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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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

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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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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- **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.**

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- **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;**

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LIST OF WITNESSES

Associations and Individuals	Date	Meeting
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Robert Peterson, Director General, Therapeutic Products Directorate, Health Products and Food Branch		
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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 Pieterson, 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		
Department of Health	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		
Patented Medicine Prices Review Board		
Wayne Critchley, Executive Director		
Robert Elgie, Chairperson		
Réal Sureau, Vice-Chairperson		
Department of Health	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 Pieterson, 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		

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

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Vancouver Native Health Authority		
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Marnie Mitchell, Chief Executive Officer		
Canadian Centre for Policy Alternatives		
Carol Cole		
Canadian Nurses Association		
Rob Calnan, President		
Centre for Health Services and Policy Research, University of British Columbia		
Steven Morgan, Assistant Professor, Medicine, Health Care and Epidemiology		
Faculty of Pharmaceutical Sciences, University of British Columbia		
Robert D. Sindelar, Professor and Dean		
Pharmawatch		
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University of British Columbia Therapeutics Initiative		
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David Bougher, Director, Pharmaceutical Policy and Programs		
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Jeffrey May, Director, Government & Regulatory Affairs		
Lori Turik, Vice-President, Public Policy		
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André Corriveau, Chief Medical Officer		
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Consumer's Association of Canada — Alberta	30/09/2003	52
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Larry Phillips, President		
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Dale Watson, Red Deer Chapter		
Health Law Institute, University of Alberta		
Tracey Bailey, Executive Director		
Institute of Health Economics		
Devidas Menon, Executive Director and Chief Executive Officer		
Native Council of Canada (Alberta)		
Richard Long, Executive Director		
Doris Ronnenberg, President		
Glen Stashko		
Seniors' Action and Liaison Team		
Brian Staples, Chair		
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Margaret Akan, Manager		
Canadian Arthritis Patient Alliance		
Anne Dooley, Vice-President		
Community Health Services (Saskatoon) Association		
Patrick Lapointe, Administrator		
Kathleen Storrie, President		
Government of Saskatchewan		
John Nilson, Minister of Health		
Heather Nord, Senior Ministerial Assistant		
Kevin Wilson, Executive Director, Drug Plan and Extended Benefits		
Saskatchewan Health Coalition		
Dale Holmberg, President		
The Arthritis Society (Saskatchewan Division)		
Sherry McKinnon, Executive Director		
As an Individual		
John McConnell		

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

Associations and Individuals	Date	Meeting
Government of Manitoba	02/10/2003	56
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		
Indian Council of First Nations of Manitoba		
Andrew Kirkness		
Tom Kirkness, Secretary Treasurer		
Glenn McIvor		
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Barb Byers, Executive Vice-President		
Cindy Wiggins, Senior Researcher		
Canadian Union of Public Employees		
Stan Marshall, Senior Research Officer		
Congress of Union Retirees of Canada		
Ronald Lang, Eastern Ontario Representative		
Larry Wagg, First Vice-President		
Council of Canadians		
Guy Caron, Health Care Campaigner		
National Union of Public and General Employees		
James Clancy, National President		
Brogan Inc.	22/10/2003	60
Tom Brogan, President		
Joan Fearnley, Senior Economist		
Canadian Institute for Health Information		
Louise Ogilvie, Director, Health Resources Information		

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

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

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

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

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

Associations and Individuals	Date	Meeting
Rx & D — Canada's Research-Based Pharmaceutical Companies	04/11/2003	69
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		
Gilead Sciences Inc.	05/11/2003	70
Mick Hitchcock, Vice-President, Health		
Alix Israels, Marketing Manager, Canada		
IMS Health		
Gary Fabian, Vice-President, Corporate Relations		
Anita Fineberg, Corporate Counsel and Chief Privacy Officer		
Roger Korman, President		
University of Ottawa		
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		
Canadian Federation of Nurses Union	06/11/2003	71
Tom O'Brien, Director of Communications and Campaigns		
Linda Silas, President		
Pauline Worsfold, Secretary-Treasurer		
Canadian Medical Association		
Isra Levy, Director, Office of Public Health		
Sunil Patel, President		
William Tholl, Secretary General and CEO		
The Royal College of Physicians and Surgeons of Canada		
Michel Brazeau, Chief Executive Officer		
Jean Gray, Vice-President, Executive Committee		

APPENDIX B
LIST OF BRIEFS

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