05-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

CANWEST MEDIAWORKS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF ANN SZTUKE-FOURNIER

I, Ann Sztuke-Fournier, of the City of Gatineau, in the Province of Quebec, do solemnly affirm:

INTRODUCTION

1. I am presently the manager of the Regulatory Advertising and Risk Communications Section of the Therapeutic Effectiveness and Policy Bureau of the Marketed Health Products Directorate of Health Canada. My duties include the coordination and regulatory oversight of the advertising activities of marketed health products, including drugs, in Canada in accordance with the *Food and Drugs Act,* R.S., c. F-27, s. 1 ("*FDA*") and the *Food and Drug Regulations,* C.R.C., c. 870 ("*Regulations*"). I have had responsibility with respect to the regulatory oversight of the advertising activities of marketed health products in Canada since 1997.

2. I received a Bachelor's Degree in Pharmacy from the University of Montréal in 1979. Before I joined Health Canada in 1989, I had ten years of professional work experience in community pharmacy settings.

3. The Regulatory Advertising and Risk Communications Section is responsible for the provision of specialized scientific and regulatory advice, services and policy guidance relating to the advertising and the dissemination of drug safety and effectiveness information of marketed health products. The section provides these services to the therapeutic products industry, independent advertising pre-clearance agencies, the medical community, health care providers, Canadian consumers, national and international audiences, and the management and staff of Health Canada.

4. This work includes:

a) the development, editorial control and publication of the Canadian Adverse Reaction Newsletter (CARN);

b) the development of standards, policies, procedures and maintenance of systems regarding the dissemination of risk communication products to a list-serve community of over 12,000 Canadians including direct dissemination to the health professional community;

c) the development of standards, policies, procedures and systems regarding the collection, analysis, interpretation and dissemination of information on the advertising of marketed health products in compliance with the applicable sections of the FDA and the Regulations; and

d) the development of scientific risk communications advice, strategies, planning activities and services relating to therapeutic products for the Marketed Health Products Directorate (MHPD), Therapeutic Products Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD), Natural Health Products Directorate (NHPD) and the Health Products and Food Branch Inspectorate (HPFBI) of Health Canada.

5. The role of the MHPD is to work with the pre-market directorates of Health Canada so that all of the Health Products and Food Branch programmes

utilize a cohesive and consistent approach to the monitoring, assessment and making of interventions across all product types, and to provide the Branch with leadership in post-market surveillance pertaining to all marketed health products. The MHPD is also the focal point in the Branch for the development of post-market surveillance frameworks and strategies pertaining to regulated health products, working in close alliance, collaboration and communication with the other HPFB directorates of the Branch, and with other involved Branches, the Department, and the Regions.

6. I joined Health Canada in 1989. I first worked in the Bureau of Dangerous Drugs and was responsible for monitoring and investigation activities related to narcotic and controlled substances, including the Methadone Programme. Organizational changes at Health Canada led to my position becoming part of the Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance where I worked until 1997.

7. The purpose of this affidavit is to:

a) provide a legislative history of the provisions in the *FDA Regulations*, which restrict direct-to-consumer advertising of prescription drugs. More specifically, these are s. 3 and Schedule A of the *FDA* and s. C.01.044 of the *Regulations*. This legislative history will describe the policies behind, the purpose for and the objectives of the current restrictions on direct-to-consumer advertising of prescription drugs, being one tool in an overall regulatory scheme which seeks to contribute to and maintain the health and well-being of the Canadian public;

b) describe the larger regulatory scheme relating to prescription drugs. The regulatory regime, which includes restrictions on prescription drug advertising as referred to below, seeks to ensure that Canadians have access to drugs and other therapeutic products that meet prescribed safety and efficacy requirements and that the benefits of drugs and therapeutic products are optimized while the associated harms are minimized; and

c) describe the regulatory regime relating to Health Canada's oversight of advertising activities relating to drugs. I provide representative examples to demonstrate the challenges and

difficulties which Health Canada and other overseeing bodies encounter when attempting to ensure compliance with the existing provisions which restrict direct-to-consumer advertising of prescription drugs.

A. LEGISLATIVE HISTORY

8. For the purpose of responding to this application, research on the legislative history of the provisions in question was carried out by a historian employed by Health Canada. A legislative history was prepared on the basis of that research. Documents relied upon include documents which are part of the department's corporate records, including archived records. To the best of my knowledge these are accurate records of the department.

1) Introduction

9. The *FDA* prohibits both (1) the sale to the general public of ***any*** food, drug, cosmetic, or device advertised as a treatment, preventative, or cure for certain diseases and conditions listed in Schedule A to the *FDA*; and (2) the advertising of said products to the general public as treatments, preventatives, or cures for Schedule A diseases and conditions.[1] In the case of prescription drugs, the *Regulations* prohibit the making of representations to the general public other than with respect to brand name, proper name, common name, price, and quantity of the drug.[2]

10. The prohibition against the sale of any food, drug, cosmetic, or device advertised as a treatment for Schedule A diseases and conditions has been in effect since 1934, while the prohibition against making representations to

[1]Section 3(1).

[2]Section C.01.044(1).

the general public regarding the efficacy of such products has been in effect since 1953. Attempts to control therapeutic product advertising, however, were part and parcel of the federal government's earliest health protection policies, implementation of which began shortly after Confederation.

2) Historical Background

11. Starting in 1875, the year in which provisions prohibiting the adulteration of food, drugs, and alcoholic beverages were enacted, health protection policy in Canada had four elements, as demonstrated by sections 1, 2, 8 and 14 to 24 of the *Inland Revenue Act of 1875*, S.C. 1874, c. 8 (the "1875 Act"):

a) First, it sought to differentiate between the various food products, drugs, and spiritous liquors then available to the Canadian consumer. Drugs, for example, were defined as "all articles used for curative or medicinal purposes";

b) Second, it endeavoured to establish minimum standards of quality through the licensing of businesses that manufactured or sold the products named in the 1875 Act;

c) Third, it required that food, drugs, or spirits be properly labelled;

d) Fourth, it established an enforcement regime consisting of federal inspectors and analysts invested with the authority to procure and examine food products, drugs, or spirits for purity, and, where impurities were discovered, to refer the offending business to criminal proceedings and possible sanctions.

Attached to this affidavit as "Exhibit 1" is a copy of the 1875 Act.

12. Section 8 of the 1875 Act, which dealt with labelling, required only that manufacturers designate their products by 'some label or brand' containing their names and addresses. No truth-in-advertising provisions accompanied the labelling requirement.

13. However, the requirement soon became more stringent. Section 25 of the *Adulteration Act,* S.C. 1885, c. 67 (the "1885 Act") provided that:

> Every person who knowingly attaches to any article of food, or any drug, any label which falsely describes the article sold or offered or exposed for sale, shall incur a penalty not exceeding one hundred dollars and not less than twenty dollars, with costs.

Attached to this affidavit as "Exhibit 2" is a copy of the 1885 Act.

14. The meaning of this provision was clarified in 1894, when Parliament enacted *An Act in restraint of Fraudulent Sale or Marketing* (the "1894 Act"). Section 1 of the 1894 Act provided that:

> No person shall mark, brand or label any article or any package containing any article mentioned in the first column of schedule A to this Act [which referred to dry white lead ground in pure linseed oil], with the word "pure," "genuine," or any word equivalent thereto, or sell, or offer or expose for sale, any such article or package so marked, branded, stamped or labelled, unless such article or the contents of such package are pure within the meaning of the second column of said schedule.

15. Section 3 of the 1894 Act provided that anyone who violated the labelling provisions was liable to a penalty not exceeding one hundred dollars. When federal statutes were revised and consolidated in 1906, sections 1 and 3 of the 1894 Act were re-enacted as sections 21 and 38, respectively, of the *Adulteration Act*, R.S.C. 1906, c. 107 (the "1906 Act"). Schedule A to the 1894 Act became the Fourth Schedule to the 1906 Act. A supplementary amendment, enacted in 1915 by section 3 of *An Act to amend the Adulteration Act*, S.C. 1915, c. 9 (the "1915 Act"), increased the amount of the fines levied for labelling offences, and, for the first time, added imprisonment to the array of possible sanctions. **Attached to this affidavit as "Exhibit 3", "Exhibit 4" and "Exhibit 5" are copies of the 1894 Act, the 1906 Act and the 1915 Act, respectively.**

16. While a truth-in-advertising requirement was implicit in the labelling provisions of Canada's early health protection statutes, no explicit measures were undertaken in this regard until after the First World War. *The Food and Drugs Act, 1920*, S.C. 1920, c. 27 (the "*1920 Food and Drugs Act*") was the first such statute of the "modern" era. **Attached to this affidavit as "Exhibit 6" is a copy of the *1920 Food and Drugs Act*.**

17. Section 14(1)(b) of the *1920 Food and Drugs Act* conferred on the Governor-in-Council the power to make regulations "requiring a label to be attached to any article of food or drug designed to prevent the public or the purchaser being deceived or misled as to the character, strength, quality or quantity of the article." Section 22 of the *1920 Food and Drugs Act* provided that anyone who attached to the packaging of a food product or drug a label containing "any untrue or misleading name, device or statement", or who neglected or refused to label said product in accordance with the requirements of the Act, was liable to fines, imprisonment, or both. Furthermore, section 5(h) of the *1920 Food and Drugs Act* declared a food product or drug to be misbranded, and therefore in contravention of the Act, "if the package containing it, or the label on the package, bears any statement, design or device regarding the ingredients or the substances contained therein, which statement, design or device is false or misleading in any particular."

18. When federal statutes were revised and consolidated in 1927, sections 14(1)(b), 22 and 5(h) of the *1920 Food and Drugs Act* were re-enacted with minor changes as sections 3(b), 32 and 7(h), respectively, of the *Food and Drugs Act*, R.S.C. 1927, c. 76 (the "*1927 Food and Drugs Act*"). **Attached to this affidavit as "Exhibit 7" is a copy of the *1927 Food and Drugs Act*.**

19. The prohibition against making efficacy claims in patent medicine advertising was an outgrowth of the federal government's attempts to combat the opium trade. Following the 'Anti-Asiatic Riot' in Vancouver's Chinatown in

September 1907, Parliament passed the *Opium Act*, S.C. 1908, c. 50, which placed severe restrictions on the sale, importation, and manufacture of opium in Canada. Those found guilty of violating the *Opium Act* were liable to be punished with penalties ranging from a fifty-dollar fine to three years' imprisonment. **Attached to this affidavit as "Exhibit 8" is a copy of the *Opium Act*.**

20. In central Canada, pressure for curbing the use and distribution of opium came neither from rioters nor from demagoging politicians, but rather from physicians, whose representatives issued dire warnings about the harm that could result if patent medicines containing opium were not more strictly regulated. In 1908, Parliament passed *The Proprietary or Patent Medicine Act*, S.C. 1908, c. 56 [the "PPMA"]. **Attached to this affidavit as "Exhibit 9" is a copy of the PPMA.**

21. Section 7 of the PPMA required that proprietary or patent medicines containing heroin and other drugs listed in the schedule, list their contents on the label. It also limited the amount of alcohol permitted therein to that which was necessary to act as a solvent. Use of cocaine in patent medicines was prohibited entirely. Pursuant to section 12, infractions of the PPMA were punishable by fines of up to one hundred dollars and the loss of registration for the product involved.

22. In 1919, an amendment was made to the PPMA whereby claims that a patent medicine could cure specific diseases were expressly prohibited. The amendment was made pursuant to clause 7(1)(e) of section 1 of *An Act to amend The Proprietary or Patent Medicine Act*, S.C. 1919 (9-10 Geo. V), c. 66 [the "Act amending the PPMA"]. **Attached to this affidavit as "Exhibit 10" is a copy of the Act amending the PPMA.**

3) The Prohibition Against Direct-to-Consumer Sales of Products Advertised as Treatments, 1934

23. Differences in the manner in which efficacy claims were dealt with under the *Food and Drugs Act* and the PPMA hampered federal officials in their efforts to protect the Canadian public from unscrupulous purveyors of questionable "remedies". The problem, as described by the Minister of Health in 1934, was that, when a dealer found he was prevented from selling a medicinal preparation as a remedy under the PPMA, he sought and usually was able to obtain permission to market the same 'remedy' under the *Food and Drugs Act*. **Attached to this affidavit as "Exhibit 11" are pages 2764 to 2770 of *House of Commons Debates* (3 May 1934), which reported the statement by the Hon. Murray MacLaren, Minister of Pensions and National Health. The issue referred to in this paragraph is addressed on page 2764.**

24. Armed only with the *Food and Drugs Act*'s misbranding provisions, officials were limited to three courses of action. First, they could bring charges to enforce the *Act*'s truth-in-advertising provisions. Yet this route was identified as problematic, as there was a concern that courts could, in some instances, be mislead or confused by "clever expert evidence". **Attached to this affidavit as "Exhibit 12" is page 75 of a paper written by A. Linton Davidson, entitled "The Genesis and Growth of Food and Drug Administration in Canada", published by the Department of National Health and Welfare in 1950, which discusses this possible course of action.**

25. Second, officials could try to instill in manufacturers "the value and the virtue of being scrupulously honest about their recommendations to people who as a rule are not and are not expected to be in a position to appraise such statements," while at the same time issuing warnings to Canadians about "unwarrantable claims of merit for medicinal preparations in advertising by circular, brochure, label, carton, [bill]boarding, poster, magazine, newspaper, and

upon the air[waves]." Public education was a long-term process, however. Moreover, foreign manufacturers, whose product labels and advertising had only to abide by the often less stringent requirements of their home countries, usually ignored such educational campaigns. **Attached to this affidavit as "Exhibit 13" are pages 97 and 98 of *Report of the Work of the Department of Pensions and National Health … for the Year Ending March 31, 1938*. Attached to this affidavit as "Exhibit 14" is page 99 of *Report of the Work of the Department of Pensions and National Health … for the Year Ending March 31, 1939*.** Both of these exhibits discuss this possible course of action.

26. Third, federal officials could seek authority to extend the definition of the type of false, exaggerated, or misleading statements referred to in the labelling provisions of the *Food and Drugs Act* to include claims that a medicinal preparation was a treatment or remedy for certain diseases. In fact, such authority was granted in February 1934. **Attached to this affidavit as "Exhibit 15" is a letter dated February 17, 1934, from W. Stuart Edwards, Deputy Minister of Justice, to J.J. Heagerty, Chief Executive Assistant, Department of Pensions and National Health, regarding labelling regulations**. Before regulations to this effect could be enacted, however, the discrepancy between the *Food and Drugs Act* and the PPMA was eliminated.

27. In April 1934, the government introduced a bill, Bill No. 70, to amend the *Food and Drugs Act.* **Attached as "Exhibit 16" is page 2593 of the *House of Commons Debates*, (26 April 1934)**. The bill sought to amend the Act by preventing the sale in Canada of various 'remedies' as treatments for those diseases and/or conditions already listed in the PPMA. **Attached to this affidavit as "Exhibit 17" is a letter dated December 21, 1934, from J.J. Heagerty, Chief Executive Assistant, Department of Pensions and National Health, to H.K. Finlayson, Private Secretary to the Prime Minister, regarding the role of the Department of Pensions and National Health.**

28. As explained by the Minister of Health during the House of Commons debates, the aim of Bill No. 70 was to discourage self-treatment "in the case of diseases where valuable time may be lost and recovery delayed by [resort to] self-administration instead of medical treatment." The minister assured the House that "it is [only] the advertising of remedies for self-administration in the treatment of these [listed] diseases and their sale to the public for that purpose that we are seeking to prevent." The Minister expressed the concern that Canadians often "depend on these advertisements and believe that they are going to obtain benefit from these remedies, when such is not the case." **Attached as "Exhibit 18" is the related page, page 2766 of the *House of Commons Debates* (3 May 1934).**

29. As his office explained in response to a constituent who was concerned about the bill's effect on her continued access to a treatment for epilepsy, "the reason for this amendment is that self treatment has limitations and may in some cases be the cause of delaying the proper medical treatment[,] with serious results." **Attached to this affidavit as "Exhibit 19" and "Exhibit 20" a letter dated June 18, 1934, from M.F. Carndry to the Prime Minister and a letter dated June 22, 1934, from J.J. Saucier, Secretary, to M.F. Carndry, respectively, which detail this exchange.**

30. Bill No. 70 was passed into law as *An Act to amend the Food and Drugs Act*. **Attached to this affidavit as "Exhibit 21" is a copy of *An Act to amend the Food and Drugs Act*, S.C. 1934 (24-25 Geo. V), c. 54.**

31. The amended *Food and Drugs Act* contained a new schedule (Schedule A) that listed thirty-four diseases and conditions, the former including cancer, diabetes, heart disease, and tuberculosis. The schedule was to be subject to periodic review and, when needed, revision. The amended *Food and Drugs Act* also contained a new section, numbered 6A, which stipulated that "no person shall import, offer for sale, or sell any remedy represented by label or by

advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule." By adding this section to the Act, Parliament extended the prohibition against direct-to-consumer advertising beyond patent medicines to the sale (to the general public) of any drug advertised as a remedy for the diseases and/or conditions listed in Schedule A.

32. Underlying the government's statements about the risks of self-medication, which were offered as the primary justification for amending the *Food and Drugs Act* in 1934, was a commentary on the desirability of seeking the advice of a doctor, or some other qualified health professional, prior to obtaining treatment and medication for serious diseases and/or conditions. This was understood and accepted at the time, even by the government's critics. For example, during the debate on Bill No. 70, an opposition member, himself a physician, stated that he could support the proposed section 6A, provided its intent was only "to prohibit other than medical men or qualified persons from importing and offering for sale medicines of a nature not safe ... to take without directions." (page 2766 of *House of Commons Debates* (3 May 1934), Exhibit "18" above)

33. Another opposition member agreed with the government that "remedies for the diseases mentioned in this schedule [what became Schedule A] should be carefully prescribed and taken only on the instructions of a qualified medical practitioner." **Attached to this affidavit as "Exhibit 22" is page 2767 of *House of Commons Debates* (3 May 1934), which records this statement.**

34. It was this belief in the "learned intermediary" principle that in 1927 had informed the insertion of a clause into the *1920 Food and Drugs Act* regarding the distribution of drug samples. This clause, section 21A of the Act (which became section 31 of the *1927 Food and Drugs Act*) provided that "no person shall distribute, cause or permit to be distributed from door to door or in a

public place or on a public highway or through the mail, any sample of any drug, provided that this section shall not prevent manufacturers or wholesale dealers from distributing samples by mail or otherwise in compliance with individual requests for same, or from distributing samples to physicians, veterinary surgeons, dentists, registered nurses, hospitals, or to retail druggists for individual redistribution to adults only." **Attached to this affidavit as "Exhibit 23" is a copy of *An Act to amend the Food and Drugs Act, 1920*, S.C. 1927 (17 Geo. V), c. 56.**

35. In prohibiting the dispensing of drug samples to the general public, this clause recognized that the distribution of drug samples to qualified individuals, and, through them, to the general public, was a legitimate practice. Given a physician's extensive training in pharmacology, no one, arguably, was more competent to assess both the benefits and the possible side effects of a particular drug. **Attached to this affidavit as "Exhibit 24" is page 57 of the *Minutes of Proceedings and Evidence from the Special Committee on Food and Drugs* (2 June 1964), which discusses this concern.**

36. From the arguments offered during the debate on Bill No. 70, it appears that the Opposition's main objection to section 6A had little to do with the restrictions it placed on the sale of "remedies", but rather that it seemed superfluous. As one member put it, "the absurd part of the bill is this long list of disease conditions in connection with which people are not to be allowed to apply to other than medical men for relief." It was his opinion that there was virtually no danger of this. On the contrary, the member believed that "ninety-nine per cent of the people suffering from these diseases will appeal to medical men for relief." **Attached to this affidavit as "Exhibit 25" is pages 4017-4030 of *House of Commons Debates* (15 June 1934). The above passage is recorded at page 4024.**

37. In the debates in the House of Commons over Bill No. 70, the Minister indicated that it was not the government's intention to prevent the manufacture or sale of drugs as remedies for certain diseases and conditions, only to prohibit their sale to the public if advertised as such. Nothing in section 6A, the Minister of Health had assured the House during debate on Bill No. 70, "contemplate[d] the suppression of the manufacture of drugs of all kinds" (page 2769 of *House of Commons Debates* (3 May 1934), "Exhibit 11" above). Nor did section 6A prevent the sale of a legitimate remedy like quinine. Moreover, manufacturers of legitimate remedies would be permitted to continue advertising their products to physicians. The Minister indicated that the government was "trying to do something in the proper way," and that the bill's objective was to "inform the people" (page 4020, *House of Commons Debates* (15 June 1934), Exhibit "25").

38. The limited purpose of section 6A was perhaps best explained by Robert E. Curran, the chief legal adviser to the Department of National Health and Welfare during the 1940s and 1950s. In Curran's opinion, section 6A had been added to the *Food and Drugs Act* "to make unnecessary the proof in each case that a food or a drug is either unsafe or valueless" for the treatment of one of the serious diseases or conditions listed in Schedule A.

39. Schedule A was not meant to deny consumers access to drugs that might relieve the symptoms of certain conditions, such as the common cold, rheumatism, or arthritis, for which there was no known cure or effective treatment. In the case of such conditions, Curran conceded, there were many analgesics and other drugs on the market which, while not cures, did offer some relief to sufferers. It would have been overly restrictive, then, to prevent the sale to the general public of legitimate drugs advertised as providing relief for the symptoms associated with such conditions. Accordingly, only those products advertised as treatments or cures for the diseases and/or conditions listed in Schedule A could not be sold to the general public. **Attached to this affidavit as**

"Exhibit 26" is page 188 from Robert E. Curran, *Canada's Food and Drug Laws* (New York: Commerce Clearing House, c. 1953).

40. Between 1934, when the prohibition against direct-to-consumer sales of products advertised as treatments for serious diseases and conditions was first invoked, and 1946, when the issue was again broached by Parliament, the *Food and Drugs Act* was revised only once. This occurred in April 1939, when several housekeeping amendments were enacted. **Attached to this affidavit as "Exhibit 27" is a copy of *An Act to amend the Food and Drugs Act*, S.C. 1939 (3 Geo. VI), c. 3.**

41. The most significant of these amendments dealt with the manner in which labelling/advertising offences were to be dealt with under the Act. Inserted immediately after section 32, under which violators of its labelling/advertising provisions were liable to fines, imprisonment, or both, was a new section, numbered 32A, which clarified and expanded what constituted such an offence. According to subsection 32A(1), "every person shall be guilty of an offence under this Act who advertises any food or drug in a manner which is misleading or likely to create erroneous impressions regarding its value, composition, merit or safety, either by reason of statements made or device made use of in such advertisement, or because of failure to disclose in such advertisement essential facts concerning the actual properties of such food or drug." In addition, it would no longer be possible for manufacturers to blame false or misleading advertising on printing errors. As elaborated in subsection 2 of section 32A, "responsibility for the advertisement shall rest upon the person who causes the advertisement to be issued and not upon the printer, publisher or other party who issues such advertisement in good faith."

4) Clarifying the Prohibition Against Direct-to-Consumer Sales of Products Advertised as Treatments, 1946

42. In 1946, as part of an act amending the *Food and Drugs Act*, a seemingly minor yet important change was made to section 6A. Previously, this section, inserted into the act in 1934, provided that "no person shall import, offer for sale, or sell any remedy represented by label or by advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule."

43. The new version of section 6A provided that "no person shall import, offer for sale, or sell any food or drug represented by label or by advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule." **Attached to this affidavit as "Exhibit 28" is a copy of *An Act to amend the Food and Drugs Act*, S.C. 1946 (10 Geo. VI), c. 23.**

44. In the wake of the revision of the Act in 1946, new *Food and Drug Regulations* were enacted in 1949. The new format consisted of four parts: administrative, food, drugs, and vitamins. Each part was divided into sections, with each section numbered according to a decimal system. **Attached to this affidavit as "Exhibit 29" is page 95 of A. Linton Davidson, *The Genesis and Growth of Food and Drug Administration in Canada* (Ottawa, 1950), which discusses this point.**

45. These new regulations contained no companion prohibition against direct-to-consumer sales of food products or drugs advertised as treatments for the diseases and/or conditions listed in Schedule A to the *Food and Drugs Act*. However, the department's advertising and labelling division began to compile

interpretations of the act's labelling and advertising provisions. The result of these efforts was a document titled *Guide for Manufacturers and Advertisers* ("the 1951 Guide"). Published in 1951, the guide sought to assist industry in the drafting of product labels and the preparation of advertising materials. A revised edition was published in 1961, while a special edition dealing exclusively with drugs was issued in 1973. **Attached to this affidavit as "Exhibit 30" is a copy of 1951 Guide.**

46. In referring to section 6A, the 1951 Guide described the offering of treatments for the diseases and conditions listed in Schedule A as "a form of misbranding that may be injurious to health" (p. 8). Accordingly, the importation or sale of such a treatment was "prohibited completely". On the other hand, claims that a medicinal preparation could "prevent" Schedule A diseases and conditions were not prohibited. However, industry was advised that the distinction between claims that offered prevention and those that offered treatment (i.e., cure) would be made by departmental officials. Based on experience, the 1951 Guide predicted that "it will be found in many, if not all, cases that prevention may be unattainable in which case a claim to prevent would be likely to be [found] objectionable." (p. 8)

47. The 1951 Guide also made clear that, while the Act did not prohibit the advertising of products as offering temporary relief of some of the symptoms associated with the diseases and conditions listed in Schedule A, such advertising was tightly controlled. After all, "correct diagnosis of disease or of nutritional deficiencies is exceedingly difficult even in the hands of those who have made it their special task and who are assisted by the most modern diagnostic aids and who actually examine the patient." (p. 13) Thus, the 1951 Guide advised that "the recital of vague, general lists of common symptoms to induce the public to diagnose their condition as one which will be alleviated by a particular food or drug offered for sale is basically unsound and is likely to be objected to" (p. 13) by the department.

48. In 1952, the *Food and Drugs Act* was consolidated and re-enacted. **Attached to this affidavit as "Exhibit 31" is a copy of the *Food and Drugs Act*, R.S.C. 1952, c. 123.** In the 1952 consolidated Act, the former section 6A of the Food and Drugs Act was renumbered section 7.

5) The Prohibition Against Direct-to-Consumer Advertising of Therapeutic Products, 1953

49. In 1953, Parliament passed a new *Food and Drugs Act* ("The 1953 *Food and Drugs Act*"), which contained fairly significant changes to the existing labelling and advertising provisions:

a) First, a separate prohibition against direct-to-consumer advertising not tied to the sale of a given product was proposed. The new subsection 3(1) amounted to a blanket prohibition against direct-to-consumer advertising;

b) Second, the existing prohibition against direct-to-consumer sales was strengthened by further restricting the kinds of representations that could be made regarding efficacy. Whereas previously only the advertising of a specific product as 'treatment' was forbidden, the proposed change would also ban the advertising of a specific product as 'preventative' or 'cure';

c) Third, the bill clarified the type of products which could neither be advertised to the general public as treatments, preventatives, or cures for certain diseases and/or conditions nor sold to the general public if so advertised. Whereas previously the Act had referred to remedies and then to food and drugs, the proposed change prohibited the advertisement of 'any food, drug, cosmetic, or device' as a treatment, preventative or cure for one of the Schedule A diseases and/or conditions.

Attached to this affidavit as "Exhibit 32" is a copy of the *Food and Drugs Act*, R.S.C. 1952-53 (1-2 Eliz. II), c. 38.

50. Section 3 of the 1953 *Food and Drugs Act* provided as follows:

> *3(1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.*

> *3(2) No person shall sell any food, drug, cosmetic or device (a) that is represented by label, or (b) that he advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A.*

51. Schedule A listed thirty-six diseases and conditions, almost all of which had appeared in the act's previous incarnations.

52. With regard to the blanket prohibition in subsection 3(1), the rationale provided was that, while section 7 had been "useful and effective", the ban on direct-to-consumer sales "has been subjected to arguments as to whether or not certain practices clearly within its intent ... were within its [current] language." One of the practices considered to have been within the intent of the 1953 *Food and Drugs Act* was the prohibition against the advertising of a food or a drug to the general public as a treatment for any of the Schedule A diseases and conditions. **Attached to this affidavit as "Exhibit 33" is Explanatory Statement of Bill No. 48, An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices, n.d. [1953], p. 16, Banting Library, FDA Act 1953/54, Explanatory Notes, which explains this point.**

53. During the House of Commons Debates over the 1953 *Food and Drugs Act*, the Minister of National Health and Welfare addressed the prohibition against direct-to-consumer advertising of products represented as treatments, preventatives, or cures for Schedule A diseases and conditions. Reminding the House that nothing in the revised section prevented doctors from recommending such products to their patients, the Minister then described the case of a Commons employee whose wife had died of cancer the previous year.

54. The woman, he recalled, had been taking a pill recommended to her by an unidentified "practitioner" who utterly failed in his responsibilities. The pill, which had no therapeutic value, had been advertised as a treatment for

cancer in a publication that eventually came to the attention of the Department of National Health and Welfare. Had the woman gone to a doctor "who might have given her assistance", the minister indicated that perhaps things would have turned out differently. Subsection 3(1), by prohibiting the direct-to-consumer advertising of any product represented as a treatment for a Schedule A disease or condition, whether said product was a legitimate treatment or not, would pre-empt, or at least reduce the frequency of, potentially harmful self-medication within the Canadian public at large. **Attached to this affidavit as "Exhibit 34" are pages 4141-4146 of *House of Commons Debates* (21 April 1953) that record these statements.**

55. The intent of the subsections 3(1) and 3(2) of the *1953 Food and Drugs Act* was explained to industry in a 1961 revision of the Department of National health and Welfare's earlier *Guide for Manufacturers and Advertisers* (the "1961 Guide"). **Attached to this affidavit as "Exhibit 35" is a copy of the 1961 Guide.**

56. The 1961 Guide advised that the prohibition against the advertising of food, drugs, cosmetics, and therapeutic devices as treatments was necessary, because "according to expert opinion", the diseases and conditions listed in Schedule A "cannot be diagnosed by the individual nor can the individual treat himself adequately or safely for these conditions." Yet this did not mean a complete ban on the sale or advertising of certain products to the general public. As had been the case with the previous section 6A of the *Food and Drugs Act*, the new subsections were not intended to deny consumers either access to or information about products that might offer temporary relief of some of the symptoms associated with the diseases and/or conditions with which they were afflicted.

57. For example, one of the conditions listed in Schedule A was "disorders of menstrual flow". According to the 1961 Guide, "the ban placed by

Schedule A on the sale and advertising to the general public of treatment for disorders of the menstrual flow is directed against amenorrhea and retarded menstruation" (p.23). This ban did not apply 'to analgesics to assuage pain that sometimes occurs at menstruation, or to appropriate medication for the menopause, leukorrhea, and dysmenorrhea.

58. The 1961 Guide also indicated a number of symptomatic exceptions including the alleviation of pain associated with rheumatism, arthritis, neuritis, lumbago, and related conditions. Linked to Schedule A by virtue of being a potential indicator of scheduled diseases and/or conditions such as Bright's Disease or kidney stones, the department asserted that "the successful treatment of these conditions depends on early professional diagnosis ... [and] competent and continued treatment under medical advice and supervision," (p. 24) and thus interpreted the Act to mean that "no preparation may be advertised as a treatment for these conditions or as capable of restoring normal or complete function of joints and muscles, or to reduce swelling and inflammation, or to correct or prevent deformities, or to restore movement to stiff or crippled joints or muscles" (p. 24). On the other hand, "recognized analgesics", when taken in proper dosage, "may be offered as a help in relieving or temporarily alleviating rheumatic, arthritic or neuritic pains." (p. 24). Similarly, the department acknowledged that "local applications of rubefacients or counter-irritants, especially when applied with massage, may also help to relieve pain at the site of application" (p. 24). To ensure compliance with the Act, advertisements were to make it clear that such products were for "relief of pain only", with the word "pain" to be given "adequate prominence" in any advertising copy employing expressions like "pain of rheumatism, arthritis or neuritis" (p. 24).

59. Still other symptomatic exceptions involved diseases of the liver, kidneys, and bladder. In the case of liver disease, linked directly to Schedule A by virtue of the listing of alcoholism and indirectly because the bile flow problems associated with liver disease could be confused with Schedule A diseases and

conditions such as appendicitis or gallstones, products were not to be represented “as relieving diseases of the liver”. On the other hand, reference could be made to their “temporary relief of discomforts due to constipation associated with insufficient bile” (pp. 26-7). In the case of diseases of either the kidneys or the bladder, linked to Schedule A by virtue of the listing of Bright’s Disease, kidney stones, and bladder stones respectively, products could be advertised as “helping to increase the flow of urine [i.e., their diuretic effect] thus relieving irritations of the bladder and urinary tract and resultant back ache or discomfort” (pp. 26-7).

60. According to the 1961 Guide, manufacturers were prohibited from advertising products as treatments, preventatives, or cures for either coughs or colds. In the case of the former, the rationale was that coughing could be symptomatic of some of the diseases and conditions listed in Schedule A, the most obvious being cancer, pneumonia, pleurisy, and tuberculosis. The connection to Schedule A was more tenuous in the case of the common cold, notwithstanding the listing of influenza as a scheduled disease, but the department seems to have been intent on preventing claims to the effect that a product could “stop, abort, prevent, or lessen the frequency” of colds (p. 25). Relief of symptoms was another matter, however. Cough syrups or cough drops could be advertised as “palliative” for coughs due to colds, for example. Similarly, cold remedies could be represented as offering relief for some of the symptoms associated with the common cold.

61. One of the more interesting passages in the departmental guide involved obesity. Listed in Schedule A, obesity was recognized both as a disease and as a “symptom”. When it occurred as a result of glandular malfunction, it was considered to be a disease. As such, no food, drug, cosmetic, or device could be imported, advertised, or sold to the general public as a treatment, preventative, or cure for it. On the other hand, when obesity was caused by overeating, a condition recognized by the department, manufacturers of weight-

reducing plans and products were given some latitude in making representations to the public, provided that any claims offered in support of such plans or products, such as their efficacy in controlling hunger, “be substantiated by adequate data” (p. 6).

62. The Department of National Health and Welfare also produced departmental publications regarding the *Food and Drugs Act* aimed at educating the general public. For example, in 1966, the Department issued a consumer memo entitled “That Prescription of Yours Isn’t Just a Piece of Paper” (“1966 Consumer Memo”), which contained admonitions about the potential hazards posed by the unsupervised use of prescription drugs. In this document, consumers were provided with a fairly lengthy and detailed explanation of both the system whereby prescription drugs were dispensed and the rationale for it. **Attached to this affidavit as “Exhibit 36” is a copy of the 1966 Consumer Memo.**

63. The 1966 Consumer Memo acknowledged and reinforced the central role played by the physician in the prescription drug dispensing system. “Before writing your prescription,” the document indicated that a patient’s “doctor uses his scientific knowledge and skill to choose the right medicine for you, and, to do this, he has to examine you as an individual” (pp. 1-2). Moreover, the 1966 Consumer memo indicated that in choosing the proper drug, a patient’s doctor “considers such factors as your physical condition, your state of health, your individual allergies, and the possible unusual responses you may have to certain drugs, as well as the best drug suited for the treatment of your illness” (pp. 1-2). Once a drug has been decided upon, “the doctor includes on the prescription order the instructions which must appear on the label of the drug which the pharmacist will dispense, and the pharmacist maintains a complete record of the prescription” (pp. 1-2).

64. The 1966 Consumer Memo indicated that the reason for this system was that prescription drugs were "likely" to be misused or abused. Moreover, the dangers associated with the misuse or abuse of potent pharmaceuticals were beyond the competence of most consumers. Only a physician, for example, would be in a position to know that a particular drug was one on which animal or clinical experiments had indicated serious side effects, or that it had been designed for the treatment of a specific disease, or that the potential injury from its misuse was insidious and therefore not apparent until (too) far advanced, or, finally, that its unsupervised use might lead to addiction. That was why dispensing such a drug without a prescription or refilling an existing prescription without a doctor's authorization was not permitted. The 1966 Consumer Memo explained that this was also why the advertising of these drugs to the general public was prohibited (pp. 2-3).

6) The First Regulations Prohibiting the Direct-to-Consumer Advertising of Drugs, 1953

65. The first series of amendments to the *Food and Drug Regulations* made under the amended *Food and Drugs Act* appeared shortly after the act had received royal assent (the "1953 Amendments"). **Attached to this affidavit as "Exhibit 37" is a copy of *Food and Drugs Act – amendments, Food and Drug Regulations,* S.O.R./53-212, P.C. 1953-817, C. Gaz. 1953.II.504.**

66. The 1953 Amendments included the addition of a short paragraph to that part of the *Regulations* (Part C) that dealt with drugs. Numbered section C.01.044, the paragraph read as follows: "No person shall advertise to the general public a drug named or included in Appendix IV." Appendix IV comprised a list of nine drugs and their derivatives, all of which could only be obtained on prescription. Though drafted independently of the act, section C.01.044 was the regulatory companion to the prohibition against the advertising to the general public of various products, including drugs, as treatments,

preventatives, or cures for any of the diseases, disorders, or abnormal physical states listed in Schedule A to the act.

67. With the coming into force of the revamped *Food and Drugs Act* in 1954, Appendix IV was moved from the *Food and Drug Regulations* to Schedule F of the Act, said schedule having been inserted into the act to assist in controlling the distribution of drug samples. In its new formulation, Appendix IV became Part I of Schedule F. Concurrently, the wording of section C.01.044 was amended to reflect the change. As of December 8, 1954, the section stipulated that "no person shall advertise to the general public for human use a Schedule F drug". In July 1963, in conjunction with the tightening of the provisions governing the distribution of drug samples to health professionals (see below), Schedule F was returned to the *Food and Drug Regulations*. **Attached to this affidavit as "Exhibit 38", "Exhibit 39" and "Exhibit 40" are copies of the following documents, which explain and make these amendments: *Minutes of the 91st Meeting of the Committee on Policy and Scope* (14 October 1953); *Food and Drugs – Food and Drug Regulations,* S.O.R./54-664, P.C. 1954-1915, C.Gaz.1954.II.2680; and *Food and Drugs Act* – Food and Drug Regulations, amended, and Schedule F to the Act, Amended, S.O.R./63-269, P.C. 1963-1119, C.Gaz.1963.II.752.**

7) Tightening Controls on the Distribution of Drug Samples to Health Professionals, 1962-63

68. Following the enactment of the revised act and regulations in 1953, no changes were made to the advertising provisions contained therein for the next fifteen years. Still, the issue did not disappear entirely. In the wake of the events related to the use of thalidomide, where a number of women who took the drug in the late 1950s and early 1960s subsequently gave birth to severely deformed babies, several amendments to the *Food and Drugs Act* were proposed.

69. One of these involved the imposition of tighter controls on the distribution of drug samples to doctors. As explained by the Minister of National Health and Welfare, the purpose of the amendments was "to permit of regulations being made which will specifically govern the circumstances under which drugs may be distributed by way of sample and, in particular, with respect to the present practice of the furnishing of unsolicited samples of drugs to professional groups." **Attached to this affidavit as "Exhibit 41" is a copy of a Memorandum to Cabinet by J. Waldo Monteith, dated September 5, 1962, explaining the purpose of these amendments.**

70. Subsection 14(2) of the *Food and Drugs Act*, which exempted physicians, dentists, veterinary surgeons, and pharmacists from the prohibition against drug sample distribution was amended by *An Act to amend the Food and Drugs Act* in 1962. This act added the phrase "under prescribed conditions" to the statutory exemption. **Attached to this affidavit as "Exhibit 42" is *An Act to amend the Food and Drugs Act*, S.C. 1962 (11 Eliz. II), c. 15.**

71. In accordance with this statutory change, consequential amendments to the regulations were promulgated in the summer of 1963. **Attached to this affidavit as "Exhibit 43" is a copy of a Trade Information Letter from the Director, Food and Drugs Directorate, dated September 27, 1963, explaining and attaching the changes to the regulations.**

72. These regulatory amendments included a requirement that the distribution of Schedule F drugs as samples be preceded by receipt of a written order from a certified member of one of the professions listed in the act, the imposition of stringent record-keeping requirements on both distributors and recipients of samples, and a prohibition against the distribution of samples to the general public by pharmacists.

8) Removing the Prohibition Against Direct-to-Consumer Advertising of Certain Contraceptives, 1969-70

73. While the *FDA* has been subjected to several substantive revisions since 1953, section 3 was amended only once during that time, in June 1969 ("the 1969 Amendment"). The 1969 Amendment related to the advertisement of contraceptive devices and drugs.

74. In 1966, the Standing Committee on Health and Welfare recommended that the *Criminal Code* prohibition against the sale and advertisement of contraceptives be repealed and that the *Food and Drugs Act* be amended to allow for the advertising of contraceptives to the general public under certain conditions. According to the Minister of National Health and Welfare, a ban on contraceptive advertising was undesirable because it would impede the work of *bona fide* family planning offices and other responsible agencies. He suggested that a better approach was to amend the *Food and Drugs Act* so as to prohibit the advertising of contraceptives to the general public except as authorized by regulation. Regulations could then be enacted that would protect the public while at the same time not interfering with the dissemination of birth control information by legitimate family planning organizations. **Attached to this affidavit as "Exhibit 44" is a copy of a Memorandum to Cabinet from Allan J. MacEachen, Minister of National Health and Welfare, dated January 1967, regarding proposed changes to contraceptive advertising in the *Food and Drugs Act*.**

75. The Minister's recommendation was carried out by the enactment of amendments to the *Food and Drugs Act*, the *Narcotic Control Act,* and the *Criminal Code.* **Attached to this affidavit as "Exhibit 45" is a copy of *An Act to amend the Food and Drugs Act, the Narcotic Control Act and to make a consequential amendment to the Criminal Code,* S.C. 1969 (17-18 Eliz. II), c. 41.**

76. This legislation amended subsection 3(3) of the *Food and Drugs Act* to provide that "except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception."

77. Companion regulations permitting the advertising of contraceptive drugs and devices to the general public under certain conditions were issued about six months later. **Attached to this affidavit as "Exhibit 46" is a copy of *Amendments to the Food and Drug Regulations,* O.I.C. P.C. 1970-37 (*Food and Drugs Act*).**

9) Removing the Prohibition Against Direct-to-Consumer Advertising of Prescription Drug Prices, 1975

78. Concurrent with the enactment of subsection 3(3) of the *Food and Drugs Act*, a second, more far-reaching exception to the prohibition against direct-to-consumer advertising was conceived. The Minister of Consumer and Corporate Affairs was looking for ways to effect a reduction of prescription drug prices in Canada. Based on the recommendations of three high-profile inquiries that had been convened during the 1960s to investigate the high cost of drugs. These were, respectively, the Restrictive Trade Practices Commission (also known as the Hilliard Commission), the Royal Commission on Health Services (also known as the Hall Commission), and the Special Committee of the House of Commons on Drug Costs and Prices (also known as the Harley Committee). The proposed regulatory revision would have afforded Canadian consumers the possibility of comparative price 'shopping' by lifting the prohibition against direct-to-consumer advertising of prescription drugs inasmuch as their price was concerned. **Attached to this affidavit as "Exhibit 47" is a copy of a Memorandum from A.B. Morrison, Deputy Director-General, dated July 21, 1970, discussing this proposal.**

79. According to the drug cost inquiries of the 1960s, the problem of high prescription drug prices in Canada was attributable to the absence of competition in the pharmaceutical industry. This, in turn, was seen as resulting from the virtual monopoly exercised by foreign multinationals (the majority of which were headquartered in the US) over the manufacturing, pricing, distribution, and marketing of prescription drugs in Canada. In fact, as of the mid-1960s, in excess of ninety-five per cent of the patents on drugs sold in Canada were held by multinationals. **Attached to this affidavit as "Exhibit 48" and "Exhibit 49" are documents which discuss this issue: a copy of a Memorandum from R.W. Hyndman to D.H.W. Henry, dated c. September 28, 1967 and page 1516 from *House of Commons Debates* (17 October 1968).**

80. Moreover, owing to certain provisions contained in the Canadian patent legislation of the period, it was exceedingly difficult for domestically-owned generic drug firms to obtain licences to manufacture and sell a patented drug. Even Canadian subsidiaries of the multinationals were restricted in this regard, since the nature of the subsidiary system meant that no parent company would allow one of its branches to independently develop, manufacture, and market a drug in direct competition with it. **Attached to this affidavit as "Exhibit 50" is a copy of a Memorandum from R.M. Davidson to D.H.W. Henry, dated January 25, 1965, which discusses this issue.**

81. Evidence given at each of the drug price inquiries revealed the various ways in which multinational drug companies used their virtual monopoly to suppress competition and deny domestic firms even a modest foothold in the Canadian market. One of these methods involved advertising. As the head of the Canadian Medical Association (CMA) lamented in his testimony before the House of Commons Special Committee on Food and Drugs in 1964,

> *pharmaceutical manufacturers have several avenues open to them in promoting their products after they have been approved for sale in Canada. Advertising in medical journals has been mentioned. Direct mail of letters, brochures,*

> *reprints, etc is commonly practised. Medical and scientific exhibits at conventions and meetings of the medical profession are another effective means of disseminating product information and this is closely akin to the work of representatives commonly known as "detail men" in calling on doctors and pharmacists to present the products of their firms. The indiscriminate distribution of drug samples has recently been brought under control in this country and the current situation appears to be satisfactory [a reference to the 1962-63 amendments to the Act and Regulations described above]. The whole matter of promotional activity has been criticized as unnecessarily expensive, contributing substantially to the cost of drugs... We [the CMA] have made representations to the CPMA with a view to moderating the flood of direct mail and the apparent wasteful distribution of unsolicited samples which formerly pertained.*

Attached to this affidavit as "Exhibit 51" is page 60 from the *Minutes of Proceedings and Evidence from the Special Committee on Food and Drugs,* (2 June 1964), which records this statement.

82. Witness evidence like the foregoing made a strong impression on committee members. As the parliamentarians noted in their final report,

> *the doctor's time is limited. While some of the material issued by drug companies is very useful, a great portion of the doctor's mail is never studied and the large volume of product advertisement is wasted as a shower of multi-coloured advertisements hits the wastepaper basket, unread. The "ads" in journals are often not read as the physician prefers more impartial reports in the body of the issue itself. The doctor sees the detail man, with one eye on his demonstrations and the other on his watch. As most detail men represent the large manufacturing firms he never hears actual presentations from the smaller firms. The doctor is concerned with the growing reports of diseases caused by drugs he can prescribe and by the multiplicity of side effects they can produce. He prescribes those drugs he has heard of, has read of, and has some knowledge of - he is a cautious man and prescribes the drug manufactured by a company known to him. He may or may not know what the drug costs and he may or may not realize there are cheaper "equivalents" on the market.*

Attached to this affidavit as "Exhibit 52" is an excerpted copy of the *Second (Final) Report of the Special Committee on Drug Costs and Prices* (1966-1967), which records this statement.

83. Bill C-190, introduced in December 1967, sought to extend the authority of the Commissioner of Patents to grant compulsory licences to third parties for the purposes of (1) importing a patented invention, (2) using a patented medicine to produce a generic one, and (3) selling the patented medicine in bulk dosage form. In other words, the government was seeking to allow a generic drug company to obtain, on payment of a royalty, a licence which would allow it to import a patented medicine for the purpose of copying, manufacturing, and selling it, both in Canada and abroad. **Attached to this affidavit as "Exhibit 53" is page 6627 of *House of Commons Debates* (12 February 1968), which explains the purpose of the bill.**

84. Parliament adjourned before Bill C-190 was passed, but in the following session, Parliament introduced Bill C-102, an *Act to amend the Patent Act, the Trade Marks Act, and the Food and Drugs Act*. Similar to Bill C-190, especially in the manner in which it proposed to deal with the issue of drug patents, C-102 sought to allow compulsory licensing to applicant firms wishing to import patented drugs for the purpose of copying, manufacturing, and selling them in Canada and abroad. Bill C-102 was passed in Parliament and received royal assent in June 1969. **Attached to this affidavit as "Exhibit 54" is a copy of *An Act to amend the Patent Act, the Trade Marks Act and the Food and Drugs Act*, S.C. 1968-1969 (17-18 Eliz. II), c. 49.**

85. While compulsory licensing might have made it easier for generic drug companies to produce lower cost copies of patented drugs, thereby engendering competition and, ultimately, an overall lowering of drug prices, it was not clear how generic drug companies would be able to make inroads into

the market share of the pharmaceutical giants without first generating public awareness as to the existence of their lower cost products. As one opponent of the proposed changes to Canadian patent legislation observed during the Senate's debate on Bill C-102, even if the proprietor of a small enterprise succeeded in clearing the various economic, legal, and regulatory hurdles attendant with the sale of drugs in Canada, he would still have to persuade medical practitioners to prescribe his product. Echoing testimony given before the House of Commons Special Committee on Food and Drugs, the senator, a physician, put himself in the place of his colleagues in private practice. As far as a new generic drug was concerned, he opined that

> *most doctors would not know the name under which the importer must sell it. They probably would not know the name or reputation of the importer or manufacturer. They would[, on the other hand,] know the trade marked name of the original preparation and the reputation of its manufacturer. They have seen medical reports on the advantages and limitations of the trade-named drug, and these have been confirmed at staff meetings - which are held in our hospital each week - by the experiences of their colleagues. Why should they take a chance with an unknown product of an unknown company? Am I going to take a chance on an unknown product with one of you senators? No sir, I am not!*

Attached to this affidavit as "Exhibit 55" are pages 1336-1345 of the *Senate Debates* (24 April 1969). The above statement is recorded on page 1341.

86. The proposal of the Minister of Consumer and Corporate Affairs to lift the prohibition against direct-to-consumer price advertising of prescription drugs initially met with opposition from the Department of National Health and Welfare and stakeholder groups representing physicians, the pharmaceutical industry, and pharmacists. These groups were unanimous in their rejection of the proposal. **Attached to this affidavit as "Exhibit 56" is a copy of a Memorandum from A.B. Morrison to J.M. LeClair, dated February 1, 1973, setting out this opposition.**

87. As noted in the Memorandum, the various provincial colleges of pharmacy voiced resistance to the proposed changes at a joint meeting of the Registrars of Physicians and Pharmacists held in Ottawa in May 1970. In a resolution adopted unanimously, the registrars went on record “as being opposed to any relaxation of the regulations concerning the advertising of drugs to the general public”, asserting that “any benefit which could be derived at lower unit cost would be far outweighed by the undesirable increase in demand and abuse of these potent drugs.”

88. Although the Department of National Health and Welfare was against the direct-to-consumer price advertising of prescription drugs, the Department was receptive to the regulated dissemination of drug price information. In May 1971, it established the Quality Assurance [subsequently changed to Assessment] Drugs Program (QUAD) in May 1971. Conceived in response to a key recommendation of the House of Commons Special Committee on Food and Drugs - namely, that, in order to effect a reduction in the price of drugs, it had to be demonstrated that drugs of comparable quality to, but lower price than, the brand-name products were readily available in Canada - the QUAD program was launched with the express purpose of enabling both members of the health professions and bulk purchasers like provincial governments to decide “on the basis of scientific and technical facts” the drugs that could be safely dispensed at reduced cost.

89. The scientific and technical facts were to be derived following completion of four types of comparative investigation of various brands of the same drug - chemical analysis, evaluation of manufacturing capabilities, measurement of clinical effectiveness, and publication of the data. The data gleaned from QUAD testing, it was hoped, would provide health professionals and bulk purchasers with the information they needed to select brands of high quality, low cost drugs. **Attached to this affidavit as “Exhibit 57” is a copy of**

excerpts from the Department of National Health and Welfare's Annual Report, 1973, explaining the QUAD program.

90. While the proposal to allow direct-to-consumer drug price advertising was shelved in September 1970, the government decided in 1975 to permit prescription drug price advertising. This amendment was made pursuant to *Food and Drug Regulations, amendment,* S.O.R./75-274, P.C. 1975-1026, C.Gaz.1975.II.1239. **Attached to this affidavit as "Exhibit 58" is a copy of *Food and Drug Regulations, amendment,* S.O.R./75-274, P.C. 1975-1026, C.Gaz.1975.II.1239**. Among the amendments was an amendment to section C.01.044 of the *Food and Drug Regulations,* that provided that "no person shall advertise to the general public a Schedule F drug except in respect of the name, price and quantity of the drug."

91. In 1978, a further amendment was made that removed the prohibition against direct-to-consumer advertising of prescription veterinary drugs. **Attached to this affidavit as "Exhibit 59" is a copy of *Food and Drug Regulations, amendment,* S.O.R./78-424, P.C. 1979-1517, C.Gaz.1978.II.2212.**

10) Departmental Interpretations of the Direct-to-Consumer Advertising Provisions of the Food and Drugs Act and the Food and Drug Regulations, Post-1975

92. Since 1975, the Department of National Health and Welfare - renamed the Department of Health in 1993 - has occasionally updated its guides on drug advertising. One such update was published in 1984. **Attached as "Exhibit 60" is a copy of the *Guide to Consumer Drug Advertising, 1984* ("the 1984 Guide").**

93. The 1984 Guide was the first guide issued following the enactment of the name, price, and quantity exception in May 1975, and was "intended for use by all those who advertise drugs for human use to the general public." The

1984 Guide provided a complete list of the legislative and regulatory authorities governing the advertising of drugs in Canada. However, in recognition of the fact that the provisions were often of a general nature, the document also provided "guidance to drug advertisers regarding the implications, applicability and interpretation of specific regulations".

94. For example, the diseases, disorders, and abnormal physical states comprising Schedule A of the *FDA* were described as those "for which there is no cure or preventative or which, by their nature[,] require the intervention of a practitioner for treatment." Accordingly, manufacturers were reminded at page 2 of the 1984 Guide that no drug was permitted to be advertised to the general public as a treatment, preventative, or cure for Schedule A diseases and conditions.

95. Schedule F of the *Regulations*, on the other hand, comprised a list of drugs "which may be sold for human use only on a prescription given by a practitioner." Since the intervention of a medical practitioner was required in order to supply these drugs to the general public, the advertising thereof, manufacturers were advised, was restricted by section C.01.044 of the *Regulations* to name, price, and quantity.

96. As elaborated by the 1984 Guide, the provision of name, price, and quantity information to the general public was permitted in order to "facilitate comparative shopping by the consumer." Yet even this type of advertising was tightly controlled. In cases where product lines consisted of a drug to which advertising restrictions did not apply and another drug to which they were applicable, the 1984 Guide indicated that "no mention or depiction of the latter ... [was] permitted in a promotional advertisement for the former." (p. 4)

97. In keeping with the practice adopted in earlier versions of the guide, the 1984 Guide noted several examples of 'symptomatic' exceptions to the

prohibition against direct-to-consumer advertising. For example, at pages 5-6, the 1984 Guide noted that while any advertisement to the general public for a drug as a treatment, preventative, or cure for the Schedule A condition referred to as “anxiety state” was prohibited by subsection 3(1) of the *Food and Drugs Act*, what was described as “an acceptable drug” was permitted to be promoted for the treatment of edgy nerves, nervous headaches, nervousness, edginess, jitteriness, insomnia or sleeplessness, provided that any advertisement was qualified by phrasing that made it clear that such conditions were “due to overwork, tiredness or fatigue”.

98. In the case of arthritis, a longstanding Schedule A disease, the 1984 Guide noted at page 6 that drugs described as “suitably medicated products” were permitted to be represented to the public as “aids in alleviating the pain of arthritis” or as being for “the relief of arthritic pain”.

99. In the case of “disorders of menstrual flow”, the 1984 Guide indicated at page 6 that “suitable” products could be advertised as being “helpful to relieve the pain associated with menstruation, premenstrual tension, symptoms associated with menopause, and premenstrual syndromes.”

100. Finally, the 1984 Guide noted at pages 6 and 7 that the promotion of drugs to assist in the treatment of obesity was considered by the Department to be “acceptable” under certain conditions. These included where (1) the drug be marketed in conjunction with a reducing plan, program, or diet which promoted a reduced intake of dietary calories along with a possible increase in physical activity; (2) it had to be clearly indicated to the consumer that it was the modification of dietary intake or physical activity which was the instrument whereby weight would be lost; and (3) the purpose of the drug in the weight loss plan had to be clearly identified as an aid to curb hunger and to improve compliance with the program.

B. REGULATION OF PRESCRIPTION DRUGS IN CANADA

1) Overview

101. Drugs are made available to Canadians through a complex system of federal and provincial authorities. These authorities generally align to optimize the benefits of drugs and minimize associated harms.

102. As part of this system, drugs are subject to federal requirements for development, market authorization and surveillance to provide Canadians with drugs that are of high quality and that meet the safety and effectiveness requirements set out in the *Regulations*.

103. At the provincial level, further requirements include the regulation of professionals who are qualified and licensed to prescribe and dispense drugs.

104. Taken together, the federal and provincial systems manage considerable amounts of information about drug benefits and risks. Currently, there are approximately 22,000 drug products permitted to be marketed in Canada. Of those, roughly 7,000 have been designated as prescription drugs. It is within this complex structure of drug regulation that restrictions upon advertising assist in accomplishing the overall goal of optimizing the benefits and minimizing the risks of drugs.

2) Pre-market Drug Review Activities

105. As provided under the *FDA* and *Regulations*, any person who wishes to sell a drug in Canada must first obtain from the federal government, through Health Canada, authorization to market the drug in Canada.

106. In order to obtain authorization for the marketing of a drug in Canada, there must be substantial evidence of both the safety and efficacy of the drug under its recommended conditions of use, as well as the quality of the drug. Safety and efficacy are assessed in both animal and human studies for new drugs. The recommended conditions of use include the indication (reason for treatment), contraindications to treatment (for example a pre-existing medical condition that would make drug use unsafe or the use of concomitant drugs), dosage, and frequency of treatment. The quality of a drug is assessed by a review of the chemistry and manufacturing processes used in its production, and the tests conducted to determine that potency, purity and stability remain consistent during its shelf life, as submitted by the manufacturer of the drug.

107. The evidence required in the regulatory review process is obtained by scientific methods in order to obtain objective information with the least amount of bias. This information is gathered by the drug industry through a well-defined development process.

108. Drug development, from first identification to marketed product, may take years or decades to complete. Active pharmaceutical ingredients that pass an extensive initial screening process are subjected to laboratory and animal studies that characterize their basic pharmacologic properties, and assess their toxicities and potential clinical benefits. These investigations are generally carried out in accordance with internationally recognized methods.

109. Information gained from animal studies is used to decide whether or not to proceed with clinical trials in humans.

110. Clinical trials are conducted in humans to address the uncertainties regarding the harms or benefits of drugs in humans. Because there are inherent risks in the assessment of investigational drugs, international practices have been established to protect research subjects and to ensure that clinical trials are

designed, conducted and analyzed according to sound scientific principles and a systematic drug development strategy. **Attached to this affidavit as "Exhibit 61" and "Exhibit 62" are "ICH Harmonized Tripartite Guideline: Guideline for Good Clinical Practice" and "ICH Harmonized Tripartite Guideline: General Considerations for Clinical Trials", which summarize these international practices.**

111. Traditionally, there are three pre-marketing phases of the drug evaluation at the clinical trial stage. A fourth phase relates primarily to post-marketing changes. These phases are found in the Regulatory Impact Analysis Statement (RIAS) in Division 5, Canada Gazette Part II, Vol. 135, No. 13 SOR/DORS/ 2001-203. **Attached to this affidavit as "Exhibit 63" is a copy of the RIAS.**

a) Phase I - Initial safety studies on a new drug, including the first administration of the drug into humans, are usually conducted in healthy volunteers. Phase I trials are designed mainly to determine the pharmacological actions of the drug and the side effects associated with increasing doses. These initial studies help determine dose and whether or not there are toxic concerns. Pharmacokinetic as well as drug-drug interaction studies are usually considered as Phase I trials, regardless of when they are conducted during drug development, as these are generally conducted in healthy volunteers;

b) Phase II - These "proof-of-concept" clinical trials are conducted by the manufacturer to evaluate the efficacy of the drug in small numbers of patients having the medical condition to be treated, diagnosed or prevented and to determine the side effects and risks associated with the drug. If a new indication for a marketed drug is to be investigated, then those clinical trials may start as Phase II trials;

c) Phase III- Large trials with hundreds of participants having varying characteristics and medical problems and who have the targeted disease or symptoms, are conducted after preliminary evidence suggesting efficacy of the drug has been demonstrated. These are intended to gather the additional information about efficacy and safety that is needed for further risk-benefit assessment of the drug in a wider target population. In this phase, clinical trials are also

conducted in special patient populations (e.g. renal failure patients), or under special conditions dictated by the nature of the drug and disease. Phase I, II and III trials are not capable of identifying very rare side effects due to the limited size of those studies. A very rare side effect, according to the definition of the Council for International Organizations of Medical Sciences in conjunction with the World Health Organization (WHO), is one that occurs less than 1 incidence in 10,000; and

d) Phase IV - All studies performed after the regulator has authorized the drug for the market, and related to the authorized indication, are known as Phase IV in the regulatory process. These studies are often important for optimizing the drug's use. They may be of any type but must have valid scientific objectives. Commonly conducted studies include safety studies and studies designed to support use under the authorized indication. Examples include mortality and morbidity studies or epidemiological studies. These trials are not necessary to obtain initial marketing authorization from Health Canada, nor are authorizations to conduct the studies required under Division 5 of the *Regulations* (see C.05.006(2)). These trials are frequently carried out by the drug manufacturer and also by independent researchers.

112. In order to conduct a Phase I, II or III clinical trial in Canada on a drug not authorized for sale in Canada, a drug manufacturer must seek permission by filing a clinical trial application with the Therapeutic Products Directorate or the Biologic and Genetic Therapies Directorate.

113. The reviews of clinical trials by Health Canada are performed in accordance with Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, of the *Regulations*. Authorization of a clinical trial application will *not* be granted if the proposed trial endangers the health of a trial subject, if it is contrary to the best interests of the subject, or if it will not achieve the research objectives. Authorization is contingent on a research ethics' board approval of the protocol. **Attached to this affidavit as "Exhibit 64" is a copy of Health Canada's guidance for clinical trial sponsors titled "Clinical Trial Applications".**

114. As stated above, following completion of all necessary animal and clinical trials, a drug sponsor must obtain authorization from Health Canada prior to marketing a drug in Canada. The federal drug review process is provided for in Part C of the *Regulations*, and is administered by the Therapeutic Products Directorate and the Biologic and Genetic Therapies Directorate within the Health Products and Food Branch of Health Canada. Regulatory authorization for the marketing of new drugs is issued in the form of a Notice of Compliance ("NOC") and Drug Identification Number ("DIN").

115. Some drugs are subject to the requirements for the issuance of a DIN alone. They are drugs that are not defined as "new drugs". Some of these may require prescriptions, such as warfarin, a blood thinner; and phenobarbital, a treatment for epilepsy.

116. To obtain a NOC and a DIN, a drug manufacturer is required to file a drug submission with the Health Products and Food Branch. Drug submissions for new drugs are typically made in the form of a new drug submission ("NDS").

117. Subsection C.08.002(2) of the *Regulations* provides for the content requirements of a new drug submission. This includes a description of the drug, identification of the manufacturer, and all relevant data relating to the chemistry, manufacturing and specifications of the drug. In addition, information must be provided regarding the drug manufacturing plant and production machinery so as to ensure consistent quality of the drug once it is marketed. Finally, the submission must include all the animal and human trial data to establish the safety and effectiveness of a drug under the desired conditions of use as required by the *FDA* and *Regulations*. Fulfilment of these requirements usually entails the submission of 100-300 volumes of data.

118. The assessment of a new drug submission is informed by detailed guidance documents and policies, which are publicly available. **Attached to this**

affidavit as “Exhibit 65” and “Exhibit “66” respectively are lists of the published "Guidance Documents" and "Policies", as they appear on the Therapeutic Products Directorate website.

119. Each drug submission is reviewed by trained professional staff to determine whether the nature and extent of the research data compiled by the drug manufacturer meet regulatory requirements. In addition to staff holding the basic qualifications of an M.D. or a Ph.D., the Branch employs specialists in toxicology, pharmacology, biochemistry and chemistry, as well as the various medical specialties.

120. If a drug meets the requirements of the *FDA* and *Regulations* and is authorized for sale, a NOC and a DIN are issued. **Attached to this affidavit as “Exhibit 67” is an example of a NOC**. The issuance of the NOC is accompanied by the final authorized version of the product label, including the product monograph. Health Canada reviews and comments on the content of product labels and monographs prior to the issuance of the NOC. This is to ensure that important conditions of use for the drug, such as dosage, warnings and contraindications are accurately described such that the benefits of the drug are optimized and unbiased information is provided to both prescribers and patients.

121. The product monograph is a factual, scientific document describing the drug product and is devoid of promotional material. It is composed of three parts, as outlined in Health Canada’s “Guidance for Industry, Product Monograph”:

a) health professional information, which contains information required for the safe and appropriate prescribing, dispensing and administering of the medication;

b) scientific information, which contains more in-depth and complete scientific/research information such as toxicology and data from animal studies and human clinical trials; and

c) consumer information.

Attached to this affidavit as "Exhibit 68" is a copy of "Guidance for Industry, Product Monograph".

122. **Attached to this affidavit as "Exhibit 69" is a copy of an example of a product monograph.**

123. In particular, "Part III: Consumer Information" ("Exhibit 69"), is a lay-language translation of the scientific information contained in the other parts of the product monograph. It helps the consumer understand what the drug is, how to use it and what the potential side effects are. It is also intended to serve as a guide for health professionals to easily identify the information needed for counselling patients. It is presented in a language and format that is appropriate for a consumer audience.

124. Manufacturers are required to update the information in product monographs after the drug is initially marketed and more is learned about the drug and its effects in the wider population. This may include updating information on safety concerns, drug interactions, or the use of the drug in unique populations such as children. When a manufacturer updates the information in a product monograph, it must be reviewed and authorized by Health Canada.

125. Product monographs are also used as sources for the Compendium of Pharmaceuticals and Specialties (CPS), which is published annually by the Canadian Pharmacists Association, as a source of drug information for health professionals. It contains information on close to 3000 current product monographs as well as quick reference drug information and clinical tools, directories of sources of drug and health care information, a list of discontinued products and a comprehensive cross-referenced index of generic and brand names. **Attached to this affidavit as "Exhibit 70" is a copy of the**

"CPS at a Glance", as detailed on the website of the Canadian Pharmacists Association.

126. The CPS is the most comprehensive and frequently used source of Canadian drug information for health care professionals. **Attached to this affidavit as "Exhibit 71" is a copy of the CPS's Editor's Message.**

3) Other Risk Management Tools: Assigning Drugs As Prescription, Over The Counter Or "Behind The Counter"

127. In addition to federal pre-market review, there are additional safeguards that optimize the benefits and minimize the risks of drugs. The principal safeguard for drugs with highest levels of risk (prescription drugs) is the requirement for them to be prescribed by a qualified practitioner who is licensed in the province/territory.

128. Prescription drugs are identified federally through their assignment to Schedule F of the *Regulations* (C.01.041). Drugs are considered for inclusion on Schedule F if they meet a criterion outlined in Health Canada's policy titled "Factors for listing drugs in Schedule F". **Attached to this affidavit as "Exhibit 72" is a copy of this policy**. Included in the various factors are considerations that prescription status is recommended when:

a) the drug is used in the treatment of a serious disease easily misdiagnosed by the public;

b) there are potential or known undesirable or severe side effects at normal dosage levels;

c) the drug has a high level of risk relative to expected benefit (i.e. drugs that regulate heart rhythm);

d) individualized instruction or direct practitioner supervision is required (i.e. some chemotherapeutic agents); and

e) there is a narrow margin of safety between therapeutic and toxic

doses (i.e. digoxin or warfarin).

129. The relevant factors are considered during the drug review process by Health Canada and a recommendation regarding prescription status is made to an internal committee, the Committee on Drug Scheduling Status (DSS committee). If the DSS committee agrees with the recommendation to include the drug on Schedule F, the drug is added to the schedule through the regular gazetting process.

130. For non-prescription, or over-the-counter (OTC) drugs, it is presumed that the terms of market authorization of the drug will be sufficient to inform a consumer of the benefits and risks of the drug.

131. For some non-prescription drug products, however, further measures can be taken provincially, such as designating a drug as “behind the counter”, so that a consumer must request the product from the pharmacist in order to purchase it (e.g. products containing acetaminophen plus low-dose codeine).

132. Schedule A is a schedule to the *FDA* that lists diseases that require a learned intermediary for appropriate diagnosis and treatment. As such, it is generally not appropriate for drugs for these diseases to be available without a prescription and the advertising of cures, preventatives, and treatments for these disease states is prohibited.

133. The purpose of this Schedule A prohibition is to ensure that consumers are not deceived or misled concerning the potential benefits of products for serious diseases, such as cancer, and that advertising does not result in a patient selecting an inappropriate treatment for a serious disease that may cause injury through a delay in appropriate diagnosis and treatment, or from the product itself.

4) Post-market Activities

134. Following the introduction of a drug to the Canadian market, the risks and benefits of a drug continue to be monitored and assessed. This is conducted through a combination of federal and provincial/territorial activities.

135. As referred to above, the manufacturer is required to make changes to the product monograph to update safety and efficacy information. Significant changes are made by the manufacturer by filing with Health Canada a Supplemental New Drug Submission or Notifiable Change, for which a separate NOC or a No Objection Letter is issued if regulatory requirements are met. Such changes include significant changes to the terms of market authorization information, including warnings, indications or contraindications, and side effects. The supporting data for such changes can be considerable, and can in some cases be based upon extensive further clinical studies.

136. Even slight changes to the wording of the terms of market authorization information, especially affecting the benefit or risk information, are carefully provided for under the *Regulations*. This is an ongoing process as more information is gained about a drug as it becomes available to the wider population over time.

5) Marketed Health Products Directorate

137. The Marketed Health Products Directorate (MHPD) of Health Canada, in collaboration with other pre-market directorates, consistently monitors and co-ordinates the safety surveillance of marketed drugs in Canada and conducts assessment and risk communication activities of all marketed health

products. **Attached to this affidavit as "Exhibit 73" is a copy of the MHPD's Information Brochure.**

138. The MHPD's activities include:

a) monitoring and collecting adverse reaction reports;

b) reviewing and analyzing marketed health product safety information;

c) conducting risk/benefit assessments of marketed health products;

d) communicating product related risks to health care professionals and the public; and

e) overseeing of regulatory advertising activities.

Attached to this affidavit as "Exhibit 74" is a copy of the website describing the MHPD's activities.

139. Although the authorization of a drug for sale in Canada is based on the review of extensive data within a new drug submission, the amount of information about the effects of a drug is limited as the drug has been made available only to carefully selected patients in a clinical trial and not to the general population. After marketing, the drug can be used by many more people. As a result, much more knowledge is gained over time about how the drug works in the wider population. This provides the opportunity to learn more about the benefits and risks of the drug, including less common adverse events.

140. The objective of a coordinated approach to the collection, analysis, and dissemination of drug information is to provide health professionals and patients with the most accurate and current information about the benefits and risks of a drug. This monitoring is described in Health Canada's guidelines for the Canadian pharmaceutical industry on reporting adverse reactions to marketed

drugs titled “Guidelines for Reporting Adverse Reactions to Marketed Drugs”. **Attached to this affidavit as “Exhibit 75” is a copy of these guidelines.**

141. Where sufficient significant adverse drug reaction reports or other information requiring a change to the terms of market authorization are warranted, the MHPD will make a recommendation to the Health Canada pre-market directorates. The pre-market directorates will request the manufacturer to update the labelling to reflect the new risk information.

142. Other measures of communication about a risk can be issued, such as a Public Advisory or a Health Professional Communication. **Attached to this affidavit as “Exhibit 76” is a copy of Health Canada’s guidance for industry titled “Issuance of Health Professional Communications and Public Communications by Market Authorization Holders”**. This document outlines the procedure for the issuance of safety and therapeutic effectiveness communications by market authorization holders.

143. As stipulated on page 1 of this guidance document (Exhibit “76”), the purpose of the communication tools is as follows:

> *HPCs (health professional communications) and the accompanying PC (public communication) are risk management communication instruments aimed at informing health care professionals and the public of newly recognized and clinically significant safety concerns, recalls, or withdrawals affecting a health product – they are not marketing tools. It is important that messages intended to inform health care professionals of health safety issues not be mistaken for advertising or any other type of information. The effectiveness of risk communications, in particular through HPCs, has been shown to depend in part on the attention of health care professionals to the vehicle, which may be adversely affected if the recipient perceives it as advertising.*

144. In rare instances, MHPD, in conjunction with other directorates, may recommend stronger regulatory action such as the withdrawal of a drug from the market. This occurs when risk minimization strategies cannot mitigate an unfavourable risk benefit profile. The *Regulations* provide for the suspension of a NOC or the cancellation of a DIN in such circumstances.

C. REGULATORY OVERSIGHT OF ADVERTISING ACTIVITIES

145. Only drugs that Health Canada authorizes for sale in Canada may be advertised. Specific requirements exist for advertisements of prescription drugs to consumers. Under the *FDA*, advertising for conditions listed in Schedule A is prohibited. Advertising to the general public of drugs listed in Schedule F, Part 1, (prescription-only drugs for human use) is prohibited by section C.01.044 (1) of the *Regulations*, with the exception of advertising for name, price, and quantity.

146. A drug firm cannot combine promotional information on a specific prescription drug product and a particular disease in a single advertisement. However, two types of prescription drug messages can be disseminated to consumers under the existing regulatory provisions:

a) Reminder ads: where the name of a prescription drug is mentioned but no reference to a disease state appears in the ad; or

b) Help-seeking announcements: where a disease state is discussed but no reference is made to a specific drug product.

147. As a supplement to this regulatory provision, Health Canada has issued policies that distinguish between “advertising” of prescription drugs and non-promotional “information” about prescription drugs. The regulatory provisions only apply if a message is deemed to be advertising of a product and

do not apply if the message is information of a non-promotional nature. **Attached to this affidavit as "Exhibit 77" is a copy of this policy entitled "The Distinction Between Advertising and Other Activities".**

148. Advertising requirements under the *FDA* and *Regulations* are administered internally within MHPD in conjunction with the Health Products and Foods Branch Inspectorate (Inspectorate). Externally, Advertising Standards Canada (ASC) and the Pharmaceutical Advertising Advisory Board (PAAB) also contribute to the oversight of advertising activities. **Attached to this affidavit as "Exhibit 78" is a copy of Health Canada's document, "Overview of Drug Advertising", which contains a general description of their respective roles**.

149. The PAAB is an autonomous body, endorsed by Health Canada, that conducts the independent review and pre-clearance of drug advertising and promotional materials intended for healthcare professionals. The PAAB standards for advertising to professionals are set out in the PAAB Code which conforms with the relevant requirements of the *FDA* and *Regulations* and Health Canada's guidelines and policies.

150. **Attached to this affidavit as "Exhibit 79" is a copy of the "PAAB Code of Advertising Acceptance".** On occasion, the PAAB consults with Health Canada regarding advertising and complaints, as outlined in Health Canada's policy issues document "PAAB and Health Canada Roles and Consultation Related to Advertising Review". **Attached to this affidavit as "Exhibit 80" is a copy of this document**.

151. ASC is a national association endorsed by Health Canada that attempts to secure voluntary compliance with standards agreed upon by a variety of industry sectors, including the manufacturer of non-prescription drugs. ASC is responsible for pre-clearing consumer-directed broadcast and mass media print advertising for non-prescription drugs, and natural health products, and for

administering complaints and appeals procedures, and related sanctions and remedial measures. **Attached to this affidavit as "Exhibit 81" is a copy of the ASC's "Canadian Code of Advertising Standards", which references the criteria for acceptable advertising and the complaints procedures.**

152. ASC and PAAB provide advisory opinions on messages directed to consumers for prescription drugs to ensure they meet the regulatory requirements. ASC and PAAB review and pre-clear advertising material in order to determine compliance with the regulatory provisions of the FDA and Regulations and the various codes of advertising. The agencies verify that advertising is accurate, balanced and evidence-based.

153. During either the pre-clearance review or processing of appeals or complaints, the ASC may consult with Health Canada. The roles and responsibilities of ASC and Health Canada are outlined in Health Canada's policy "Advertising Standards Canada and Health Canada's Roles and Consultation Related to Advertising Review and Complaint Adjudication". **Attached to this affidavit as "Exhibit 82" is a copy of this policy**.

154. Health Canada sets the minimum standards to be met in drug advertising by establishing the terms of product authorization, developing appropriate regulations, guidelines and policies and bringing these standards to the attention of the PAAB and ASC. Health Canada, through the Health Products and Food Branch Inspectorate (Inspectorate) and MHPD, reviews and processes complaints concerning advertising when:

a) marketed drug products (including natural health products) where the advertisement poses too great of a health risk to be handled by the PAAB or ASC;

b) marketed drug products where the complaint is referred by either the PAAB or ASC because of continued non compliance on the part of the responsible party;

c) complaints about the direct-to-consumer advertising of Schedule F drugs; and

d) advertisements of unauthorized drug products and medical devices not authorized by Health Canada for sale in Canada.

155. The primary role of the Inspectorate is to deliver a national compliance and enforcement program for products (excluding food products) under the mandate of the Health Products and Food Branch, as outlined in the Inspectorate's SOP 0198, "How to Handle an Advertising Complaint". **Attached to this affidavit as "Exhibit 83" is a copy of this document**.

D. SAMPLE CASES OF DTCA ENFORCEMENT ACTIVITIES

156. Based on my knowledge and MHPD records, as well as information received from the Inspectorate's Operational Centres regarding complaints made about direct-to-consumer advertising for the purpose of providing evidence in this application, I believe the information I refer to in the following paragraphs to be an accurate reflection of the Branch's interventions. The names of the drugs and manufacturers are omitted for privacy reasons.

157. From 2000 to February 2006, the Inspectorate received approximately eighty complaints about direct to consumer advertising. The sources of the complaints included departmental officials, health care professionals, companies, consumers, consumer associations, and independent advertising review agencies (ASC and PAAB).

158. In nearly all the cases, action taken consisted of sending a letter or contacting the subject of the complaint by telephone. Of the complaints that have been completed (26 are still pending completion), the results are as follows:

- No violation – 6
- No follow-up required – 1

- Compliance achieved – 33
- Compliance achieved pending interpretation – 3
- Disposition data unavailable - 11

159. The HPFB provides oversight in DTCA advertising complaint files to various degrees. Many files are resolved after an initial communication, such as a letter requesting compliance or a telephone conversation. Other files require years to resolve, and involve multiple communications, the issuance of warning letters, Dear Health Care Professional Letters and public advisories. Even these stronger measures can be inadequate to compel a company to remain in compliance. Several files related to vulnerable populations, such as teens, involved instances where companies either refused to comply, or repeated the advertising for periods of up to six years, despite repeated action on the part of the HPFB. The following examples are representative of the difficulties involved in overseeing drug advertising to ensure compliance with the current legislation where DTCA of prescription drugs is limited.

160. Since 2000 there have been over ten complaints regarding the advertising of a certain prescription drug targeted at young women. The advertising took many forms which were used either concurrently or at different times by the drug manufacturer and non compliance was persistent. The resolution of complaints regarding one advertising campaign was followed by the initiation of a new advertising strategy. It took five years to obtain compliance involving significant participation by several directorates of Health Canada, as well as the PAAB and the ASC. In addition, during that same time, safety concerns about the drug were identified and had to be addressed. Some of the particulars of the process are summarized:

- From October 1999 to June 2000, the advertising included multiple print ads in consumer journals, postcards, a company website and a toll-free phone number which consumers were encouraged to use, and public posters in locations such as public washrooms, university campuses and

bus shelters. The advertising campaign was eventually broadened to include televised reminder ads;

- The initial complaints were made by other drug companies; other complainants included consumer advocacy groups and women's groups;

- The complaints were largely with respect to claims being made in the ads which were not supported by the authorized indications for use set out in the drug's Product Monograph. The complaints involved multiple representations which each had to be addressed separately and at different times;

- The PAAB investigated many of the complaints. Even with these complaints, Health Canada was required to become involved and in some instances had to conduct its own investigation;

- PAAB rulings (for the most part, finding non-compliance and requiring discontinuance of the ads, and a revision of the website) were either challenged by the drug company, or when willingness to comply was expressed, the agreements were not fulfilled. There was a need for continuing follow-up and negotiation with the drug company. Promises by the company to consult with the PAAB in developing a changed website, for example, were not initially kept;

- The drug company challenged, among other things, the PAAB and Health Canada's interpretation of the Product Monograph and in some instances took the position that the subject piece was not advertising but attempts by the company to clarify representations made about the drug;

- The process of investigating the complaints and bringing the company into compliance included numerous phone calls, letters and meetings with the drug company, as well as between the PAAB, the ASC and Health Canada;

- Even when expressing willingness to comply, the drug company delayed taking corrective action. This required continued monitoring and follow up;

- Despite the ongoing investigations of complaints about representations regarding unauthorized use of the drug, the company also placed an ad in a medical journal with these same representations;

- It took approximately eight months to come to a resolution of these initial complaints. The print ads were to have ceased and the website, which was maintained, was satisfactorily revised. Nonetheless, several years later a new complaint regarding patient information brochures found in a medical clinic was filed. In addition, several years later it came to the

attention of Health Canada that the drug was still being promoted in a college school clinic and girls' washrooms for the unauthorized use;

- Several months later, in about May 2001, a new round of complaints began involving advertising in movie theatres. There were also new concerns by the PAAB regarding statements being made in the website, as well as a video clip which formed part of the website. Once again, discussions ensued involving disagreement about whether the statements were informational or promotional. The PAAB also referred a drug-company sponsored newsletter for insertion into a medical journal. A new round of investigation, correspondence, and negotiations with the drug company followed. The non compliant representations were similar to the ones which had already been investigated and for which corrective action had been demanded earlier and largely obtained at that time;

- A poster displayed in public places was also investigated during this time. This poster was not distributed or paid for by the drug company but contained the drug logo. It was clear, however, that the drug company participated in its distribution and requests for corrective measures were directed at both the drug company and the poster's distributor. The poster was found to be in contravention of the legislation and its removal took approximately three months to achieve;

- During this time, Health Canada issued and posted a Public Advisory on the Health Canada website and requested the drug company to issue a Dear Healthcare Professional Letter/Public Advisory regarding serious risks associated with the drug. Ongoing negotiations over a period of several months were required in order to achieve compliance with this request. During this same time, the efforts to achieve compliance with the company ads were also continuing;

- Over a five year period there were multiple ongoing problems with the website content not all of which are addressed in this summary. These included the inclusion of a press release issued by doctors which was considered, in that context, to be misleading and an "Information of the Month" section. Each of these had to be investigated and required efforts to resolve similar to those described in the preceding paragraphs. Subsequent violations within the "Information of the Month" section of the website relating to other prescription drugs were also found despite the fact the company had to previously committed to take corrective action;

- A new "round" of complaints was received early in 2004. These related to a number of DTCA activities by the drug company as part of an exhibition at a women's health forum and expo which was open to the public. These included the prominent display of an ad of the drug, an appointment card, unsolicited representations by company representatives, a brochure, a questionnaire and a patient fact sheet (that made no mention of the public

advisory or DHCP letters). A warning letter was sent by Health Canada. The company agreed to take corrective action, the particular forum however, now being finished;

- In early 2005, new complaints were received regarding televised reminder ads on a variety of Canadian television channels, including channels targeted at younger viewers. At around the same time, a new complaint was received from the PAAB regarding representations now being made on the website. Health Canada investigated and advised the company of the violations that were found, reminding the company that it had been notified of similar issues in the past;

- In April 2005, Health Canada provided new policy direction to the PAAB and ASC with respect to "reminder ads" directed to the general public including references to medical specialists. Reminder ads are those which refer to the name of a drug without referring to the condition or disease they are intended to treat. They are considered to be advertising that does not go beyond C.01.044. Health Canada has determined that, while a "reminder ad" containing a reference to a specialist may not refer to a medical condition specifically, it narrows the therapeutic scope of the drug by making a representation beyond name, price and quantity and would contravene Section C.01.044. For example, the addition of statements such as "Ask your dermatologist" in a "reminder ad" conveys that the drug in question is used for a dermatological condition. Both PAAB and ASC were advised to inform sponsors of this new policy and that current advertising campaigns containing reference to a medical specialist should be discontinued;

- In October 2005, Health Canada had to once again address problems with another print ad in a periodical. Corrective action was requested and complied with.

161. In a second case, in January 2000, television commercials appeared in prime time featuring an individual talking about her personal experience, together with a sponsorship message containing the name of a prescription drug and its manufacturer. Health Canada considered these ads to be in violation of the legislation. The drug company took the position that they were developed with the input of the network and were meant to be "general information" spots.

- Correspondence and negotiations between Health Canada and the manufacturer followed in an effort by Health Canada to have the ads suspended. The drug company took the position that it had no

involvement in the development and production of the content of these "informational messages" and in any event, that they did not contravene the restrictions on advertising;

- This required Health Canada to issue a warning letter to the drug company which was considered by Health Canada to be accountable for the overall message delivered, notwithstanding the role of the broadcaster in formulating the informational portion of the broadcast. The letter was copied to the broadcaster;

- The drug company responded by indicating that it ceased the commercials but it maintained its position. At that point, the commercials had aired for at least two to three months;

- Notwithstanding this warning, in December 2000, a second series of similar commercials aired again on another channel by the same broadcaster. Health Canada issued another warning letter. The company indicated its commitment to comply;

- In the meantime, safety concerns about the drug were addressed in 2001, and with the involvement of Health Canada, the drug company had issued a Dear HealthCare Professional Letter and a consumer warning regarding these safety risks, which included the risk of seizures in some patients.

162. Complaints regarding the advertising of another prescription drug illustrate the difficulties encountered with an advertising campaign that uses the strategy of combining several ads and techniques to convey a message where taken individually, the specific ads themselves may not contravene the restrictions on advertising. In May 2000, an advertising campaign was initiated targeting primarily young women with respect to a prescription drug used only by women. The campaign included television, cinema and municipal transit ads in fifteen cities. It consisted of a series of branded and unbranded ads which would be broadcast simultaneously.

- Health Canada investigated. It conducted an assessment of the campaign and the overall message it conveyed. This included obtaining explanations from the drug company and further information regarding its plans for the advertising campaign;

- The drug company took the position that the ASC had cleared the individual ads. Health Canada's focus was on the message that was conveyed taking the ads as a whole;

- Health Canada sent a letter in November 2000 upon completion of the investigation advising the drug company that the campaign was in violation of the legislation. By this point, the drug company had completed the campaign and committed to remain in compliance with future campaigns;

- As a result of the issues raised by this campaign Health Canada also clarified with the PAAB and the ASC that the content and context in which a message is disseminated must be evaluated and that when a particular information piece can be characterized as part of a larger campaign that combines promotional information on a specific prescription drug and a particular disease or condition this could constitute a violation;

- As a result of these new activities, in November 2000, Health Canada issued a Policy Statement on the Health Canada Website on "Advertising Campaigns of Branded and Unbranded Messages". **Attached to this affidavit as "Exhibit 84" is a copy of this policy**. This policy clarified the application of Section C.01.044 and the Health Canada policy "The Distinction Between Advertising and Other Activities", attached to this affidavit as "Exhibit 77". When a particular information piece can be characterized as part of a larger campaign that combines promotional information on a specific prescription only drug and a particular disease or condition in a single advertisement, then it may be part of a larger set of activities that can constitute a violation to the Food and Drug Regulations;

- A similar advertising approach was once again adopted by as early as February 2004. An ad consisting of four different panels appeared together in television ads, magazines, public transit and movie theatres. Again, this was found to be in contravention of the legislation and Health Canada so advised the drug company. The campaign ended but at this point the ads had run for at least several months. The drug company expressed commitment to take Health Canada's comments into consideration when developing future campaigns;

- In April and June 2006, however, new complaints were received relating to ads that appeared on two university campuses, as well as in theatres as a billboard size announcement and the Internet. A video version of the same ad appeared on prime time television during the month of April. The ads combine several elements including the display of the blister pill pack, which is alleged by the complainants to point to the therapeutic use of the product. The complaint is that the

combination of these elements contravenes the legislative restrictions on DTCA. The investigation is ongoing.

163. These examples illustrate the difficulties that Health Canada, as regulator, is met with to ensure compliance with the legislation relating to drug advertising. They also illustrate the significant length of time that the Canadian public has been exposed to advertisements that violate the *Regulations* despite vigorous investigation and enforcement on the part of Health Canada. These have arisen in the context of our regulatory regime which restricts advertising directed at consumers.

164. I make this affidavit in response to this application, and for no other or improper purpose.

Affirmed before me at the City of Ottawa,
in the Province of Ontario, this day
of , 2006.

Commissioner for Taking Affidavits
(or as the case may be)

ANN SZTUKE-FOURNIER

FORM 4C – BACKSHEET – Rules of Civil Procedure, Rule 4.02(3)

05-CV-303001PD2

CANWEST MEDIAWORKS INC. AND ATTORNEY GENERAL OF CANADA

Applicant Respondent

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding Commenced at Toronto

AFFIDAVIT OF ANN SZTUKE-FOURNIER
(Affirmed June , 2006)

Department of Justice
Ontario Regional Office
The Exchange Tower
130 King Street West
Suite 3400, Box 36
Toronto, Ontario
M5X 1K6

Per: Roslyn Levine/Gina Scarcella/Joseph Cheng
Tel: (416) 973-9201/954-8111/973-3169
Fax: (416) 973-3004
Our File: 2-563638
Law Society No.: 17838A

Solicitors for the Respondent