p>Allan Oberman, Vice-Chair, President and Chief Executive Officer of Novopharm Ltd.</p>		

<b>Associations and Individuals</b>	<b>Date</b>	<b>Meeting</b>
<b>Rx &amp; D — Canada’s Research-Based Pharmaceutical Companies</b> Murray Elston, President Nestor Nituch, Director of Clinical Research, Bristol Myers Squibb (BMS) John Stewart, Chairman and Executive Vice-President and General Manager of Purdue Pharma	04/11/2003	69
<b>Gilead Sciences Inc.</b> Mick Hitchcock, Vice-President, Health Alix Israels, Marketing Manager, Canada	05/11/2003	70
<b>IMS Health</b> Gary Fabian, Vice-President, Corporate Relations Anita Fineberg, Corporate Counsel and Chief Privacy Officer Roger Korman, President		
<b>University of Ottawa</b> Judy Erola, Chairman, Advisory Committee, Health Management Program, School of Management André Potworowski, Associate Director, Research and Development, Centre for Research in Biopharmaceuticals and Biotechnology		
<b>Canadian Federation of Nurses Union</b> Tom O’Brien, Director of Communications and Campaigns Linda Silas, President Pauline Worsfold, Secretary-Treasurer	06/11/2003	71
<b>Canadian Medical Association</b> Isra Levy, Director, Office of Public Health Sunil Patel, President William Tholl, Secretary General and CEO		
<b>The Royal College of Physicians and Surgeons of Canada</b> Michel Brazeau, Chief Executive Officer Jean Gray, Vice-President, Executive Committee		

## APPENDIX B LIST OF BRIEFS

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Alliance of Seniors  
Anemia Institute for Research and Education  
Assembly of First Nations  
Best Medicines Coalition  
Better Pharmacare Coalition  
BIOTECanada  
British Columbia Persons With AIDS Society  
British Columbia Pharmacy Association  
Bury, John  
Canada's Association for the Fifty-Plus  
Canadian Arthritis Patient Alliance  
Canadian Association of Chain Drug Stores  
Canadian Auto Workers Union  
Canadian Cancer Society — Nova Scotia Division  
Canadian Cystic Fibrosis Foundation  
Canadian Diabetes Association  
Canadian Federation of Nurses Union  
Canadian Generic Pharmaceutical Association  
Canadian Health Coalition  
Canadian Institute for Health Information  
Canadian International Pharmacy Association  
Canadian Labour Congress



Canadian Medical Association  
Canadian Mental Health Association  
Canadian Nurses Association  
Canadian Pensioners Concerned Inc.  
Canadian Pharmacists Association  
Canadian Treatment Action Council  
Cassels, Alan  
Centre for Emotions and Health, Dalhousie University  
Centre for Health Services and Policy Research, University of British Columbia  
Coalition for Manitoba Pharmacy  
Coalition of Physicians for Social Justice  
Committee of People Living with HIV of Quebec  
Community Health Services (Saskatoon) Association  
Consumer's Association of Canada, Alberta  
Consumer's Association of Canada, Manitoba Chapter  
Council of Canadians  
Council of Senior Citizens Organizations of British Columbia  
Cummings Jewish Centre for Seniors  
Dalhousie University, Faculty of Medicine  
Downtown Eastside HIV/IDU Consumers' Board  
Drug Safety Canada  
Fédération des infirmières et infirmiers du Québec  
Gilead Sciences Inc.  
Government of Manitoba  
Green Shield Canada

IMS Health  
Le Groupe Jean Coutu (PJC) Inc.  
Leclair, Penny  
Manitoba Centre for Health Policy  
Manitoba Pharmaceutical Association  
Market Media International Corp.  
McMahon, Dennis  
Medical Reform Group  
Montreal Economic Institute  
Mount Sinai Hospital Foundation of Toronto  
Multiple Sclerosis Society of Canada  
National Union of Public and General Employees  
New Brunswick Department of Health and Wellness  
Nonprescription Drug Manufacturers Association of Canada  
Nova Scotia Citizens Health Care Network  
Ontario Ministry of Health and Long-Term Care  
Palmer D'Angelo Consulting Inc.  
Patented Medicine Prices Review Board  
Pharmawatch  
Project Genesis  
Rx & D — Canada's Research-Based Pharmaceutical Companies  
Saskatchewan College of Pharmacists  
Saskatchewan Drug Research Institute  
Seniors' Action and Liaison Team  
Society for Diabetic Rights

The Arthritis Society (Saskatchewan Division)

The Fraser Institute

The Royal College of Physicians and Surgeons of Canada

Union des consommateurs

United Steelworkers of America

University of Manitoba

University of New Brunswick, Faculty of Nursing

Ward Health Strategies

Women and Health Protection

Women's Health Clinic

## REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings (*Meeting Nos. 21, 40, 42 to 47, 49 to 58 and 60 to 71, of the 2nd Session, 37th Parliament, and Meetings Nos. 4 to 9 of the 3rd Session, 37th Parliament*) is tabled.

Respectfully submitted,

Bonnie Brown, M.P.  
*Chair*



## MINUTES OF PROCEEDINGS

Tuesday, March 30, 2004  
(Meeting No. 9)

The Standing Committee on Health met *in camera* at 11:06 a.m. this day, in Room 269 West Block, the Chair, Bonnie Brown, presiding.

*Members of the Committee present:* Gilbert Barrette, Hon. Don Boudria, Bonnie Brown, Hon. Gerry Byrne, Deborah Grey, Hon. David Kilgour, Réal Ménard, Rob Merrifield and Hon. Gilbert Normand.

*Acting Members present:* Hon. Hedy Fry for Hon. David Kilgour and Hon. Jerry Pickard for Hon. Gilbert Normand.

*Associate Member present:* Madeleine Dalphond-Guiral.

*In attendance: Library of Parliament:* Nancy Miller Chenier, Analyst; Sonya Norris, Analyst.

Pursuant to Standing Order 108(2) and the motion adopted by the Committee on Tuesday, February 24, 2004, the Committee resumed its study on prescription drugs.

It was agreed, — That the draft report, as amended, be adopted.

It was agreed, — That the Chair present the report to the House.

It was agreed, — That the Chair, Clerk and researchers be authorized to make such grammatical and editorial changes as may be necessary without changing the substance of the report.

It was agreed, — That, pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to the report.

It was agreed, — That the Clerk of the Committee make the necessary arrangements for a press conference to be held on Thursday, April 1, 2004, at 11:30 a.m. in the National Press Theatre, 150 Wellington St., after the tabling of the Committee's report on prescription drugs to the House; and that the Committee be represented by the Chair and a representative from each party.

It was agreed, — That the Clerk of the Committee, in consultation with the Chair, issue a news release.

It was agreed, — That the Committee call on the Health Minister to appear on Tuesday, April 27, 2004, to answer questions on the Estimates.

At 12:19 p.m., the Committee adjourned to the call of the Chair.

Carmen DePape  
*Clerk of the Committee*