NATURAL HEALTH PRODUCTS: A NEW VISION

REPORT OF THE STANDING COMMITTEE ON HEALTH

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CHAIR

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ACKNOWLEDGEMENTS

This report represents the efforts of many individuals and organizations.

Because this Committee was reconstituted in October 1998, the initial Chair, Beth Phinney and several members of the original Committee who participated in the previous year were not available to share in the final decisions for this study. Their efforts, however, were vital to the successful resolution of this work.

The Committee would like to express its appreciation to all of those who contributed to this study, including:

- the many witnesses who responded to its invitation for dialogue;
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THE STANDING COMMITTEE ON HEALTH HAS THE HONOUR TO PRESENT ITS SECOND REPORT

In accordance with Standing Order 108(2), the Committee undertook a study on natural health products.

ABBREVIATIONS

- APNHP - Advisory Panel on Natural Health Products
- CFIA - Canadian Food Inspection Agency
- DIN - Drug Identification Number
- EAC - Expert Advisory Committee
- FDA - Food and Drug Administration (U.S.)
- GMP - Good Manufacturing Practice
- GP - General Public Number
- HPB - Health Protection Branch
- NHP - Natural Health Products
- PLF - Product Licensing Framework
- TCM - Traditional Chinese Medicine
- TGA - Therapeutic Goods Administration (Aust.)
- TPP - Therapeutic Products Program

PART I: CONTEXT

CHAPTER 1 - INTRODUCTION

A. Mandate

The formal work for the House of Commons Standing Committee's study on natural health products (NHPs) began when it agreed to the terms of reference suggested in a letter from the Minister of Health, the Honourable Allan Rock, on November 13, 1997.

TERMS OF REFERENCE FOR THE COMMITTEE'S STUDY ON NATURAL HEALTH PRODUCTS

That the Standing Committee on Health consult, analyze and make recommendations regarding the legislative and regulatory regime governing traditional medicines (including, but not limited to, traditional herbal remedies, traditional Chinese, Ayurvedic and Native North American medicines), homeopathic preparations and vitamin and mineral supplements;

That the Standing Committee consult broadly with stakeholders, including, but not limited to, associations and individuals representing consumers, manufacturers, distributors, growers, importers, exporters and retailers;

That the Standing Committee consider the objectives of providing consumers freedom of choice and access to natural health products while ensuring the quality and safety of such products;

That the Standing Committee consider the legislative and regulatory regimes governing natural health products in other countries.

B. Process

In the late fall of 1997, the Committee received extensive background information from the two major divisions of the Health Protection Branch at Health Canada involved in the regulation of NHPs, the Therapeutic Products Program (TPP) and the Food Directorate. The Advisory Panel on Natural Health Products (APNHP), established in May 1997 by the Minister of Health, presented its interim report to the Committee in February 1998 and followed with a final report in May. The meetings with the broader public that began in February 1998 continued until May 1998. In addition to extensive hearings in Ottawa, our work as a Committee included videoconferencing from Calgary, Halifax and Winnipeg and travel to Montreal, Toronto and Vancouver. Overall, we received testimony from a broad range of Canadian consumer, practitioner, industry and regulatory representatives. As well, we heard from international participants from Australia, Germany, the United Kingdom and the United States.

The members of the Committee wish to thank all those who devoted their time and efforts to the Committee's study-over 300 individuals in appearances before the Committee and over 1000 individuals through letters and briefs.

C. Background

From the beginning of its study, Committee members were aware of the intensity of the debate over the regulation of NHPs. We also had knowledge of various actions taken by the federal government over the last decade that had overtly increased public awareness and discussion. These actions included Schedule 705 with its proposed list for restriction of herbs and botanicals as foods; the enactment of the *Controlled Drugs and Substances Act*; work by committees of the U.N. Codex Alimentarius Commission; and cost recovery efforts undertaken by Health Canada in the middle of the 1990s. The Advisory Panel on Herbal Remedies (later renamed Advisory Panel on Natural Health Products), established in May 1997 to advise on the development of an appropriate regulatory framework, provided a parallel forum as the Committee commenced its work.

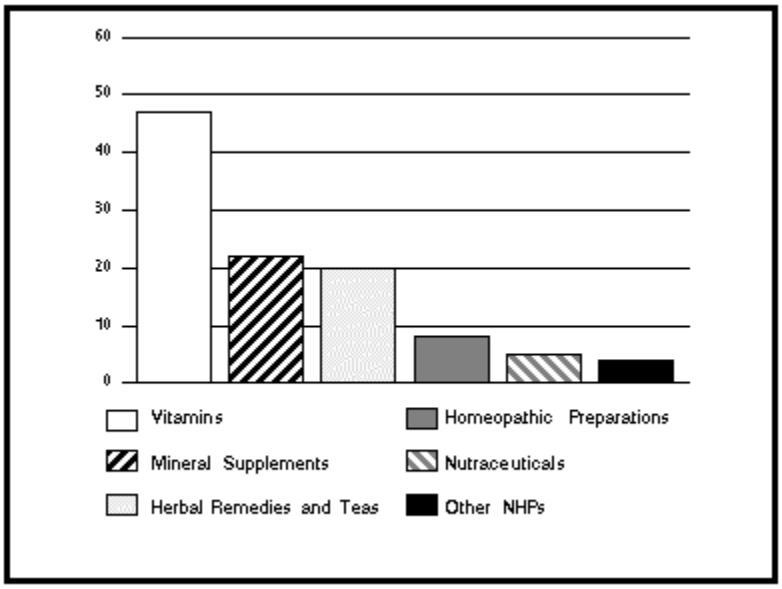
Over the months, the Committee heard about multiple forces creating pressure for regulatory changes affecting NHPs. As a backdrop, witnesses noted that the current *Food and Drugs Act* was enacted in 1952 and, although the Act itself contains only 20 pages, over 500 pages have been added to the accompanying regulations without being subject to any full parliamentary procedure or scrutiny. The results of a CTV/Angus Reid Group Poll in August 1997 indicated that 67% of Canadians feel that the federal government should regulate NHPs to ensure product safety and quality, the Committee heard repeatedly that a major reassessment is long overdue.

One pressure facing regulators emanates from the tremendous interest in and demand for NHPs and the need to accommodate both the industry and consumers in this area. Canadians are taking more responsibility for their own health and, in many cases, this has led to an increased awareness about NHPs. A survey by the Canada

Health Monitor (Survey 16, June-July 97) revealed that 56% of Canadians reported taking one or more NHPs in the past six months. Among them, 47% had taken vitamins, 22% mineral supplements, 20% herbal remedies and teas, 8% homeopathic products, 5% nutraceuticals and 4% some other products.

On the industry side, distribution channels providing access for consumers include health food stores, supplement and nutrition stores, NHP practitioners, pharmacies and drug stores, grocery stores, multilevel or network marketing; and mail, phone and Internet marketing. The extremely diverse nature of both the manufacturing and distribution sectors of this industry makes reliable data on the total market size of NHPs difficult to ascertain. However, estimates provided to the Committee suggest that the gross income of the NHP industry in Canada ranged between 1.5 and 2 billion dollars in 1997, with annual growth of 10 to 15%. The Committee was told that, while there are a few sizeable NHP manufacturing companies, the NHP industry is mostly made up of small and medium sized companies that are labour intensive. It was also indicated that the commercial growing of herbs represents a viable alternative for Canadian farmers.

FIGURE 1
CONSUMPTION OF NATURAL HEALTH PRODUCTS
IN CANADA, 1997
(Percentage of Users per Category of Products)



Committee members also became increasingly aware of international pressures for harmonization of standards. This means that NHP regulators must consider the advisability of accepting common protocols and formats for testing, data submission, inspection as well as mutual recognition of another regulatory body's decisions. Proximity to the United States, where unlike most other developed countries, NHPs are generally regulated as foods (dietary supplements), has created particular problems for Canadian regulators, as well as the industries, practitioners, and consumers involved with NHPs.

The Committee recognizes that our mandate on NHPs covers many types of products and affects many different stakeholders. We acknowledge both the complexities of the subject and the requirements for immediate action. In the following chapters, we provide our version of a framework for regulatory and policy initiatives that can be implemented by Health Canada over a short period in partnership with other interested parties. To facilitate

progress, we have recommended in our final chapter that a transition team be established immediately to begin the movement toward a new process for NHPs.

CHAPTER 2 - GUIDING PRINCIPLES

Analyzing various legislative, regulatory and policy options governing NHPs and evaluating their possible consequences was not an easy task for us as Committee members. In particular, we had to thoroughly review and understand the *Food and Drugs Act* and its Regulations, and assess the appropriateness of their application to NHPs. But foremost, we had to enhance our personal knowledge of NHPs. Although many of us are consumers of NHPs, either regularly or occasionally, we had no pretensions of being experts in the field of NHPs.

For all of us, a primary objective of any new regulatory framework for NHPs must take into account the well-being of consumers. On the whole, our desired outcome is a regulatory framework for NHPs that (1) protects the health of consumers (2) respects consumers' access to products and (3) guarantees product safety and quality.

All members of the Committee share the same objective - that the health of Canadians must remain as the most vital criterion underlying any regulatory analysis.

The work of the Committee was complicated by the fact that, although many witnesses shared similar views with respect to the regulation of NHPs, others expressed conflicting opinions. For this reason, we decided to establish a list of principles to steer us in our decisions and recommendations. This list of guiding principles was adopted unanimously by Committee members and includes:

- *Nature of NHPs:* NHPs are different in nature from and must not be treated strictly as either food or pharmaceutical products.
- *Safety*: Safety of NHPs is of primary concern.
- *Quality:* The NHP industry must meet clearly defined and established standards of quality.
- *Access*: NHP regulations must not unduly restrict access by consumers.
- *Informed Choice:* NHP consumers must be provided with pertinent information about the products they purchase.
- *Cost*: NHP regulations must not place inappropriate cost on industry, consumers and government.
- *Decision-Making*: Decision-making power must be given to a regulatory body with expertise and experience with NHPs.
- *Availability of Appea*l: An open and transparent process of appeal must be available to NHP stakeholders.
- *Transparency*: Information regarding decisions and the regulatory system must be readily available to NHP stakeholders.
- *Cultural Diversity*: NHP regulations must respect diverse cultural traditions.

CHAPTER 3 - DEFINITIONS

The Committee's terms of reference cover three major types of NHPs: traditional medicines (including Chinese, Ayurvedic, and North American Aboriginal herbal medicines); homeopathic preparations; and vitamin and mineral supplements. The *Food and Drugs Act* and its accompanying Regulations govern the sale of these products in Canada. Although the Act does not define the term "natural health products," it does contain related definitions. Under the Act, NHPs can be either foods or drugs.

If NHPs are a food product, they are governed specifically by sections 4 to 7 of the Act and Part B (titled Foods) of the Regulations. The Act provides the following definition of food:

> Includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

NHPs sold as a drug product are governed specifically by sections 8 to 15 of the Act and Part C (titled Drugs) and Part D (titled Vitamins, Minerals and Amino Acids) of the Regulations. The Act contains the following definition of drug:

> Includes any substance or mixture of substances manufactured, sold or represented for use in
>
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
>
> (b) restoring, correcting or modifying organic functions in man or animal, or
>
> (c) disinfection in premises in which food is manufactured, prepared or kept.

Currently, homeopathic preparations and vitamin and mineral supplements are sold as drugs. Some herbal products are sold as foods, while others are marketed as drugs (certain plants are even controlled under the *Controlled Drugs and Substances Act*). Health Canada's *Information Letter No. 771* on traditional herbal medicines, issued to all manufacturers and importers, indicates how the department determines whether a herbal product is a food or a drug:

The most important factors in determining whether a herbal product should be considered a food or a drug are: the pharmacological activity of the ingredients; the purpose for which the product is intended; and the representations made regarding its use, including directions for use. Other factors, such as precise dosage form,

may be considered in the determination of a product status. Herbal ingredients appropriate as foods are those that can be consumed more or less as desired due to the absence of pharmacological properties.[1]

For some witnesses, mainly those representing consumers, the current definition of food encompasses NHP products, as these, in their view, are "foodstuffs" or "nutritional supplements." By contrast, for some others, NHPs are adequately represented under the definition of drug since, they argued, NHPs are being used to address health and wellness concerns.

Most witnesses, however, contended that neither the definitions for foods nor for drugs properly describe NHPs and that, in fact, these products fall into a grey area between foods and drugs. Some described NHP products as a subset of the food category. Others defined NHPs as a subset of the drug category. For some, NHPs needed to be distinct from both the food and drug categories. These witnesses recommended that a "new" or "separate" or "third" category of products be established for NHPs.

Touching on the contention that NHPs are not adequately described as either foods or drugs, the APNHP recommended that the term "drug product" in the *Food and Drugs Act* be renamed "therapeutic product" and that this category be divided into two classes - NHPs and pharmaceutical products. The resulting APNHP definition of NHPs was echoed by other witnesses who similarly emphasised the three main components of NHPs as: substances found in nature; presented in dosage form as capsules, tablets, etc.; and with properties for health maintenance and improvement, as well as for disease prevention and treatment. The APNHP definition described NHPs as:

substances or combinations of substances consisting of molecules and elements found in nature, and homeopathic preparations, sold in dosage form for the purpose of maintaining or improving health and treating or preventing diseases/conditions.[2]

For some other witnesses, NHPs could be classified as either functional foods or nutraceuticals. The *Food and Drugs Act* does not define these terms, but according to a document by Health Canada:

[1] Health Canada, *Information Letter No. 771*, January 5, 1990, p. 1-2.

[2] Advisory Panel on Natural Health Products, *Regulatory Framework for Natural Health Products*, Final Report, May 13, 1998, p. 6.

A functional food is similar in appearance to or may be a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.

A nutraceutical is a product isolated or purified from foods and generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease.[3]

The members of the Committee acknowledge that the current definitions of a food and of a drug in the *Food and Drugs Act* do not adequately accommodate NHPs. This is reflective of the Committee's guiding principle on the different nature of NHPs. They also recognize that, when sold in various dosage forms, NHPs do have the potential for therapeutic effects. As a result, it is important to stress that NHPs sold in dosage form should comply with appropriate regulations.

The Committee also wants to note that witnesses did not reach a consensus on whether bulk herbs should be included in the NHP category (since they are not sold in dosage form). Further, witnesses did not agree on the various types of products (vitamins, minerals, amino acids, co-enzymes, etc.) that could be included in the NHP category.

Overall, the Committee does not feel it is appropriate to provide an explicit list of products or a specific definition for NHPs as members feel that they do not have the adequate expertise to undertake these tasks. Health Canada will work with a newly created and separate NHP Expert Advisory Committee to establish the new regulatory framework for NHPs. This new NHP Expert Advisory Committee, in conjunction with Health Canada, will determine whether the NHP class should include functional foods, nutraceuticals, etc. and will set out an appropriate definition. Specific recommendations about the Expert Advisory Committee are contained in the following chapter.

Therefore, the Committee recommends that:

- Health Canada, in conjunction with a new separate NHP Expert Advisory Committee, set out an appropriate definition of NHPs and amend the *Food and Drugs Act* accordingly;
- Health Canada, in conjunction with the new NHP Expert Advisory Committee, examine the status of bulk herbs for legislative purposes.

[3] Health Canada, Draft Policy Option Analysis: Nutraceuticals/Functional Foods, October 9, 1997, p. 11, footnote.

PART II: REGULATION AND REGULATORY STRUCTURE

CHAPTER 4 - EXPERTISE AND REGULATORY STRUCTURE

Many witnesses asserted that the existing level of expertise and experience within Health Canada was insufficient to review NHPs for approval for sale on the Canadian market or to ensure appropriate post-market surveillance. They explained that, although employees of the department may have attempted to learn about NHPs, they do not fully understand either how these products work or the philosophical and cultural background behind them. A number of witnesses even suggested that some personnel at the department were openly hostile toward natural health and that they exercised their authority in an overtly partisan way.

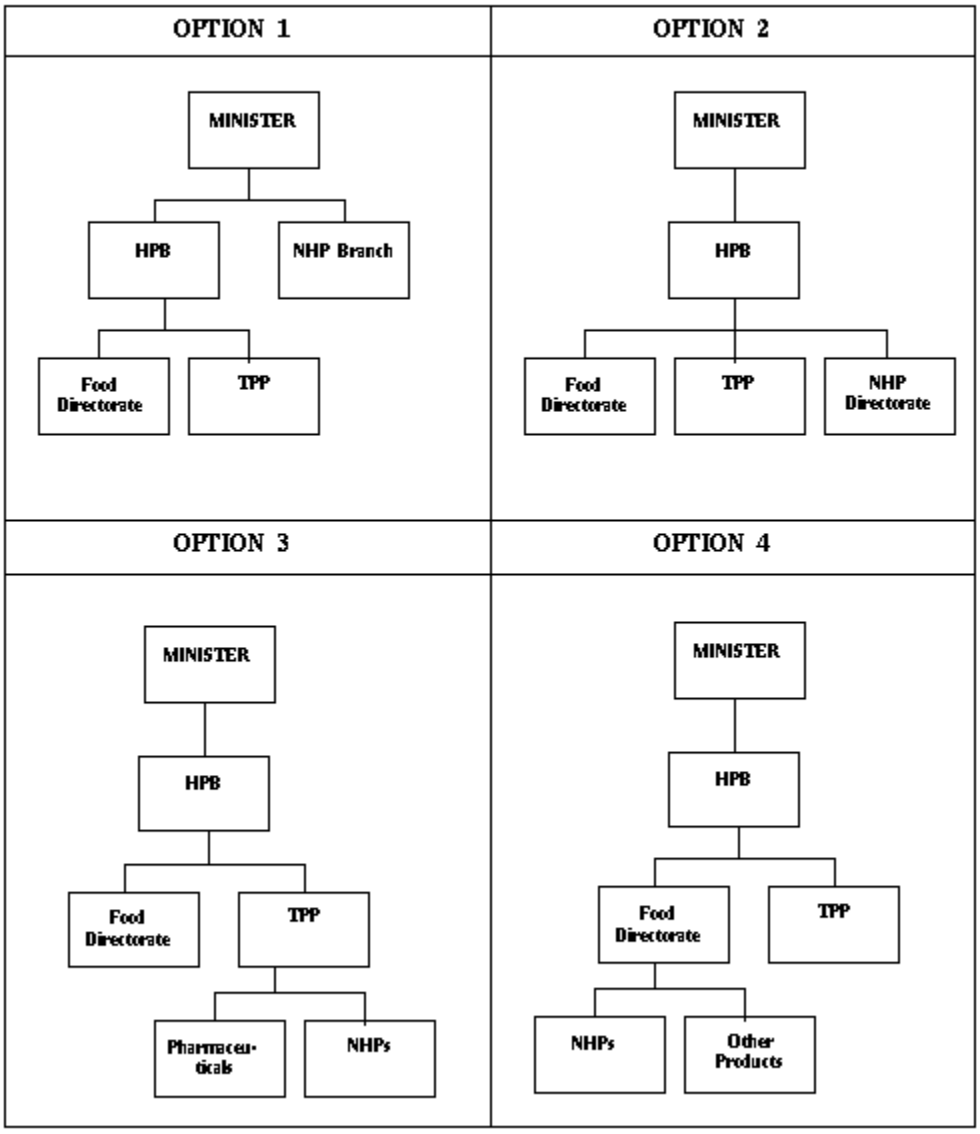
Currently, there are no naturopaths, herbalists, homeopaths or traditional Chinese, North American and Ayurvedic representatives working within Health Canada or the Canadian Food Inspection Agency. Witnesses claimed that this situation has led to a regulatory environment fraught with confusion. Policies and regulations have been and continue to be developed by non-experts. Products are removed from the market or moved from food to drug status, often without a rational justification by anyone who has experience in NHPs. Field inspectors, including those working for Customs, the Canadian Food Inspection Agency as well as the Health Protection Branch, frequently do not have an adequate knowledge of NHPs and, as a result, do not uniformly enforce regulations across the country.

The Committee was also told that the HPB closed its sole natural products division Dr. Dennis Awang headed this division, which was within the chemistry division of the Bureau of Drug Research. The natural products division was involved in the investigation of particular hazards relating to NHPs. According to documents provided to the Committee, this NHP section was well established and internationally recognized. However, it was dismantled with the closing of the Bureau of Drug Research in 1991. Recently, a Natural Health Product Division was established within the Drug Assessment Bureau of the TPP. This new division, however, does not perform the same functions as the former NHP division, nor does it have the capabilities to properly assess NHPs for the purpose of sale.

Therefore, witnesses urged that the administration of the regulatory framework pertaining to NHPs be guided by the expertise of individuals skilled in the field of natural health and, accordingly, they recommended that a new regulatory authority or structure be established. There was confusion, however, as to the precise structure and organization for this new entity. The APNHP did not reach a unanimous consensus on this issue.

The Committee strongly agrees that decisions concerning NHPs must be made by people with expertise and understanding of the products. Committee members also acknowledge that decisions by the new regulatory structure must not be overturned by others without expertise. For these reasons, the Committee considered four major options which were drawn from the testimony. These options are illustrated in Table 1.

TABLE 1 OPTIONS FOR THE NEW REGULATORY AUTHORITY



Option 1 proposes that the new regulatory authority be within Health Canada but separate from the HPB. This option was recommended by those in favour of a separate category for NHPs (some witnesses even suggested that an NHP agency be created outside Health Canada). In Option 2, the regulatory authority responsible for NHPs would be separate from, and independent of, both the Food Directorate and the TPP, but would still fall under the HPB. This option was suggested by the advocates of a new process for these products, distinct from both foods and drugs, but with regulations administered by the HPB. Option 3 assumes that responsibility for NHPs would lie within the TPP but that NHP regulations would be different from that of pharmaceutical products. This option was favoured by those who suggested that, while NHPs are different from pharmaceutical

products, the pre-market assessment and post-market surveillance for both categories of products share similar characteristics. Finally, Option 4 assumes that the Food Directorate would be in charge of administering NHP regulations. This option was mainly recommended by witnesses representing consumers who contended that the current food regulations are adequate for NHPs. They stated that no new regulations were necessary and that what was needed was the effective enforcement of sections 4 and 5 of the *Food and Drugs Act*.

The Committee considered these 4 options very seriously. All four options are consistent with the guiding principles relating to decision-making and the nature of NHPs. However, both Options 3 and 4 are problematic for the Committee. As mentioned earlier, witnesses argued that the existing levels of expertise and experience within both the Food Directorate and the TPP are insufficient to address NHPs. Some linked this lack of experience and expertise to a negative organizational bias against NHPs. The Committee in rejecting Option 3 and Option 4 gave serious consideration to these views. However, its final assessment is based on its own belief that the assessment of NHPs would benefit from a fresh approach, one where NHPs are evaluated in a forum and through a process detached from either pharmaceuticals or foods.

Options 1 and 2 come closer to satisfying those who requested an administrative body separate from existing regulatory structures and modes of operating within the HPB. Both would ensure more independent decision-making with respect to NHPs. However, over the course of this study, the Committee has become aware of the level of information, equipment and personnel needed to support regulatory activities aimed at ensuring safety for Canadians. Still, the need for a new entity with a separate, small body of permanent staff is supportable. This can best be achieved without replication of existing bureaucracy and without significant cost if the new regulatory authority is placed within the HPB where it can have proximity and access to existing regulatory resources. Thus, the Committee sees Option 2 as more likely than Option 1 to result in low administrative costs. In addition, placing the NHP authority within the HPB as a directorate on equivalent terms with foods and pharmaceuticals reinforces the Committee's view that NHPs are different from, but complementary to, these other products for health.

The structure envisioned by the Committee reports directly to the Assistant Deputy Minister of the Health Protection Branch. With reference to lower administrative costs, the Committee members see it as consisting of a small number of permanent, full-time staff drawing external support as needed from the newly-created NHP Expert Advisory Committee and appropriate working groups. We feel that there can be a sharing of relevant resources already existing within HPB and a greater use of electronic linkages to facilitate information flow from outside resources and experts across Canada.

Committee members also want to stress that time is of the essence. The Committee agrees with the overwhelming view offered by witnesses that no one should tolerate a long wait for the system to be modified, which could happen if we have to wait for legislative changes. The Committee feels that appropriate regulatory and administrative changes can and should be affected, with the necessary legislative modifications to follow. The new regulatory authority can and should be established as soon as possible: a six-month period seems quite reasonable.

It may be difficult to establish a new structure with staff from all the various fields of NHPs. For this reason, the regulatory authority for NHPs, which would include only a limited number of administrators, should have the ability to establish working groups when necessary to examine specific products, specific claims, etc. These working groups would report their findings to the new regulatory authority. The Committee believes that in-house expertise, combined with relevant external consultation through electronic networking, will result in appropriate management of the NHP regulatory framework.

At this time, the Committee feels that it may not be necessary to hire new inspection staff. However, all inspectors dealing with NHPs must be provided with training specific to NHPs.

Overall, the Committee recommends that:

- The Government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch;
- The structure for this new regulatory authority be established within the next six months and be permanently staffed by individuals with expertise and experience in the field of NHPs;
- The selection of personnel be agreeable to both government and NHP stakeholders;
- When necessary, working groups reflecting the various segments that make up the NHP category be set up to advise the new regulatory authority;
- All relevant inspection personnel be provided with training specific to NHPs;
- The necessary process to amend the Food and Drugs Act not delay in any way the implementation of the regulatory and administrative changes that can proceed at this time.

The Committee agrees with many witnesses that, in creating the new regulatory environment, a new, external, independent Expert Advisory Committee must be established immediately. Its general tasks will include assistance to Health Canada in developing new regulations, revising legislation, and setting out appropriate policies. Some of the more specific work such as defining NHPs, developing safety protocols, etc. is indicated in other Committee recommendations. This Expert Advisory Committee should also examine the closure of the former NHP section headed by Dr. Awang with a view to proposing that it be re-established or that a different laboratory entity be created. Members of the Expert Advisory Committee should be required to provide full-time commitment until all their tasks are fulfilled. In addition, they should be reconvened at least once a year, or more frequently if necessary, to report on the progress of the new regulatory framework. The Expert Advisory Committee should report to the new regulatory authority and its findings should be made public. In line with the Committee's guiding principle, this would ensure the transparency of the overall regulatory system. Decisions regarding NHPs must be made in conjunction with those who have both the expertise and an understanding of the products and how they are used by consumers or recommended by practitioners.

Therefore, the Committee recommends that:

- An Expert Advisory Committee be established immediately to assist Health Canada in the general and specific tasks necessary to design a new NHP regulatory environment;
- This Expert Advisory Committee review the re-establishment options for an NHP section with research and laboratory capacities and report its findings to Health Canada;
- The selection of members for the Expert Advisory Committee be agreeable to both NHP stakeholders and Health Canada.

CHAPTER 5 - REGULATORY FRAMEWORK

A. Overview

1. Background

For Committee members, the subject of product assessment in relation to NHPs focused primarily on three areas: safety, quality and efficacy. Witnesses repeatedly raised questions in this regard. On safety, they asked: Will the product cause harm if taken as suggested? What are its side effects, if any? Are there any risks associated with its use? On quality, questions included: Is it what it says it is? What guarantees that the product is as described on the label? In relation to efficacy, the questions were: Will the product work as claimed? Will it improve health outcomes?

From meetings with both Health Canada and the Canadian Food Inspection Agency, members heard that these issues were addressed through assessments at various stages of production for foods and drugs. According to representatives from both bodies, their assessments are based on measures aimed at identifying the appropriate balance between possible threats and/or potential benefits to human health if the product is consumed.

The task of reconciling divergent opinions about the appropriate risk/benefit ratio to apply to individual NHPs was a major one for Committee members. We became aware that, in assessing products for human consumption, the terms "risk" and "benefit" have particular meanings. Thus, risk is generally defined as the probability of the occurrence of an adverse event from exposure to a substance combined with the harm to human health if such an event occurs. Benefit is defined as the human health improvement attributable to the product. Risk analysis includes identifying the existence of a hazard and estimating the probability of its occurrence; benefit analysis involves recognizing the existence of a benefit and measuring the kind and degree of improvement. Traditionally, where risks have been related to safety, the benefits of a product have been linked to its efficacy or desired results under ideal or recommended conditions. Thus, while risk might be measured in terms of increases in morbidity and mortality, benefits could be measured by reductions in these.

The assessment of NHPs using this accepted risk/benefit model poses particular problems. Both the risks and the benefits associated with use of NHPs are perceived differently by the various involved groups. For example, regulators who see protection of consumers as a paramount responsibility focused on documented evidence of adverse effects while members of the public who are informed consumers practising self-care emphasized their experience of positive health benefits. This situation was further complicated by different assessments emanating from those who viewed NHPs as foods, those who identified them as drugs, and those who saw them as different from either of these. Emerging from the ongoing discussion was a strong sense that the current emphasis on level of risk misrepresents the majority of NHPs and that it would be more useful to approach the products from a perspective stressing margins of safety.

In order to understand how this type of analysis might apply to NHPs, the Committee members sought greater understanding of its current applications for foods and for drugs. We wanted more knowledge of the ongoing assessment process of products intended for human consumption. This process which begins before a product is marketed continues after it is available for sale. In the case of foods and of drugs, assessment can begin at a laboratory, or in the case of plants at a greenhouse and follow through to the post-consumption stage. Once

production begins, good manufacturing practices, whether mandated through regulation or voluntary through guidelines, are crucial to ensuring safety and quality, if not also efficacy.

2. Pre-market Product Assessment

Although the *Food and Drugs Act* prohibits the sale of any food or drug that has been adulterated or represented in a manner that is false, misleading or deceptive, the pre-market approval process for foods is very different from that for drugs.

NHPs sold as foods are generally not subject to pre-market evaluation and approval requirements. As with most other food products, it is the responsibility of manufacturers/sellers/importers to ensure that NHPs are safe. In this regard, Section 4 of the Act provides as follows:

> No person shall sell an article of food that (a) has in or on it any poisonous or harmful substance; (b) is unfit for human consumption; (c) consists in whole or in part of filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; (d) is adulterated; or (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

With safety in mind, Health Canada can prohibit products from being sold as foods due to their inherent harmfulness. At the beginning of the Committee's study, there was a list of sixteen NHPs deemed to be unacceptable as foods or components of foods. This list was drawn from Schedule 705 which proposed amendments to the Food and Drug Regulations pursuant to an earlier assessment of herbs and botanical preparations. The Committee was told that the assessment of potential risks from various hazards encountered in food production systems is usually based on toxicological and epidemiological data. Despite the absence of pre-market approval requirements, Health Canada's Food Directorate does use available data to provide potential sellers with opinions on the safety of various herbal preparations and components. In addition, pre-clearance of the safety of all "additives" is required, as is the establishment of maximum residue limits for pesticides in foods.

The Committee heard that, when NHPs are sold as foods, they constitute an exceedingly small proportion of the total Canadian food system and are also considered to represent a low health or safety risk relative to other staple foods. As such, both Health Canada's Food Directorate and the Canadian Food Inspection Agency (CFIA) assign a lower priority to assessments and scrutiny of this group of products. These government bodies conduct assessments of potential problems on a case-by-case, product-by-product basis. Thus, if it is determined that any NHP sold as a food poses a threat to consumer health, the Food Directorate of Health Canada will recommend to the CFIA that appropriate compliance action be taken.

By contrast, all products sold as drugs, including NHPs, must be assessed and pre-approved before they can be marketed. Generally speaking, there are different ways of evaluating new products, known products for new uses, prescription products and non-prescription products. The pre-market evaluation is based on an analysis of benefits and risks associated with each drug product: the higher the risk, the greater the level of evidence and data required. When an evaluation shows a positive benefit-risk ratio, a market authorisation is issued by means

of a Drug Identification Number (DIN) or a General Public Number (GP). This number indicates that a product has successfully passed through a review of its formulation and labelling.

The TPP has developed and implemented particular processes for each of the three categories of NHPs included in our Committee's mandate - herbal products, homeopathic preparations, and vitamin and mineral supplements.

For traditional herbal medicines, submissions to obtain DINs must comply with the related guidelines and policy. Firstly, traditional herbal medicines must present no safety concerns. Secondly, each submission must include traditional herbal references, a monograph, reputed pharmacological actions, dosage and other information. Lastly, the indications for use must be consistent with the principles of self-medication: consumers must be able to understand clearly the purpose of products. Approval of traditional herbal medicines is based mainly on traditional herbal references, provided that the herbal medicines are not known to be unsafe in treating minor ailments. Those herbal products not satisfying traditional herbal medicine criteria are assessed through a different process. Manufacturers wishing to market herbal medicines for the treatment of more serious ailments must provide supporting scientific and clinical data; at present, there are few herbal medicines with such data.

Homeopathic preparations and indications for their use must also be approved. Firstly, indications for use must be suitable for self-diagnosis and self-treatment and correspond to self-limiting conditions. Secondly, indications for use are permitted on the labels of multi-ingredient low-dilution homeopathic preparations, but not single-ingredient or multi-ingredient intermediate- or high-dilution homeopathic preparations. Lastly, a Health Canada Labelling Standard applies if a manufacturer does not wish to include indications for use on a label. In this case, the medicinal ingredients and their concentrations are restricted to those specified in the Labelling Standard. Having recognised that sections C.01.036, C.01.038 and C.01.040 of the current Regulations block legal access to many commonly used, high-dilution, low-risk homeopathic preparations manufactured from certain potentially toxic prohibited substances, the TPP has made recommendations to revoke these sections. This change would give Health Canada the flexibility to evaluate homeopathic preparations manufactured from prohibited substances on the basis of their benefits and risks. According to Health Canada, this change would provide legal access to these products, without compromising consumer safety where higher-risk products are concerned.

Vitamins and mineral supplements are generally classified as products that present minimal risks. Extensive prior knowledge and experience regarding the safety, efficacy and quality of their active ingredients are widely available. Health claims and daily limits for vitamins and minerals are regulated under Divisions 4 and 5 of Part D of the Regulations. Some observers consider these Regulations restrictive: Health Canada requires manufacturers wishing to include health or therapeutic claims beyond the scope of claims contained in the Regulations to provide objective scientific evidence in support of these expanded claims. The department is considering the possibility of amending the Regulations in order to expand allowable health claims for vitamin and mineral supplements.

3. Post-market Product Assessment

Post-market surveillance continues the monitoring of risks and benefits. The level of monitoring after marketing is based on the degree of risk attributed to the product. The monitoring can take place during production and after consumption.

For drugs, this monitoring is required through regulations that outline procedures for reporting side-effects and for GMP licence renewals. Thus, regulations require the collection and analysis of post-approval adverse drug

reaction data. When authorized to market, the drug must be produced in adherence with GMP standards that seek to ensure that quality and safety are ensured.

For foods, equivalent monitoring activities are not regulated. The collection of data on adverse reaction to herbs and botanicals sold as foods is not required and no system is currently in place. Production practices and facility standards are not regulated; instead voluntary compliance with recommended guidelines aimed at safety and quality and developed through consensus by government and industry is encouraged.

4. Relevant Proposals for Drugs and Foods

Ongoing consultations by the federal government have yielded suggestions for changes to the way both drugs and foods and "in-between products" might be assessed.

The ongoing work to develop an appropriate regulatory framework for products being called nutraceuticals and functional foods has relevance for NHPs. As noted earlier, the working definitions developed for both categories of products have applicability to various products brought to the attention of the Committee. Thus, current ways of distinguishing between foods and drugs must be re-evaluated to include products seen as having important nutritional elements with the potential to prevent disease or to modify physiological functions.

More specifically, related to drugs, the gradual implementation of the Product Licensing Framework (PLF) aimed at streamlining the review and approval process for therapeutic products is seen as suitable for many NHPs. Products with potentially high risks will require the most comprehensive pre-market data submission and scrutiny as well as a higher level and frequency of post-market surveillance. Products of low risk will have minimal pre-market requirements and post-market assessments will be based on adverse event reporting. The Committee has borrowed from this PLF framework to develop one that is appropriate for NHPs.

One potential problem for NHPs lies in Health Canada's emphasis on particular types of scientific data in defining risk. When grouping products into the four broad categories (Category I to IV), risk is defined by the amount of knowledge/experience related to quality, efficacy and safety or known risk available on the product. On the highest risk level, Category IV products with little or no prior knowledge require comprehensive data and scrutiny while on the lowest risk level, Category I products with extensive knowledge require sponsor compliance with a pre-established monograph. Witnesses asserted that many NHPs, because of the current lack of knowledge or experience within Health Canada, would be grouped into the potentially high-risk category along with products for which there are identified safety issues.

Many witnesses readily acknowledged and supported the role of the federal regulatory system in evaluating products in terms of their benefits and risks. They also agreed that this evaluation must be based on adequate and accurate information. They did, however, have reservations about the appropriateness of using the current drug risk assessment model for NHPs. More specifically, they felt that assessments based on considerations of safety, quality, dosage, type of claim, seriousness of the disease and evidence of efficacy must be adapted for NHPs. They particularly argued that the model over-emphasized the risks of NHPs as a group and wanted more attention to the higher margin of safety associated with most products. In addition, they asserted that the requirements were slanted too strongly toward clinical trials and western science to the detriment of traditional knowledge and other culturally-based methods of assessment. They argued for a new approach that would, among other things, involve some changes to terminology, to conceptual underpinnings, and to evaluation processes.

For assessments of NHPs, the Committee favours a revised risk/benefit system that is more stringent than the one currently in place for foods but less stringent that the one applied to drugs. It agrees that the majority of NHPs are inherently safe and that regulatory efforts should be directed toward those that are less safe. In this regard, it notes that any product may be unsafe for reasons unrelated to its nature such as the way it is produced, stored or used. The following sections on safety, quality, efficacy and product licensing provide a more detailed discussion of how product evaluations might proceed for NHPs.

B. Safety

The vast majority of witnesses argued that most NHPs are safe and that assessments must be conducted with this view in the forefront. They emphasized that their uses are well known and pose minimal or no risk of harm. Witnesses noted that both mortality and morbidity rates associated with NHP use were negligible in comparison with pharmaceuticals. In fact, witnesses said that the majority of NHPs are safe if used correctly, that is when used for the appropriate indications and in correct doses. Some witnesses stated that, in the absence of scientific data to the contrary, a long history of human usage is generally sufficient evidence of a product's safety. They emphasized that it is not practical, necessary or economically feasible to conduct in vivo and clinical toxicological studies to establish the safety of most NHPs.

The Committee heard repeatedly that there were no reported deaths due to the consumption of vitamins, minerals, homeopathic preparations or traditional herbal remedies.

The discussions did point to the multiple elements that relate to safety and, in many instances, referred to factors that point in the opposite direction - toward danger. Thus, questions arose about the harm, toxicity, side effects, or risks associated with the use of a product. Witnesses acknowledged that assessing NHP safety meant testing for such things as acute and chronic toxicity of various dosage forms; evaluating finished products for contamination (bacteria, heavy metal, insect parts, artificial chemicals or pharmaceutical drugs); using epidemiological and toxicological data to identify short and long-term sensitivities and health outcomes. Others linked safety for consumers to standardization of potency, labelling, information, and professional practices.

The Committee heard from several international regulators about their method of assessing products with respect to safety. For example, Germany has a pharmacovigilance system for all medicinal products and has relied on this to ban certain products. In the United Kingdom (U.K.), the general trend is to upgrade control on products with demonstrated risk, for example, making them prescription only rather than banning them. For unlicensed herbal medicines, legislation lists products where there must be greater control over sale and supply. In Australia, restricted herbs must undergo a more extensive registration process than listed products.

Of particular concern was the fact that NHPs, like all forms of self-treatment, can present a potential risk to human health for several reasons. First, as some witnesses explained, the self-administration of any treatment may delay a patient from seeking qualified advice or cause a patient to abandon treatment without first seeking a professional opinion. They argued that people who do not receive appropriate treatment from the onset would eventually cost more to the system. Second, it was indicated that the scarcity of documented information on the interaction of NHPs with conventional medicines poses some problems with negative interactions. There is a need to identify herbal ingredients that may potentially interfere with specific categories of conventional drugs based on known phytochemical and pharmacological properties of certain herbs and documented side

effects. Third, other witnesses asserted that some NHPs are more toxic and require precise controls on dosages. They asserted that products identified as presenting a lower margin of safety and higher risk should be available only through qualified practitioners. For example, with the exception of standard TCM formulas that have been used for a long period of time for minor conditions it was suggested that most TCM formulas should be done through a practitioner. In addition, some homeopathic practitioners argued that improper or prolonged use of preparations may be harmful.

The Committee believes that it is important that clear and complete information about complementary treatments be available to people who choose to self-medicate with these products. Cautions about negative interactions of NHPs with conventional medicines must be more readily available to health care professionals and the public. Research on these types of interactions needs to be conducted and disseminated as broadly as possible. These issues are addressed further in the following sections on labelling and informed choice.

On the particular question of the inherent safety of individual products, the Committee would like to stress the principles that guided its thinking. First and foremost, safety of NHPs is of primary concern. Members also agreed that the NHPs are different in nature from either food or pharmaceutical products. We accepted the contention of the many witnesses who asserted that the vast majority of NHPs are inherently safe and weighed this alongside the equally compelling argument that it is the regulator's duty to ensure that the products undergo some form of assessment for safety. We would like evidence to be drawn from a range of sources, historical and recent, traditional knowledge and contemporary science.

The level of regulation should be consistent with the level of safety associated with a particular product.

We contend that the current TPP assessment model is not appropriate for NHPs and that existing regulatory resources would be best directed toward those products that are less safe. Recognizing that there is no absolute assurance of safety under all circumstances, we nonetheless look to the regulator for a reasonable assurance of safety. As the later section on product licensing suggests, when products are identified as having a lower margin of safety and therefore a higher degree of risk, the final assessment should also involve expertise from outside the established regulatory system.

The Committee therefore recommends that:

- The new regulatory authority assume primary responsibility for assessing safety of products;
- General safety protocols be developed by the Expert Advisory Committee based on EAC judgements of reasonable evidence;
- When necessary, this regulatory authority establish appropriate working groups to assess the safety of specific products.

C. Quality/Good Manufacturing Practices

Numerous questions from Committee members related to the quality of NHPs. They wanted to know how consumers could be certain about such factors as purity, potency, and cleanliness of the products they purchase. They heard repeatedly that Canadians must be assured that "what's on the label is in the bottle." In fact, quality

was viewed as something to be scrutinized from product development through products for final sale. In that perspective, Good Manufacturing Practices (GMPs) appear to be of paramount importance. GMPs are internationally accepted standards governing the manufacturing and distribution process to ensure the quality of products. GMP standards apply to the premises, equipment, personnel, raw material (identification), finished product testing, sanitation/cleanliness and record keeping.

There are no GMP regulations for food products in Canada. Health Canada, however, has produced voluntary guidelines for the use of food manufacturers and inspection staff from the CFIA. With respect to drug products, the general regulatory framework governing GMPs is found in Division 2 of Part C of the Food and Drug Regulations. All drug establishments (manufacturing, wholesale, packaging, importing, distribution, testing) are expected to comply with GMP standards. Compliance is assessed by regular inspections of establishments. An Establishment License is delivered annually to establishments that comply with GMP regulations. Althoug NHPs sold as drug products must conform to these general GMP requirements, the TPP has developed supplementary GMP guidelines for herbal medicinal products and for homeopathic preparations (October 1996).

The TPP has also established a GMP Enforcement Directive (December 1997). This directive states that, although the TPP will work with establishments to help bring their operations into GMP compliance, it will not tolerate chronic non-compliance. In such situations, enforcement actions will be considered in order to prevent the distribution of potentially unsafe drug products. These actions may include among others: requests to voluntarily recall drug products sold, requests to voluntarily retain or dispose of drug products for sale, refusals at Customs for entry of drug products, and seizure of drug products for sale.

Like Canada, most developed countries require that drug products be manufactured pursuant to GMPs. In Australia, products are monitored before and after they are marketed, first through GMP inspections, and second through a sampling program (random testing) for lower safety products. Establishments must hold a license to manufacture therapeutic products. As in Canada, Australia has adapted its drug GMP guidelines to accommodate herbal products. In Germany, herbal products sold as drugs must be manufactured pursuant to GMPs. In the United Kingdom, all manufacturers of drug products must have a license and must comply with GMPs. As in Canada, they are inspected on a regular basis. In the United States, drug manufacturers must also satisfy GMP requirements. However, dietary supplements are not presently covered by drug GMP regulations. The legislation grants the Food and Drug Administration (FDA) the authority to establish GMPs specific to dietary supplements and the Committee was told that the FDA is in the process of establishing these regulations.

The vast majority of witnesses who discussed GMPs were of the view that manufacturing standards were necessary to ensure NHPs' quality and safety. The compliance to current GMP guidelines has resulted in extensive renovations and the purchasing of expensive equipment by Canadian establishments dealing with NHPs to ensure these high safety and quality standards. In fact, the Committee was told that Canadian GMPs are among the highest in the world and that Canadian NHPs gain international recognition because of their high quality.

However, most witnesses suggested that current GMPs were not appropriate for NHPs. When classified as drugs, NHPs must comply with standards initially developed for the manufacture of pharmaceutical products; these standards were said to be too stringent. By contrast, food standards may not be stringent enough for NHPs. The Committee was told that the inappropriateness of both food and drug GMP standards for NHPs has resulted in a lack of uniformity in GMP requirements across the country, because of unofficial concessions by field inspectors. For these reasons, witnesses recommended that all NHPs be manufactured according to appropriate GMPs. Specific GMP guidelines for NHPs would reflect their different nature, safeguard public safety and place no unnecessary burden on the NHP industry. Appropriate GMPs should be less costly than applying

pharmaceutical GMPs and result in savings for both NHP industry and consumers. Witnesses also suggested that GMP standards address the specific needs of all types of products that make up the NHP group. Some of them, who noted that many herbal companies are small and medium-sized businesses, indicated that GMP standards should be flexible and adapted to the financial capabilities of these companies.

With respect to herbal products, botanical identity, purity and potency were stressed as particularly important factors in quality control. Poor quality of herbal products may be the result of substitution or contamination of the declared ingredients, with a more toxic botanical, a poisonous metal or a potent non herbal drug substance rather than of the pharmacological activity of the herbal ingredients themselves. The Committee was told that current GMP guidelines are inadequate because certification of botanical identity and purity testing are not mandatory and that criteria and methodology for determining identity are not specified.

The Committee agrees that NHPs sold on the Canadian market must meet high standards of safety and quality. Furthermore, the Committee acknowledges that GMP guidelines relevant to NHPs must be developed. These products are found in nature and it can be much more difficult to assess their quality and purity. Appropriate GMP guidelines will guard against packaged products that do not contain what they claim to contain. In order to ensure that Canadian products satisfy quality requirements, all manufacturers, packagers, importers and distributors selling NHPs to Canadians in Canada should hold a valid establishment license. This license would indicate continued compliance with GMPs. Overall, these observations are consistent with the Committee's principles regarding the nature of NHPs, quality and safety.

It is imperative to *assure Canadian consumers that what is stated on the label is in the bottle*

Therefore, the Committee recommends that:

- Health Canada, in collaboration with the NHP industry, establish appropriate GMP guidelines reflective of the different nature of NHPs;
- GMP standards for NHPs include specific quality control and testing for herbal products;
- Manufacturers, packagers, importers and distributors of NHPs, whether located in Canada or abroad, be obliged to hold valid establishment licenses;
- Inspection activities be performed consistently and on a regular basis by inspectors knowledgeable about the products.

D. Efficacy

The efficacy of a product is closely linked to the question of health claims. A product will only be efficacious if it produces the outcome indicated by its health claim. Thus, efficacy requires that a product "does what it says it will do."

Health claims, meanwhile, are statements of the effect of a product on the health of an individual made by the manufacturer or distributor, and displayed on the product label or literature. The Committee was told that there were generally three different categories of health claims. According to the APNHP, they are defined as follows. Structure-function claims report the effect of a product on a structure or physiological function in the human body and are based on the maintenance or promotion of good health. Risk-reduction claims relate consumption of a product to significant reduction in the risk of developing a disease or abnormal physiological state. Risk

reduction may occur in two ways. One, the product may alter a recognized major health risk factor or factors of a disease or abnormal state. Two, it may affect a body function or system so as to improve the body's capacity to resist the disease or abnormal state. Therapeutic or treatment claims report the effects of a product on the actions of a specific disease or its symptoms. Treatment can include the cure or alleviation of either the disease or its symptoms.

EXAMPLES OF HEALTH CLAIMS

- STRUCTURE FUNCTION CLAIM: "Calcium builds strong bones."
- RISK REDUCTION CLAIM: "Garlic decreases the risk of cardiovascular diseases."
- THERAPEUTIC OR TREATMENT CLAIM: "St. John's Wort is useful in the treatment of mild to moderate depression."

Source: Advisory Panel on Natural Health Products, Final Report, May 1998.

The vast majority of witnesses contended that NHPs should be eligible to make all three types of claims if sufficient or reasonable evidence supports such claims. There was no unanimity, however, over what would constitute "sufficient" or "reasonable" evidence. For most witnesses, this could include clinical studies and/or traditional references and/or appropriate scientific data where available. Reliable traditional references could include those accepted in qualified jurisdictions - for example, the European Community, the United States or Australia. For some, professional consensus could also be a valid source of information about the use of NHPs. For others, sufficient or reasonable evidence means only scientific studies and controlled laboratory experiments.

The Committee was told that NHPs were different from pharmaceutical products and that the efficacy of natural products could not be assessed the same way as synthetic products. Many witnesses indicated that the efficacy of NHPs has been demonstrated over centuries through their use by a large number of people. Therefore, according to these witnesses, experience, clinical practice and empirical verification are evidence for NHPs' efficacy.

Some witnesses suggested that NHPs, particularly herbal products, be subject to the same rules required for other therapeutic products. Others felt that, in the absence of clinical trials, long-term records of use through peer-reviewed literature, along with a good risk assessment process, could be considered. Others stated that the current approval process needs major revisions to ensure that Canadians have access to products that are proven to be efficacious. They contended that clinical trials are necessary to prove efficacy and believe that clinical trials are not too expensive even for small companies. Products meeting requirements for safety and quality, but unable to demonstrate efficacy, could continue to be made available to Canadians but without health claims.

By contrast, the Committee was also told that it is the subjective satisfaction of consumers which is the critical measure. They should be the final arbiters. Others added that consumers and professionals would be the best judges of their own interests when they can freely weigh the evidence and opinions in the open market. As a result, they were of the view that efficacy should not be subject to government regulation.

Some witnesses indicated that the label should indicate the source for the therapeutic use, with phrases such as: "traditional use of this product indicates..." or "clinical use of this product indicates..." or "scientific studies have indicated..." Others recommended that products, for which no scientific evidence exists to support their use, attach a disclaimer such as: the effectiveness of this product is not supported by the usual scientific evidence

required for non-prescription medications. It was also suggested that, if higher safety products were not to be subject to any pre-market approval, the label could include a disclaimer stating that the products have not been evaluated or approved by Health Canada for the diagnosis, treatment, cure or prevention of any disease.

Several witnesses indicated that the level of evidence needed to establish a health claim should be linked to the type of claim being made. Thus, treatment claims would need different evidence than structure/function claims. It was suggested that NHPs be permitted to make health claims only if two conditions were met: first, acceptable standards ensure that the active ingredients are present in meaningful amounts at the time of manufacture and throughout the shelf life of the product; and, second, the product is produced under conditions that meet acceptable GMP standards.

The Committee notes that there appears to be a trend in international regulation of NHPs toward more flexibility when it comes to assessing efficacy. For example, in Australia, efficacy is not perceived to be a priority for listed medicines. However, sponsors are required to keep efficacy data to be made available on request and claims are limited to minor self-limiting conditions. In the United States, dietary supplements are allowed to make health claims pursuant to the Dietary Supplements Health Education Act of 1994. Claims must be substantiated by the sponsor although pre-authorization is not required from the FDA. However, dietary supplements are not allowed to make drug claims.

The Committee agrees with the three categories of health claims as set out by the APNHP: structure-function claims, risk-reduction claims and therapeutic or treatment claims. The Committee believes that NHPs should be allowed to make all three types of claims if the rules as set out below are satisfied.

While the Committee agrees that consumers will be the final judges as to the effectiveness of a product, it does feel that the government has a role to play. If a person wishes to make a health claim about a product, we feel that reasonable evidence is required. This does not mean, however, that the evidence needed should be equivalent to that required for pharmaceutical products. No claims should be allowed where there is not appropriate evidence to support the claim. The Committee believes that this is the only way to ensure that consumers are making informed choices. If there is no basis for a claim, the product could still be sold without a claim as long as it satisfies the requirements regarding safety and quality. Adequate evidence to support health claims will help ensure that Canadians will be protected from fraudulent claims of health benefits.

The Committee rejects the suggestion that health claims should be allowed without some form of evidence.

We believe that the issue of health claims is related to the degree of safety or, conversely, the level of risk of the product. In fact, the dangers associated with product use can have as much to do with an unsubstantiated claim as with the toxicity of the product. If the claim is not valid, this can have severe consequences for the consumer. As noted earlier, the consumer might rely on self-treatment and delay seeking alternative advice or different treatment that could produce better health outcomes. The more important the claim, the higher the need to ensure that is based on accurate information and maximal safety for the consumer.

Thus, the Committee feels that the validity of a claim must be assessed. Because of the high safety of many of these products, pharmaceuticals standards are generally too rigorous. The Committee believes that the type of evidence needed should depend on the type of claim being made. For more serious claims, more rigorous evidence will be needed. While double blind clinical trials should be required for certain serious claims, other

claims should require different evidence. Thus, unlike pharmaceuticals, the evidence that is required for certain NHP claims should be more flexible. They should include generally accepted and traditional references, professional consensus, clinical evidence including but not limited to double-blind trials and other types of clinical or scientific evidence. While the TPP currently accepts traditional references for traditional herbal medicines, the Committee believes that the system must be made more flexible to also recognize other types of evidence.

As described further in the section on product licensing, the Committee favours the development of monographs that provide pre-determined product information. Thus, products would have relevant monographs containing a standardized product description to which others must conform or by which others will be judged. The person wishing to make a claim would only have to attest that they satisfy the monograph. Where no such monograph exists or where the claim is not contained in a monograph, the person would have to provide some type of evidence. The following section on product licensing contains additional discussion about evidence. The type of evidence needed for structure-function claims and risk-reduction claims should be different from the type of evidence needed for treatment claims. In addition, the type of evidence needed for minor self-limiting diseases should differ from that for treatment of more severe conditions. For treatment claims for more severe conditions, double-blind clinical trials might be appropriate. The restriction imposed on health claims by Schedule A and its list of diseases and disorders is discussed in Chapter 7 of this Report.

The Committee concurs with witnesses who suggested that the label of the product should state clearly the nature of the claim (traditional use, clinical use, scientific studies). This will ensure that consumers know the basis for health claims thus allowing them to make informed choices. In addition, this should provide an incentive for the NHP industry to conduct further research with respect to NHP claims. Alternatively or in addition to the nature of the claim, the product could have attached a disclaimer that the effectiveness of this product is not supported by the usual scientific evidence required for non-prescription medications when such evidence was not presented. The Committee feels that this will provide a more level playing field between the pharmaceutical and NHP industries.

The Committee believes that this is consistent with its principle regarding safety since only products with reasonably proven effectiveness will be allowed to make claims. The procedure set out above also ensures that consumers will be allowed to make informed choices. This also keeps in mind the unique characteristics of NHPs and the need to respect cultural diversity.

Therefore, the Committee recommends that:

- NHPs be allowed to make health claims, including structure-function claims, risk-reduction claims and treatment claims;
- Claims be assessed to ensure that there is reasonable evidence supporting the claim;
- The evidence not be limited to double blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence;
- The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims;
- The label indicates clearly the type of evidence used to support the claim.

E. Product Licensing

Many witnesses appeared before the Committee to recommend the establishment of a new marketing process for NHPs. We received numerous suggestions regarding how products should be marketed. It is not practical to summarize all the recommendations that were presented to the Committee. However, we want all stakeholders to be assured that their recommendations were analyzed. The suggestions ranged from a notification system based on monographs, to a system based on the pharmaceutical model, to a system of total or partial deregulation.[4]

The Committee agrees that a new and more efficient product licensing system is needed for NHPs. While the Committee does not agree with post-market notification, as recommended by many witnesses, including the APNHP, it does see the need for a revised and more effective pre-approval process. As described in previous sections, the approval process must ensure that products are safe and that claims are supported by reasonable evidence. In addition, post-market surveillance (including GMPs) is also part of product licensing and helps to ensure the quality of products.

The Committee feels it is imperative that products be able to reach the Canadian market quickly when this is warranted.

The Committee agrees with many witnesses that the new process must be based on a risk management approach that recognizes that NHPs fall along a continuum of relative safety and therefore require different levels of control. The Committee was told that many NHP products are safe and therefore government intervention should be at a minimum. When a product is considered as having lower safety, the regulatory system should be more stringent. The system must keep in mind the higher margin of safety of the majority of NHPs. The Committee stresses, however, that in no circumstances should these products not be regulated. As stated earlier, the difference is that the level of regulation should be consistent with the level of safety associated with a particular product.

We are of the view that categories must be created within the NHP class to determine what level of regulation is appropriate for the particular products. For example, the APNHP suggested higher safety and lower safety classes. We do not feel qualified to determine what classes should be created but agree that products should be differentiated based on the risk they represent. This way of proceeding will ensure that the full impact of the regulation will only be felt by lower safety products. Health Canada should undertake the task of creating these classes in conjunction with the Expert Advisory Committee.

Obviously, the framework will not be an improvement if most NHP products are classified as lower safety products. The Committee does not believe this will occur since individuals with expertise and understanding of these products will now take decisions. Some of the factors used to determine higher or lower safety would surely include the inherent risks of the product, the type of claim being made, the seriousness of the disease, etc. For example, the safety of the product would only be one of the factors in determining the risk of the

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[4] Only a limited number of witnesses discussed deregulation. Total deregulation means that no regulations whatsoever (with respect to pre-market approval or GMP requirements or labelling standards, etc.) would govern the sale of NHPs on the market. Under such a system, the role of government is very minimal and limited to proving that a product may be or has been harmful. Partial deregulation refers to a relaxation of some of the current regulations.

product. A product that is inherently safe could become a lower safety product if it makes a serious treatment claim. In addition, the way the product is produced could have an impact on its margin of safety. As was explained in previous sections, products that have lower safety margins would be held to different standards. In addition, the quality aspect would be assured with GMPs and Establishment Licensing. With respect to claims, evidence would vary depending on the claim.

The Committee acknowledges that the regulatory system set out in previous sections imposes stricter regulations as the risk of the product rises. The Committee believes this is the best approach for regulating NHPs. For higher safety products with minor claims, there would be different evidence needed than for a lower safety product making a treatment claim for a serious illness. The safety and effectiveness of a product should be based on submitted data and its assessment. The required data should also be consistent with the product's margin of safety.

As indicated earlier, the Committee favours a licensing system based on monographs containing previously agreed standardized product information against which other products could be assessed. The monographs could be developed from information already available in other countries as well as that provided by manufacturers and the Health Protection Branch. The information could then be reviewed and monographs issued as an authoritative standard for products entering the market. A major requirement for a person wishing to market the product would be to attest to the monograph. The product would then be able to make any claim referenced in the monograph, if all other conditions are satisfied. This would include structure function claims, risk reduction claims and treatment claims. As stated previously, we do not agree, however, that the notification to the regulator should be post-market. The person marketing the product should notify the regulator before the product is marketed. The regulator would have a short period of time (for example 30 days) to approve the application and issue an NHP number. Once the application is approved, the person would be allowed to market. This would allow the regulator to deal with any potential problems before the product is marketed.

The Committee notes that monographs for NHPs are not widely available in Canada. The Committee feels that Health Canada with designated working groups should review this issue and create new ones following acceptable formats and procedures. The Committee did hear that other countries have monographs and standards and therefore feels that these should be used as a basis for the creation of Canadian monographs. Obviously, these would have to be reviewed but we feel that there is no reason to replicate the work done in other countries. The creation of a Canadian pharmacopoeia where all monographs could be collected together would be a major undertaking. However, there is no reason that we could not start with individual standardized monographs consisting of information on product identity, claims, warnings, etc. with the long-term goal of creating a pharmacopoeia. Once more monographs achieve recognition in Canada, the NHP industry will be able to market products without unreasonable delay.

A product monograph is a document that describes the source, characteristics, biological activities, toxicity, pre- cautions, dosage and contraindications, etc., of a given plant or product.

With respect to products that do not have monographs, evidence should be presented to and reviewed by the regulator before they are marketed. Product assessment would be undertaken pursuant to the guidelines set out above and in previous sections. Once a product is approved, the regulator would issue an NHP number and

provide what information is to be indicated on the label and other controls necessary to mitigate a product's potential harm.

The Committee also believes that post-market monitoring is crucial. The product should be easily tracked through its life cycle and its quality, safety and efficacy should be regularly monitored. As with the pre-market assessment, the Committee feels that the level of post-market monitoring should be based on the level of safety of the product. We are convinced that an NHP adverse event reporting system would be an important part of this post-market assessment. Therefore, establishments marketing products would be required to maintain and analyze post-market data of their products. For products that are of lower safety, more extensive reporting of adverse reactions would be required. Less frequent and detailed reporting would be needed for higher safety products. Reporting should be extensive enough to include interaction with other NHPs, with pharmaceutical products and with foods. The Committee also feels that an adverse reaction hotline must be made available to practitioners and the general public to report problems they may encounter with certain products. This hotline must be made as user friendly as possible. This would allow the regulator to better mitigate any risks associated with a product.

The Committee notes that Australia has an adverse reaction reporting system and this system is an important element of their post-market monitoring. Companies are obliged to report any known adverse reactions occurring during the marketing of a product. In addition, the Therapeutic Goods Administration (TGA, the equivalent of the TPP) encourages health practitioners to submit reports of adverse reactions and they have an Adverse Drug Reaction Committee that analyses reports and ranks them as probable, possible and not necessarily related to that particular substance. This helps in determining whether additional controls or warnings are needed or what action needs to be taken in relation to products. To date this has focused on conventional pharmaceuticals but is looking at ways to encourage practitioners of natural therapies to start reporting adverse reactions for these products.

The Committee desires a system that would recognize the different nature of NHPs while ensuring the safety and quality of accessible products. The overall result should be a system where lower safety products with a greater potential to cause harm would:

- require comprehensive pre-market submissions;
- undergo intensive scrutiny before being allowed on the market;
- sustain extensive controls designed to mitigate their risks;
- receive higher level and more frequent post-approval surveillance.

The Committee feels that this new framework allows the regulator to evaluate a product's potential risks (by assessing the safety of the product, by appraising the claims based on its seriousness and by ensuring compliance with GMPs) and potential benefits (by assessing product safety, efficacy and quality). Overall, it establishes a system to mitigate the risks when this is necessary (primarily by allowing additional information on labels and particular controls on the product). It is the view of the Committee that such a risk management approach is the best way to proceed.

Another aspect of risk mitigation is restrictions on the sale of certain lower safety products. The Committee feels that certain products should not be made available to the public before consultation with a qualified practitioner. The Committee realizes that it is the provinces that have the authority to regulate health-care practitioners and, in many cases, practitioners offering care that involves NHPs are not regulated. The Committee agrees that certain lower safety products should be made available pursuant to the approach

suggested by the APNHP. Some lower safety products would be allowed for sale with cautionary labelling including the following:

- a statement that the product has been classified as low-safety by the regulatory body;
- a statement of the nature of the risks associated with the use of the product;
- a statement that the consumer should consult with a qualified practitioner before using the product.

The Committee would like to make it clear that certain lower safety products should not be made available even with these warnings. Practitioner intervention is an important aspect of risk mitigation although the Committee realizes that its implementation is problematic because few NHP practitioners are regulated. Thus, certain lower safety products should only be made available with practitioner intervention while other lower safety products would be made available with the statements listed above. Providing this information to consumers can mitigate the risks associated with a product.

The Committee notes that the proposed product licensing framework should lower the costs for the NHP industry. It sees two reasons for such an outcome: in many cases, less extensive data requirements will be required and reduced levels of regulation should be accompanied by lower fees.

In conclusion, the cornerstones of our new framework would be to identify the potential risks of NHP products and to control those risks where necessary. The risk of a product can be mitigated by product labelling and practitioner intervention and other controls on the product. Government intervention would be minimal unless clear safety concerns associated with a product emerge.

The Committee believes that the new framework should be phased in to allow sufficient time for the stakeholders and the regulator to modify the current DIN system and conform to the new regulations. A six-month phase in period would seem appropriate. The Committee believes this product licensing framework is consistent with our guiding principles with respect to the nature of NHPs, safety, quality, access, informed choice and costs.

Therefore, the Committee recommends that:

- The new product licensing framework be based on a risk management approach that emphasizes the margin of safety associated with a particular product;
- Health Canada, in conjunction with the Expert Advisory Committee, establish categories within the NHP class to determine what level of regulation is appropriate for a particular product;
- A product licensing system based on monographs be used when they are available. Such a system should rely on a pre-market approval process and the regulator should have a short period of time (for example, 30 days) to review the application;
- Health Canada, in conjunction with the Expert Advisory Committee, establish procedures to create new Canadian monographs based on work already accomplished in other countries;
- Manufacturers of products that do not have monographs be required to provide evidence to Health Canada before a product is marketed. The level of evidence would be consistent with the margin of safety associated with the product;
- The level of post-market monitoring be based on the margin of safety associated with the product and include an NHP adverse event reporting system for industry and an adverse reaction hotline for practitioners and the general public;
- Certain lower safety products be made available to consumers with appropriate warnings and other lower safety products only be made available with practitioner intervention;

- The new framework be phased in over a period of months to allow sufficient time for the stakeholders and the regulator to review the current DIN system and conform to the new regulations.

CHAPTER 6 – LABELLING

The Committee heard repeatedly that the current regulations severely limit the information that can be placed on NHP labels and that these restrictions do not allow consumers to make informed choices with respect to these products. Some even argued that current regulations are contributing to a vacuum of consumer information.

On the one hand, food labelling is very restrictive, as it does not allow information such as a product's potential benefits and how it should be used. On the other hand, drug labelling is also restricted, as NHP suppliers must conform to the use of information specified by Health Canada.

The Committee was told that there are risks arising from inadequate labelling. These risks include:

- over consumption by uninformed users;
- over dosage of children;
- usage in the presence of contraindicated conditions;
- failure to seek timely professional medical treatment;
- failure to recognize adverse effects (especially the more subtle chronic toxicity effects such as hepatotoxicity, teratogenicity and carcinogenicity);
- adverse herb-drug and herb-herb interactions;
- improper preparation and/or storage;
- improper application (ex. internal use of products intended for external application); and,
- allergic or adverse reactions due to undeclared ingredients.

Many witnesses requested that labelling be standardized. They provided a detailed list of the information that should be put on the label of NHPs. They were of the view that this type of information would allow consumers to make informed choices when selecting NHPs. The information requested included among others:

- health claims and/or therapeutic use (this subject has already been discussed previously);
- lot or batch number to allow for GMP quality control, and to facilitate recall action;
- expiration date to advise the consumer of the estimated shelf life of the product under normal storage conditions;
- special storage conditions if required;
- identification (scientific name) and amount (or proportion) of each ingredient;
- name and address of manufacturer;
- correct dosage for both adults and children and mode of administration;
- total number of dosage units (tablets, capsules, etc.) per package;
- quantity of ingredient(s) per dosage;
- warnings and contraindications for children, seniors, expectant and nursing mothers, people with specific medical conditions, and possible side effects;
- potential interactions with other NHPs or conventional medication or with foods.

Internationally, most developed countries have strict guidelines with respect to the labelling of therapeutic products. For example, Australia reviews labelling information during product assessment and warnings are

permitted on labels. In the United Kingdom, a licenced product is required to have warnings while this is optional for unlicensed herbal remedies. In Germany, warnings and full labelling are required for drugs and warnings are even allowed on some foods. In the United States, if a product is a drug, a review of the labelling is part of the review process and there are strict guidelines with respect to labelling. Adequate directions and warnings must be included on the labelling. Food legislation also set out requirements for the labelling of foods. Internationally, the question of whether a product can make a claim generally revolves around the issue of whether the product is a food or a therapeutic product. Foods are generally not allowed to make health claims. One exception is the United States, where dietary supplements (foods) are allowed to make structure and function claims but not therapeutic claims.

The Committee agrees that consumers must be provided with all pertinent information when they are buying NHPs. Many of these products will be available over the counter and are intended for self-medication. In these circumstances, it is crucial that the consumer be permitted to make an informed choice regarding these products. This will also alleviate many of the potential risks associated with a certain product. Clearly, the information supplied on labels is linked to safety since it can be used to warn certain members of the population (i.e. pregnant women, the elderly, or children) that there is a danger for them in using a certain product. Also, if there is a potential hazard associated with the use of a product, particularly if it is being used outside its traditional setting, then this can be indicated on the label. In addition, the label could indicate to a consumer when consultation with a qualified practitioner is warranted or when health care providers should be informed of NHP product use. One of the benefits of detailed labelling is that it is a vehicle for education.

The Committee views extensive information on labels as a cornerstone of its risk management approach.

We wish to stress that pertinent information must be provided not only on the label that is actually on the product's container but also on other modes of information such as the packaging and inserts.

The Committee agrees with the recommendations that were made by the APNHP with respect to this issue: At a minimum, product information must encompass:

- identity of the product;
- directions for use;
- cautions, warnings or restrictions on the use of the product;
- lot batch number to allow for GMP controls and to facilitate recalls;
- expiry date to guide consumers on the expected shelf life under specified storage conditions;
- special storage conditions, if any;
- approved health claims.

The Committee feels that Health Canada should review this list in conjunction with the new Expert Advisory Committee to ensure that all relevant information will be available to consumers. We note that the following recommendations satisfy our principles of allowing consumers to make informed choices, of providing quality control measures and of enhancing the safe use of these products.

Therefore, the Committee recommends that:

- Health Canada consult with its new separate NHP Expert Advisory Committee to determine what information is to be included on the labelling, consisting of, at a minimum, the items recommended by the Advisory Panel on Natural Health Products;
- NHP labelling provide consumers with all relevant information needed to make informed choices;
- NHP labelling be standardized to provide clear and consistent product information.

CHAPTER 7 - SECTION 3 AND SCHEDULE A OF THE *FOOD AND DRUGS ACT*

Section 3 and Schedule A of the *Food and Drugs Act* are inter-related. Subsections 3(1) and (2) prohibit advertising or selling to the general public of a food or drug as a treatment, preventative or cure of any of the diseases, disorders or abnormal physical states referred to in Schedule A. Section 3 states the following:

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

Some of the diseases, disorders or abnormal physical states listed in Schedule A include alcoholism, arthritis, asthma, cancer, depression, diabetes, disease of the prostate, heart disease, liver disease and many more. Diseases can be added or deleted from the Schedule by regulation. The effect of these provisions is an outright prohibition even though there might be evidence supporting a health claim.

Apparently, the purpose of these provisions and Schedule A is to ensure that individuals will seek medical attention for serious diseases, to restrict advertising when self-diagnosis and self-treatment is not considered advisable and to limit the possibility of fraudulent claims being made with respect to foods and drugs.

The Committee was told that section 3 in combination with Schedule A can unintentionally restrict the dissemination of information that can be beneficial to consumers and be in the interests of public health. Apparently, the impact is more severe on products from other cultures, particularly traditional Chinese products, many of which are used for conditions listed in Schedule A. Witnesses added that the Schedule is outdated and no longer reflects the reality of products available on the market today. The Committee was told that the Schedule should be eliminated or at the very least made more flexible. Other witnesses did not recommend that Schedule A be eliminated but that the list of diseases be reexamined. In the short term, section 30 should be invoked to remove diseases currently listed in Schedule A.

The Committee notes that some of the objectives of section 3 and Schedule A appear to be satisfied by other regulatory measures. For example, in cases where self-diagnosis and self-treatment is not considered advisable, the product can be made available by prescription only. This restricts product availability to individuals who have obtained advice from a health practitioner. This also restricts the advertising of such a product to the public since prescription products cannot make representation other than with respect to the brand name, proper name, common name, price and quantity of the drug. Thus, advertising is limited even without recourse

to section 3 and Schedule A. For non-prescription drugs, it is not clear why those dealing with Schedule A diseases should be prohibited. Health Canada would have assessed the safety and efficacy of the product and any unwarranted claim would not be approved.

With respect to the prevention of fraud, it should be remembered that foods are generally not allowed to make health-related claims. With respect to drug claims, as stated above, Health Canada must first approve them. In addition, sections 5 and 9 prohibit advertising that is false, misleading or deceptive with respect to both foods and drugs. Thus, it is not clear that Schedule A is needed to prohibit fraudulent claims since other provisions of the Act and its Regulations already seem to regulate such activities.

The Committee is aware that similar limitations are applied in other countries. In the U.K. there are fairly stringent regulations on the types of claims allowed for medicines. Generally, they are limited to minor self-limiting diseases and there are regulations listing certain conditions for which advertising is not permitted, for example, bone and cardiovascular diseases. Germany also has a catalogue of diseases for which products are not allowed to be advertised for purchase by the general public. An expert committee continually updates this list. In Australia, claims for minor self-limiting conditions of listable products are related to the Therapeutic Goods Advertising Code which sets out the guidelines for what is permitted in public advertising. The Code is developed in a co-regulatory approach through a committee, the Therapeutic Goods Advertising Code Council, which comprises of industry, professionals, consumers and regulatory representatives. It should be noted that the Code sets out a negative list of indications, disease states that may not be referred to in advertising or claims, for example, heart disease, diabetes and cancer. There is also a complaint mechanism for consumers who feel that sponsors have exceeded permitted claims. The Council is currently reviewing the advertising Code.

The Committee feels that the current provisions may unduly restrict health promotional advertisement that may be beneficial to consumers and may prevent self-medication in cases where it is warranted. At a minimum, the diseases included in Schedule A should be thoroughly reviewed to ensure that only appropriate diseases are included in the list. In addition, we observe that many of the diseases listed in Schedule A are broadly defined. Thus, we feel that, in appropriate cases, specific diseases should be exempted by regulation from the broadly defined term and consequently from the requirements of subsections 3(1) and (2).

The Committee also believes that Health Canada should conduct a study to determine whether Schedule A still serves a purpose and whether either subsections 3(1) and (2) should be deleted or all of the diseases be removed from Schedule A. The study should be conducted with participation from stakeholders representing consumers, the food, natural health product and pharmaceutical industries, and health practitioners.

These changes appear necessary considering the new products that should become available in Canada as a result of the new regulatory framework for NHPs. The implementation of these strategies would be consistent with our principle of providing more information to consumers and at the same time keeping in mind safety concerns; it would allow consumers to make informed choices while still controlling fraudulent advertising. This is also compatible with our principle of respecting diverse cultural traditions.

Therefore, the Committee recommends that:

- Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulation from the broad terms found in Schedule A;
- Health Canada, subsequently, conduct a study with the participation of representatives from consumer groups, the food, natural health products and pharmaceutical industries, and health practitioners to

determine whether subsections 3(1) and (2) of the *Food and Drugs Act* or all of the diseases listed in Schedule A should be deleted.

PART III: POLICIES

CHAPTER 8 - IMPORTATION OF HUMAN-USE DRUGS FOR PERSONAL USE

It is currently prohibited to import for sale into Canada drug products that do not meet the requirements of the Food and Drugs Act and its Regulations. These products would not receive approval from Health Canada and would not be granted a DIN number. A DIN is required for a drug product to be legally sold in Canada.

Health Canada's policy is to permit individuals to import a three-month supply of a drug product for their own personal use, even though the product has not been approved in Canada. Similar policies are found in other countries. NHPs imported for personal use, but for which commercial imports are prohibited, are thus not subject to the same review with respect to safety, quality and efficacy as are approved NHPs.

It is important to note that the Bureau of Drug Surveillance at Health Canada has responsibility for the Controlled Drugs and Substances Act, which regulates the importation of controlled substances (narcotics, controlled and restricted drugs). Drugs that fall under the authority of this Act cannot be imported for personal use.

The Committee has heard that many NHPs that are prohibited for sale in Canada are available in other countries, particularly the United States, and are imported into the country for personal use. We have been told that this has resulted in a vast underground economy in which Canadians are purchasing hundreds of product lines direct from foreign suppliers, through cross-border shopping and mail order catalogues. Cross-border advertising and easy access to information on the health benefits of products through magazines and the Internet fuel demand.

Many consumers and industry representatives expressed concerns with this policy. They were of the view that this imposed a double standard whereby products were permitted into the country pursuant to the personal importation policy while these same products were not available for sale from Canadian suppliers. Consumers stressed that the present regulations limit their access to products of their choice that are available in other countries. They were concerned that they could be considered as "drug dealers" for importing NHPs not commercially available in Canada. Industry representatives (retailers, distributors and importers), meanwhile, were mainly concerned about a significant loss of sales to foreign (largely American) suppliers. They stated that the customer base of Canada's NHP suppliers is continually eroding, as consumers import both products not legally available here as well as other legal products. Industry representatives, along with consumer groups, argued that the restrictions over the sale of products, particularly those available in the United States and other countries without any evidence of harm, should be lifted. Many other witnesses told the Committee that there is no mechanism to ensure that products being personally imported and consumed by Canadians are safe and of high quality.

The Committee was reminded that Health Canada does not have legislated jurisdiction over the importation for personal use. The Food and Drugs Act gives the department the power to intervene and regulate only when the

importation is for the purpose of sale. Legislative changes to the Act would be needed in order to regulate the importation for personal use of NHPs.

The Committee was also told that other countries also allow importation for personal use of unapproved products. For example, Australia allows such importation but there are some restrictions on certain products such as narcotics. Individuals can import up to three months' supply at any one time and up to five shipments per year. The United Kingdom and Germany also allow importation for personal use with restrictions on certain products.

The Committee feels that most of the concerns raised with respect to the personal importation policy are related to the fact that certain products are not available in Canada rather than to the policy itself. We have adopted the principle that controls on NHPs must not unduly restrict access to consumers and believe that many of the concerns will be alleviated when more NHP products gain access to the Canadian market. In many cases, consumers will no longer need to obtain their products from foreign suppliers. In addition, this should remedy many of the disadvantages faced by the Canadian industry.

Keeping in mind the Committee's objective of enhancing access to NHPs, we do not feel that any change to the personal importation policy is required at this time.

The Committee is concerned, however, that Canadian consumers will continue to import from other countries products for personal use that do not satisfy Canadian requirements for safety, quality and efficacy even when these products become available in Canada. The Committee feels that the policy should be revisited when more NHP products are available on the Canadian market from domestic suppliers. We believe that it is in the best interest of Canadians to obtain products that are safe and of high quality. We believe that it is necessary to provide an appropriate balance among safety, quality and access to products.

Therefore, the Committee recommends that:

- When the new regulatory framework is implemented, the personal importation policy be reviewed by Health Canada and the Expert Advisory Committee to determine if it is still appropriate and to outline permissible changes.

CHAPTER 9 - COST RECOVERY

Health Canada currently charges three types of fees to manufacturers whose products, including NHPs, are classified and regulated as drugs:

- Firstly, since January 1995, the department has charged manufacturers annual Authority to Sell Drug Fees for all products for which they hold DINs. In general, these annual fees are $500 for a non-prescription product generating $20,000 or more in gross sales; they amount to $250 for a homeopathic preparation. The fees are reduced to $50 per product for which related gross sales amount to less than $20,000.
- Secondly, Health Canada has charged, since September 1995, Drug Evaluation Fees in order to process DIN submissions. These fees must be paid before the products are sold in Canada, and vary depending

on the quantity of data to be evaluated by the department: $720 for herbal medicines and homeopathic preparations supported by traditional herbal references; $310 for vitamin and mineral supplements (and for other Category IV products, for which monographs or labelling standards exist); and over $143,000 for new drugs containing new chemicals. Unfinished products or raw materials, such as bulk herbs, sold for further processing, do not require DINs. Therefore, no DIN fees apply to them.

- Lastly, since July 1997, Health Canada has charged Establishment Licensing Fees. Licenses are issued not only to manufacturers, but also to packagers, labellers, importers, distributors, wholesalers, and testing laboratories that respect GMP standards; establishment licenses are not required for retailers. These annual fees, which are based on the costs of the inspection and product analysis activities performed by the TPP, vary with different firms but must not exceed 1.5% of an establishment's annual drug gross sales. Establishments handling only NHPs are currently exempt from these fees. Establishments handling a mixture of NHPs and other drug products are exempt from fees related to NHPs. Health Canada estimates that, if these exemptions were lifted, revenue from Establishment Licensing Fees on NHPs could amount to $2 million annually.

Cost recovery for services rendered by the government to the NHP and drug industries is not a policy unique to Canada. Australia has moved to full cost recovery since the summer of 1998. As in Canada, there are fees for applications, for product assessment, as well as an annual product fee. Fees may be waived, however, when sales volume is low. In the United States, all drug manufacturers must be registered and all drug products must be listed unless they are specifically exempt. Legislation in 1992 set out fees for the approval of certain drugs. However, most NHPs in the United States are sold as dietary supplements and, therefore, are not subject to any drug related fees.

Many witnesses stated that drug related fees were too high for NHPs. It was explained that these fees, which are currently charged on a per product basis, are cumulatively more onerous for NHP suppliers who carry extensive product lines to meet consumers' needs. Some witnesses contended that fees should reflect the higher safety nature of NHPs. Others indicated that annual DIN fees should be based on a schedule of fees for certain services, rather than on a percentage of gross sales. They contended that a percentage of sales is indeed a tax and would prefer a fee-for-service scheme. Industry representatives pointed out the fact that they were at a disadvantage to their American counterparts who do not face any fees at all.

With respect to Establishment Licenses, a few witnesses were of the view that the current exemption of NHP establishments should be lifted as it is unfair to other manufacturers in the drug sector. They explained that, if meeting GMP standards increases NHPs' quality and safety, then it is a small and normal price to pay for doing business within the Canadian health environment. They recommended that Establishment Licensing Fees be applied across the board to all manufacturers of drug or therapeutic products in Canada. Many other witnesses, however, stressed that, at their current level, Establishment Licensing Fees could eliminate many of the NHP companies, particularly the small segment of the industry with a gross annual income less than $ 2 million. They explained that the cost of licenses and inspections and the demanding requirements in terms of manufacturing conditions threaten the survival of these companies and could eventually cause harm to the regional economy in which they are located. They asserted that many small companies are well established in their communities, provide jobs, create new outlets for agricultural products, help diversify crops, and develop local expertise concerning the cultivation and the processing of herbal products. While some witnesses suggested that these fees should not apply to NHPs, others recommended that they be lowered and made more flexible.

The Committee was told that, since NHP practitioners import NHPs for the purpose of sale, they would be subject to establishment licensing requirements and the related fees if the moratorium was lifted. These

practitioners explained that the primary reason to maintain extensive in-office dispensaries is to ensure that the NHPs they recommend are readily available to their patients and, accordingly, they requested that they be exempt from licensing fees.

Many witnesses contended that the overall cost recovery policy could have a significant impact on both the availability of NHPs, as many small companies would go out of business, and on the final price to consumers. Therefore, this would limit the access to NHPs.

The Committee acknowledges that cost recovery, which implies the transfer of costs from the general taxpayer to those who most directly benefit from government services, may result in higher cost for the NHP industry and, therefore, higher prices for NHP consumers. However, the Committee considers that any cost recovery program for NHPs should be fair and reasonable and not result in unnecessary restriction of access to NHPs. Further, we believe that the right balance must be established between the cost to be borne by the government and that of the final consumer. On the one hand, appropriate levels or structure of fees must not unduly restrict access to products by consumers. On the other hand, the industry must participate in the cost of public services that enhance the safety, quality and image of its products on the market.

We are strongly committed to avoiding the imposition of inappropriate costs on consumers, industry and government.

Therefore, the Committee recommends that:

- Health Canada conduct a review analysing the impact of the overall cost recovery policy on the different segments of the NHP industry;
- The NHP industry stakeholders be consulted in the establishment of the most appropriate fee structure and amount;
- As a result of this review, the existing fee levels be re-examined if necessary.

CHAPTER 10 - APPEAL PROCESS

A number of witnesses expressed concerns about what they described as arbitrary actions on the part of Health Canada and others involved in regulating NHPs. Their concerns applied to both regulatory and policy sectors and covered areas affecting manufacturers, importers, retailers, practitioners and consumers. They called for more appropriate, available and effective appeal procedures.

Witnesses offered various examples of actions that could be subject to appeals. Two key areas where an appeal procedure was deemed necessary related to product licensing and establishment licensing decisions. Different groups, however, had different views of problematic actions. For manufacturers, the issues related primarily to decisions that affected whether or not a product could be marketed as a drug or a food. If a product was deemed by the regulator to be a drug, decisions affected whether it could be licensed for marketing and if it could stay on the market after approval. Importers provided examples of NHP products that had been confiscated by Customs officials and left in storage, often resulting in goods that were unusable when retrieved. Retailers talked about raids on their stores where products were removed without explanation or compensation. Practitioners talked about the Special Access Program where they were refused access to products needed by their patients without adequate justification. Consumers were concerned about access to

NHPs, asserting that the current system meant that changing guidelines and policies at the regulator's level often interrupted the availability of products in Canada. All groups argued that current processes to appeal such actions were unclear or weighted toward the regulator.

From Health Canada, the Committee heard that most such actions were related to non-compliance with existing regulations and policies that had been identified during an investigation. Departmental powers legitimately extend to monitoring compliance and to enforcing relevant legislative requirements. Officials at Health Canada asserted that anyone with a specific concern was encouraged to discuss it with staff at the regional offices. They also stated that many decisions could be appealed. For example, in their policy governing the management of drug submissions, TPP indicates that there are several levels of appeal to allow parties to discuss controversial issues. The first level allows appeal through the Bureau Director; the second allows appeal to the Director General and a three-person appeal committee. At both levels, particular procedures and time frames are established. The second-level three-person appeal committee consists of one member nominated by the sponsor and two by the TPP.

Questions of cost, convenience and complexity are significant to many participants. What the Committee did not hear clearly from either government officials or witnesses was how appropriate, accessible and effective the existing appeal structure or process currently is to NHP stakeholders. We would like to know when and where appeals would be appropriate. We also feel that it is important to understand whether such appeals are readily available on a variety of complaints through administrative routes as well as legal avenues. We would like some assessment of how effective existing avenues are in achieving outcomes desired by all parties. From the Committee's perspective, it appears that many of these concerns expressed by various stakeholders could be resolved by improved communication and increased information dissemination

One example of an appeal structure and process that may have useful characteristics for NHPs is outlined in the Canadian Environmental Protection Act, (Sections 89-97). The legislation states that, when a person files a notice of objection in respect of a decision or a proposed order or regulation, the Minister can establish a board of review to provide an impartial arbiter to inquire into the nature and extent of the danger. This board is to consist of not fewer than three members and is to have the powers of a commissioner appointed under Part I of the Inquiries Act. It may award costs and it aims to provide a reasonable opportunity, consistent with the rules of procedural fairness and natural justice, of appearing, presenting evidence and making representations. On conclusion of its inquiry, the review board is expected to report to the responsible minister or ministers with evidence and recommendations and the report is to be made public.

The Committee agrees with those witnesses who felt that there must be an appeal process for various decisions on NHPs outside the realms of either the department or the courts. The intention would be to provide an alternative avenue that is perceived to be neutral and objective and accessible. It would adhere to our guiding principle that calls for an open and transparent process of appeal available to NHP stakeholders. In addition, it would be established and operated in a way that would not place inappropriate cost on industry, consumers and government. As noted earlier, we expect that, with the expertise, knowledge and experience built into the new regulatory body, the possibility of decisions being taken for the wrong reasons will become very low and that the appeal of regulatory decisions will be greatly reduced.

Therefore, the Committee recommends that:

- As part of the immediate process for NHPs, Health Canada work with stakeholders to establish appropriate, accessible and effective appeal processes for relevant policies and possible inclusion into a revised regulatory and legislative framework.

PART VI: RELATED ISSUES

CHAPTER 11 - INFORMED CHOICE

The Committee takes the position that informed choice is fundamental. We believe that Canadian consumers are intelligent, independent, and capable of making responsible choices with respect to their health. When it involves their own bodies, people have the right to make decisions, provided that such decisions do not cause serious harm to themselves or others. To ensure successful decision-making, we feel that people must have both knowledge and authority. We believe that both are essential for individual autonomy, empowerment, and meaningful health judgements.

For us, individual knowledge and authority have two prerequisites: first, ready availability of relevant and comprehensive information about various options and their implications; second, accountability on the part of regulators who make decisions about the products and the practitioners who use the products in practice. In relation to NHPs, consumers need access to information from the beginning to the end in order to understand what they are and which ones are appropriate for health.

Most consumers advocated deciding for themselves on the basis of adequate information or advice. Since the sale of many NHPs is restricted on the Canadian market, a growing number of consumers feel they are being denied access to beneficial products by their own government, against their will and their wishes. They argued that, if the regulators have evidence of harmful outcomes, these should be communicated clearly and immediately. Overall, consumers wanted to be more aware of, and involved in, proposed changes on product availability.

Committee members feel that the availability of substantive, accurate, and up-to-date information about products is the prerequisite for true freedom of choice. Nonetheless, while acknowledging the high motivation of many NHP consumers, we are cognizant that the reliable and consistent data needed for informed decisions is not readily available. The Committee envisions greater responsibility on the part of organizations representing practitioners to ensure wider public education and information dissemination on appropriate product use. It sees more extensive research and data analysis on the part of industry and wider efforts to provide this to regulators, practitioners and the general public.

We support the view that Canadians should be in a position where they can educate themselves about their health and about any interventions to maintain or promote well-being

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But, in the Committee's opinion, the regulator has a particularly significant role in facilitating informed choice. In this regard, we see the need for greater accountability, transparency and openness in federal decision-making

around NHPs. Consumers (as well as practitioners and industry) have a right to be told which products are not available or have been removed from the market and to receive full public explanations about why various actions were taken. The continuing refrain from witnesses about the perceived secrecy surrounding the list of "banned products" causes great concern for the Committee members. The regulator must do a better job at dispelling any perception of concealment of information or of aversion toward wider use of the products.

From the Committee's perspective, there is a dual role for the regulator; first, in ensuring that full and accurate information is readily available and second, in facilitating consumers' ability to make reasonable decisions about product use. These objectives can be achieved in two ways: through research and through information dissemination.

On research, the federal government has a role, not only through its internal departmental capacities, but also through its various research funding bodies. While bodies like the Medical Research Council have a clear role in clinical trials, there is also a place for the Social Science and Humanities Research Council in providing culturally sensitive interpretations of product use. In addition, Health Canada provides funding for various projects related to Aboriginal peoples, seniors, children, etc that could be directed to this area. Providing incentives to conduct research in the area of NHPs would be commendable.

On information dissemination, Health Canada can play a key role and has several possible avenues already available for furthering its role. On the department-wide scale, there has been a strengthening of the electronic mode of information dissemination through the Canadian Health Network. As well, the 1997 Federal Budget provided funding for a population health clearinghouse and a national health surveillance network. Integrating information on natural health products into existing systems can provide the general public and health practitioners with up-to-date, credible information that will enhance informed health decisions. At the branch level, there are communication formats (press releases, warnings, information sheets, doctors' letters) that could be adapted to ensure that the information is issued in a timely fashion to a wider audience.

This thinking is in line with several of our principles; first, that NHP consumers must be provided with pertinent information about the products that they buy and second, that information regarding decisions and the regulatory system must be readily available to NHP stakeholders.

Therefore, the Committee recommends that:

- Health Canada immediately utilise existing formats and forums for more open and transparent communication on NHPs with the broader public and practitioners;
- Communication efforts include details about decisions and actions regarding NHP products (removal from market, change of status, etc.);
- Relevant consumer, industry and practitioner groups be consulted on a regular basis about the nature of the required information;
- The federal government research bodies, including Health Canada, begin immediately to encourage research on NHPs. This could include studies focusing on the interactions of herbal products with conventional medications as well as studies that explore different uses by various groups in Canada;
- Health Canada undertake, through its various established avenues, the dissemination of the resulting information to health care professionals and consumers.

CHAPTER 12 - NHP PRACTITIONERS

The increased demand for NHPs has translated into a growing number of practitioners. The Committee heard from conventionally-trained medical physicians who use herbal remedies, homeopathic preparations and vitamin and mineral supplements as part of their regular practice as well as from a number of pharmacists who increasingly are gaining knowledge of these NHPs. However, it became clear that these products are more likely to be recommended by individuals who practice as herbalists, homeopaths, naturopaths or within the realm of traditional Chinese, Ayurvedic or Aboriginal healing.

The Committee was told that regulating NHPs without regulating practitioners would not be appropriate. Of particular importance is the fact that, although products used by all health care providers are regulated federally, the way that they are put to use by individual professionals in their practice falls under provincial jurisdiction. Witnesses argued that access through practitioners is often limited because of the lack of standardization of education and practice for the practitioners and also because legislative restrictions on the use of certain NHPs prohibit many practitioners of complementary health from providing the products to clients.

For the Committee, it became clear that complementary practitioners provide a crucial avenue of access to NHPs.

Many witnesses were concerned at the lack of appropriate and consistent training and education for practitioners using NHPs. Because there is little standardization among provinces in their approaches to registering herbalists, homeopaths, naturopaths, consumers have no assurance of common standards of practice. With regard to established or conventional medical practitioners, the concern related to their lack of specialized knowledge about the products and on occasion, their open aversion to their use. In the sphere of provincial regulation of complementary practitioners, the Committee heard that only naturopathic practitioners are regulated under provincial law and through a licensing board in four provinces - Ontario, British Columbia, Manitoba and Saskatchewan. Witnesses felt that actions to standardize education, training and practice would simultaneously ensure higher quality services and protect the public from unscrupulous individuals who might masquerade as genuine health professionals. In addition, once standards were established, they suggested that it would be easier to work towards the development of a more integrated health care system. Witnesses suggested that the federal government press the provinces to take the immediate and necessary steps to regulate NHP practitioners or that a joint federal/provincial committee be established to examine this issue with national and regional associations.

Another dimension of the practitioner issue involves access to products. Many witnesses called for some NHPs, particularly those presenting a higher risk, to be prescribed only by qualified practitioners or taken on the advice and/or supervision of NHP providers. Presently, the Food and Drugs Act through its reference to provincial designation of practitioners places some restrictions on product use by complementary practitioners. It does not acknowledge traditional Chinese doctors, naturopaths, homeopaths, herbalists as practitioners unless they have provincial recognition. Some practitioners told the Committee that they are restricted from prescribing substances under various Schedules of the Controlled Drugs and Substances Act; do not have access to the Special Access Program (formerly emergency drug release program); and cannot import substances that they require to treat their patients. In addition, Schedule A of the Food and Drugs Act hinders the practice of

complementary practitioners by limiting the labelling of practitioner-produced products that state the purpose of the products.

Witnesses argued repeatedly that standards for education, training and practice should be established for all NHP practitioners.

The subject of regulation of NHP practitioners was a continuing theme during Committee hearings. As members, we agreed that we would like to see a future where NHP practitioners are appropriately qualified and required to adhere to established standards regarding the provision of NHPs. We are, however, aware that the process of achieving this goal is complex. In addition to the federal and provincial jurisdictional issues, it involves major participation and organisation on the part of practitioner groups. We encourage a study of international efforts that might provide useful models. For example, Germany regulates practitioners who provide NHPs; thus, non-medical practitioners can be licensed to practice but cannot provide prescription-only products. In Australia, there are state-driven efforts to provide some form of accreditation for practitioners of traditional Chinese medicine with the aim of allowing them access to certain controlled substances.

The Committee feels that the question of access to the products through qualified practitioners is obviously tied to the issue of their education, training and licensing. We want to emphasize that established medical practitioners are not exempt from the need to standardize their own professional approach to the provision of natural health products. Not only do they need education about the products so that they can provide them or work with practitioners who do, but they also need to be aware of their patient's current or potential usage of such products. Overall, the issue of practitioners is tied to our principles on safety, access, and cultural diversity. However, the Committee recognizes that this matter falls under provincial jurisdiction.

The Committee therefore recommends that:

- Health Canada inform its provincial and territorial counterparts of the regulatory changes with regard to NHPs and of the concerns raised by practitioners.

CHAPTER 13 - OTHER ISSUES

A. Enforcement

The Committee has heard that, while some of the enforcement of the legislation is done through proactive inspection by regulators, much of the enforcement in based on reactions to complaints by either consumers or competitors with respect to a specific product. Other enforcement action can be based on information gathered by the regulators regarding the safety of a product.

The Committee was told that more consistent enforcement of the legislation was needed and that it was not appropriate that competitors be required to denounce each other in order to have the legislation enforced.

The Committee agrees. We feel that the legislation should be enforced in a regular and consistent manner. This would help ensure that only products that satisfy Canadian standards are allowed on the market. Canadians must be guarded against products that do not satisfy the requirements of the new framework. This is consistent

with the Committee's principles regarding the safety of products and the transparency of the system. All those involved should be aware that there are rules and that they will be applied. In addition, consistent enforcement creates a level playing field between competitors. Enforcement activities should be undertaken in conjunction with education to inform stakeholders of the reasons why a product is being removed from the shelves, why a company has not satisfied GMP requirements, etc. A heavy-handed approach is not appropriate unless there are significant violations to the regulatory framework.

Therefore, the Committee recommends that:

- The new regulatory framework for NHPs be enforced in a regular and consistent manner and done in conjunction with education;
- Sufficient resources be provided for enforcement activities.

B. Aboriginal Healers

Witnesses representing Aboriginal communities expressed their concerns to the Committee regarding the application of a new regulatory framework for NHPs on their traditional use of natural products. They felt that this framework should not apply to products prepared by healers within the Aboriginal community and requested an exemption from the legislation.

It is the Committee's understanding that the regulatory framework would not apply to products prepared by Aboriginal healers where the product was prepared for an individual patient. Thus, the legislation only applies when there is an attempt at commercialisation and not when a product is extemporaneously compounded for a particular person. Thus, Aboriginal healers can prepare medicine from raw herbs without being concerned about the effect of the regulatory system, unless the product contains ingredients that are otherwise restricted. The Committee notes that these comments also apply to others that prepare products extemporaneously compounded for a particular person.

The Committee was told that such an exemption is provided in Australia. In relation to herbal, traditional and natural medicines, practitioners who are dispensing for individual patients are exempt from the need to put their products on the register. Thus, pharmacists and natural practitioners do not need to register products if it is for the individual patient.

If the products described above are not exempt from the regulatory framework, the Committee would recommend that the legislation be modified to provide for such an exemption. This is consistent with the Committee's principles regarding access to products and respect for different cultures.

Therefore, the Committee recommends that:

- If a product that is extemporaneously compounded for a particular person is not exempted from the regulatory framework, that such a product be exempted.

C. Plant Conservation

The Committee is concerned about the protection of herbs and plants in developing countries because of the upsurge in demand by developed nations. This is an important issue because not only are these products valuable world-wide, but they are also, in developing countries, often the only source of treatment.

In addition, we must ensure that we do not deplete natural resources used by Aboriginal peoples in this country. It is important that those harvesting these products be respectful of Aboriginal traditions and practices.

Therefore, the Committee recommends that:

- Health Canada work with Foreign Affairs and International Trade to ensure that existing International Agreements that currently protect biological diversity are not violated and that additional strategies are developed if needed to prevent depletion of these valuable health resources.

CHAPTER 14 - TRANSITION

Because of the scope of this report and the complexity of the subject matter, we realize that the required changes cannot be accomplished overnight. Thus, we suggest that the interim enforcement policy regarding NHPs should continue to be applied until the new framework is in place. Many witnesses indicated that the interim policy had been very helpful. The public must continue to be protected from unsafe products while industry must be in a position to market their products while the new framework is implemented.

In addition, the Committee sees an urgent need to act and recommends that the Minister immediately appoint a transition team. This team would be responsible for ensuring that the steps required for establishing this new framework be undertaken as quickly as possible. This team should consist of experts in the field on NHPs and appropriate personnel from Health Canada.

Therefore the Committee recommends that:

- The interim enforcement policy regarding NHPs continue to be applied until the new framework is in place;
- The Minister appoint, immediately, a transition team responsible for ensuring that the new framework is established quickly.

PART V: CONCLUSION

CHAPTER 15 - MOVING FORWARD

The health of Canadians is of crucial importance to all of us. We had two key objectives through this study: providing Canadians with informed access to NHPs while at the same time ensuring that there is minimal risk to their safety. Although we feel that the government has a responsibility to protect public health and safety, this should not be applied in a way that unreasonably denies consumers access to products that they perceive to be necessary for their well-being. Thus, a balance must be struck between safety and access. We believe that our approach recognizes these facts and goes a long way toward achieving the balance.

The Committee found its designated mandate to be very complex on a philosophical as well as on a regulatory level. By adopting a framework of guiding principles, we have navigated through both spheres and have achieved an outcome that aims to provide future direction on this very significant subject. It is important to note that, while this report sets out the general guidelines for the regulation of NHPs, many of the details of the new

framework will have to be established by Health Canada and the Expert Advisory Committee that will assist them in this process.

Although the model set out in previous pages might be used for other types of low risk products, the Committee stresses that this particular regulatory framework was chosen keeping in mind the uniqueness of NHPs and their general low risks to health and safety. We are not however promoting one type of product over another (for example, pharmaceutical versus NHPs). There are legitimate uses for both and both need to be appropriately controlled.

The Committee's framework does acknowledge and give credence to the consumer demand for non-allopathic therapies. These therapies may be beneficial, but more importantly, witnesses stated that they enhance psychological well being by increasing the level of control individuals have in the management of their health. The choice of which product to take should be left to individuals, and where appropriate, in consultation with their practitioners. The Committee notes that the framework must allow for more products to be marketed to provide people with that choice.

The Committee believes that better access to NHPs with proper information regarding their use could be a solid foundation for a strategy for improved health among Canadians. Because the use of NHPs is often accompanied by modifications in other parts of the consumer's life, NHPs could contribute to a reduction in morbidity and to cost-savings for the health care system. This is one of the areas where we believe that more research could be supported through the social as well as the physical sciences.

We did review how these products were regulated in other countries and have learned a great deal with respect to how other countries handle the multiple issues around NHPs. We have tried to impart this knowledge and to suggest when its application might be relevant to Canadians. However, we believe that the decision with respect to a framework ultimately comes down to what is relevant for each individual country. It would not be appropriate to adopt another country's framework as a whole.

On behalf of all the Canadians and others who participated in this study, we urge Health Canada to take immediate action to remedy apparent inconsistencies that unduly limit access to safe natural health products. We encourage actions that will satisfy the guiding principles developed and utilised by this Committee in reaching its conclusions.

APPENDIX A
LIST OF WITNESSES

Associations and Individuals	Date
Health Canada	Thursday, November 27, 1997
Mary Carman, Director, Bureau of Pharmaceutical Assessment, Therapeutic Products Program	
Jean Lambert, Director, Quebec Region, Therapeutic Products Program	
Dann Michols, Director General, Health Protection Branch, Therapeutic Products Program	
Health Canada	Tuesday, December 2, 1997
Ron Burke, Acting Director, Bureau of Food Regulatory, Interagency and Intergovernmental Affairs, Food Directorate	
Mary Carman, Director, Bureau of Pharmaceutical Assessment, Therapeutic Products Program	
Harry Conacher, Acting Director, Bureau of Chemical Safety, Food Directorate	
Jean Lambert, Director, Quebec Region, Therapeutic Products Program	
Dann Michols, Director General, Therapeutic Products Program	
Advisory Panel on Natural Health Products	Tuesday, February 3, 1998
Frank Chandler, M.D., Chair	
André Gagnon, Member, National Association for Natural Health Products	
William LaValley, M.D., Founding President, Canadian Complementary Medical Association	
Mary Wu, M.D., Director, Toronto School of Traditional Chinese Medicine	
Canadian Coalition for Health Freedom	
Valerie Dugale, Secretary	
Maureen Horne-Paul, Member	
Joel Thuna, Member	
Michael Vertolli, President	
Canadian Health Food Association	Tuesday, February 3, 1998
Serge Lavoie, Executive Director	
Michelle Marcotte, Intersect Alliance	

HerbTech Inc. — Wednesday, February 4, 1998

Ken Broadfoot, President

Toronto School of Traditional Chinese Medicine

Tony Cheung, General Manager and Owner

Jai Li, M.D., Practitioner of Traditional Chinese Medicine

Mary Wu, Director

Canadian Health Coalition — Thursday, February 5, 1998

Kathleen Connors, President

Michael McBane, National Coordinator

Citizens for Choice in Health Care

Robert McMaster, President

Citizens' Voice for Health Rights

Debbie Anderson

Randy Gomm

Friends of Freedom

Susanna Davis, Complementary Health Practitioner

Shirley Skinner, Concerned Consumer

Trueman Tuck, Health Food Store Owner

Health Action Network Society

Catherine Gabriel, Executive Administrator

Lorna Hancock, Executive Director

National Coalition for Health Freedom

Miriam Hawkins

Canadian Pharmacists Association — Tuesday, February 10, 1998

Jeff Poston, M.D., Director

Noëlle-Dominique Willems, Director

Committee for Preserving the Integrity of Chinese Herbology and Traditional Chinese Medicine — Tuesday, February 10, 1998

William Chan, M.D., Member and President, Treasure Box Products

Henry Lu, M.D., Director

Joseph Wen-Teng Wu, M.D., President

Fédération des professionnels et professionnelles salarié(e)s et des cadres du Québec — CSN	
Claudine Larocque, Secretary-General	
Ontario Homeopathic Association	
Lynda Shannon, President	
Doug Smith, Member	
Personal Health and Nutrition	
Paul Hogarth, Owner/Founder	
Canadian Academy of Herbal Medicine	Wednesday, February 11, 1998
Linda Brosseau, Professor	
Guilde des herboristes	
Marie Provost, Vice-President of the Board	
Valérie Lanctôt-Bédard, Member of the Board	
Ontario Herbalists' Association	
Mona Rainville, Member	
Keith Stelling, Editor	
Canadian Coalition of Herbal Associations	Thursday, February 12, 1998
Chanchal Cabrera, Member	
Michael Vertolli, President	
First Nations Health Commission	
Brenda Thomas, Senior Policy Analyst	
Tzu Chi Institute for Complementary and Alternative Medicine	
Allan Best, M.D., President & CEO	
Canadian AIDS Society	Tuesday, February 17, 1998
Rodney Kort, National Programs Consultant	
Fibromyalgia Society of Ontario Inc.	Tuesday, February 17, 1998
Philipa Corning, Vice-President, National ME/FM President	
Jana Gagnon, Chapter 16 (Windsor)	
Lydia Neilsen, National President	
Byron Timmermans, President	
Maharishi Ayur-Veda Products of Canada	

Richard Wolfson, M.D., National Director, Maharishi Ayur-Veda College

Natraceuticals Inc.

Lionel Pasen, Vice-President, Regulatory and Government Affairs

Purity Life Health Products Ltd.

David Chapman, President

Sears Health Food and Fitness Shop

Donna Herringer, Vice-President

Supplements Plus

Stewart Brown, Owner/President

Traditional Chinese Medicine Association of B.C.

James Knights, President

Canadian Association of Chain Drug Stores — Wednesday, February 18, 1998

Sandra Aylward, Director
Ellen Mary Mills, Vice -President
Phil Rosenberg, Director

National Association for Health Products

André Aubé, Pharmacist
André Gagnon, Executive Vice-President
Pierre Morin, Counsellor
Michel Sasseville, Biochemist

Nonprescription Drug Manufacturers Association

Natalie Lazarowych, M.D., Technical Director
David Skinner, President
Brenda Watson, Director

Canadian Chinese Herbal Professional & Merchants Association — Thursday, February 19, 1998

Sunny Li, Secretary
Lin-Hoi Yu, Chairman

Chamber of Chinese Herbal Medicine of Canada

Lawrence Cheng, Vice-President
Tony Cheung, Vice-President
Andy Shih, Vice-President
Chi-To Wung, President

Ginseng Growers Association of Canada

Michael Atkins, President
Dennis Awang, M.D.
Tom Francis, M.D., Nutritional Scientist

Chung-Ja Jackson, M.D., Natraceutical
Gary Kakis, Nutritional Consultant

Kiu Shun Trading Company Ltd. — Thursday, February 19, 1998
Albert Fok, President
Mang Wah Leung, Sales Manager

Richter's Herbs
Conrad Richter, Director

Canadian College of Naturopathic Medicine — Tuesday, February 24, 1998
Paul Saunders, Associate Dean, Naturopathic Medical Affairs

Canadian Complementary Medical Association
William LaValley, M.D., Founding President

Canadian Naturopathic Association
Heather MacFarlane, Executive Director
Lois Hare, Past Chair, Board of Directors

Global Botanical Corporation Ltd.
Joel Thuna, General Manager
Sandy Thuna, Owner

L'Armoire aux Herbes
Marie Choquette, Herbalist

L'Herbothèque Inc. — Tuesday, February 24, 1998
France Lemaire, Director

Homeopathic College of Canada
Fernando Ania, President
Geoff Szymanski

Planta Dei Pharma Inc.
Ken Keirstead, President

As Individuals — Wednesday, February 25, 1998
Bell, Warren, M.D.
Buckman, Robert
Kaegi, Elizabeth

Woolf, Robert

Health Canada — Thursday, February 26, 1998

Mary Carman, Director, Bureau of Pharmaceutical Assessment, Therapeutic Products Program

Harry Conacher, Acting Director, Bureau of Chemical Safety, Food Directorate

Jean Lambert, Director, Quebec Region, Therapeutic Products Program

Dann Michols, Director General, Therapeutic Products Program

John Salminen, Head, Additives and Contaminants Section, Chemical Evaluation Division, Bureau of Chemical Safety, Food Directorate

Consumer Health Organization of Canada — Tuesday, March 10, 1998

Phil Anderson, Treasurer

Marcel Wolfe, Member

Freedom of Choice in Health Care

Josip Gabre, Member

Marilyn Nelson, Founder

Health Naturally Magazine

David W. Rowland, Co-Publisher

Herb Works — Tuesday, March 10, 1998

Richard DeSylva, Owner/Operator

Nutri-Chem

Kent MacLoed, President

My Health, My Rights Inc.

Ronald Dugas, National President

As Individual

Case, Stephen, Health Educator, Alive Magazine

Canadian Herb Society — Thursday, March 12, 1998

Dennis Awang, M.D., Director

Alison McCutcheon, Chair

Gatekeepers of Health

Aileen Burford-Mason, Spokesperson

Joan Farano, Founding Member

Gordon Piller Inc.

Kim Piller

Hilary's Distribution Inc.

Allan H. Ingles, President

Jennine Ingles-Rothblott, Director of Medical Research

Maharishi Ayur-Veda Products of Canada

Russell C. Guest, Director

Richard Wolfson, M.D., National Director, Maharishi Ayur-Veda College

Shoppers Drug Mart Limited

Martin Belitz, Vice-President, Pharmacy Operations

Wendy Brown, Director of Marketing, Health Products

Terry L. Creighton, Vice-President, Corporate Relations

As Individual

Neville, George A.

Canadian Medical Association — Tuesday, March 17, 1998

Anne O. Carter, Director, Health Programs

Victor Dirnfeld, M.D., Former President

Chinese Canadian National Council

Jonas Ma, Executive Director

As Individual

Hassard, Murrary R., Homeopath and Chiropractor

National Homeopathic Professional Association (NUPATH)

Rudi Verspoor, President

Ontario Federation of Homeopathic Practitioners

Barbara Etcovitch, Classical Homeopath

Added Dimensions — Wednesday, March 18, 1998

Del Anderson, President

Optimum Health Choices

John Biggs

Department of Nutritional Sciences, University of Toronto — Thursday, March 19, 1998

G. Harvey Anderson, Professor, Nutritional Sciences and Physiology, Co-Director, Program in Food Safety

David Jenkins, Professor, Nutritional Sciences and Medecine, Director, The Clinical Nutrition and Risk Factor Modification Centre

A. Venket Rao, Professor, Department of Nutritional Sciences and Co-Director, Program in Food Safety

Peter Shin, Program Manager, University-Industry Affiliates Office, Program in Food Safety

Health House

Andrew Boychuk, Researcher

National Association of Pharmacy Regulatory Authorities — Tuesday, March 17, 1997

Jim Dunsdon, Chairman, Inter-Provincial Regulatory Committee (NAPRA) and Registrar, Ontario College of Pharmacists

Linda Suveges, Chairman, National Drug Scheduling Advisory Committee

Barbara Wells, Executive Director

USANA Canada Inc. — Thursday, March 19, 1998

Warren Te Brugge

As Individual

Armstrong, Jennifer, M.D., Environmental Medicine

Canadian Food Inspection Agency — Tuesday, March 24, 1998

Bruce Bowen, Food Biologist, Food Division

Gerry Reasbeck, Director, Food Division

Health Canada

Harry Conacher, Acting Director, Bureau of Chemical Safety, Food Directorate

International Development Research Centre

Roger Finan, Regional Director, South Asia

Gilles Forget, Programme Administrator

Chusa Guines, Molecular Biologist

As Individual

Israelson, Lorne, President, LDI Group & Executive Director, Utah Natural Health Products Association

Manitoba Homeopathic Association — Wednesday, March 25, 1998

Judy Hughes, Project Manager & Co-ordinator

Mary Thiessen, Board Member

Manitoba Institute of Homeopathy Inc.

Denise Appelmans, Board Member

L. Nielsen, President

Manitoba Naturopathic Association

Chris Turner, President

Nielsen's Homeopathic Clinic — Wednesday, March 25, 1998

Josie Lucidi, Advisory Committee

Shoshana Scott, Assistant to Dr. Nielsen

Opasquiak Cree Nation

Henry Wilson, Counselor

Larry Dorion, Traditional Healers Committee

Turtle Island Centre Family Services

Deborah Arney KiiskeeN'tum, Executive Director

As Individual

Walker, Frank, Aboriginal Traditional Healer & Solvent Abuse Counsellor

Food & Consumer Products Manufacturers of Canada (Toronto) — Thursday, March 26, 1998

Richard Black, Director, Scientific & Regulatory Affairs

Laurie Curry, Vice-President, Public Policy and Scientific Affairs

As Individual

Brill-Edwards, Michelle

Canadian Chiropractic Association — Thursday, April 2, 1998

James P. Meschino, Chiropractic expert on nutrition and wellness

Costa Papadopoulos, Manager of Professional Affairs and Health Policy

David Peterson, President

Citizens for Choice in Health Care

Margaret D'Arcy, President

Nancy Smithers, Owner, Naturally Nova Scotia

Mark Taylor, Nova Scotia Herbalist Association

As Individual

Apse, John, Barrister & Solicitor, Trade Mark Agent

Alive Magazine Monday, April 20, 1998

Rhody Lake, Editor

British Columbia Naturopathic Association Monday, April 20, 1998

Glenn Cassie, Executive Director

Canada Chinese Child Health Foundation

Wah Jun Tse, M.D.

Canadian Association of Physicians for the Environment

Peter Carter, M.D., Secretary

Canadian Chinese Traditional Chinese Medicine and Acupuncturists Society

Sunny Lee

Canadian Coalition for Health Freedom

Chanchal Cabrera, Herbalist

Lionel Wilson, Consumer

Chinese Benevolent Association and National Congress of Chinese Canadians

Don Lee

Chinese Consumers Association of Vancouver

John Cheng, Advisor

Diana Hu

Gordon Yu, Director

Citizens for Choice in Health Care (Vancouver)

Croft Woodruff

President

Council of Women — New Westminster

Dorothy Beach

Current Health Issues

Susan Cameron-Block

Defence of Canadian Liberties Committee

Connie Fogal, Counsel

Dominion Herbal College

Judy Nelson, M.D., President

Educational Initiative Monday, April 20, 1998

David Butterfield

Flora Distributors

Bruce Dales

Suzanne Diamond

Food Irradiation Alert

Lila Parker, Chair

Health Action Network Society

Hank Berkenpas, Director of Information

Warren Casperson, Member

Judy Cross, Member

Craig Fenton, Member

Deryl Fell, Member

Cathrine Gabriel, Executive Administrator

Ron Gale, Member

Lorna Hancock, Executive Director

Inge Hanle, Member and Former President, Canadian Association of Preventive and Orthomolecular Medicine

Roger Rogers, M.D., Member

Healthy Living Guide

Amanda Howe, Herbalist

Kayson Hong Enterprise Ltd.

Joseph Chong

Multiple Sclerosis Holistic Self-Help Group

Barbara Alldritt

National Nutritional Foods Association

Michael Ford, Executive Director

Natural Designer Botanicals Corp.

George Luciuk, M.D., President

Neil Towers

Natural Factors

Roland Gahler, President

Quest Vitamins Monday, April 20, 1998

Don Beatty

Rhema Industries Ltd.

Allan Pinkney

Richmond Alternative Medical Clinic

Martin Kwok, M.D.

Richmond Asia Pacific Business Association

Stephen Ng

Saje

Jean-Pierre Leblanc, Chief Executive Officer
Brent Stewart

Sears Health Food and Fitness Shops

John Danylowich, President and CEO

Success

Mason Loh

Teck Shun Trading Co. Ltd.

Manfred Chan

Vancouver Chinatown Merchants Association

Albert Tsang, Executive Director

As Individuals

Ashlie, Ariaal
Bader, David, Master Herbalist
Bakke, Barbara
Billingham, Marilyn
Borthistle, Garth
Bund, Cecil
Charnish, Michael
Cook, Rosalind
Gagné, Leonard, M.D.
Gulland, Edith
Kluthe, Darren
Lenti, Peggy
Marshall, Jackie
Meredith, Mary Ann, Clinical Herbalist
Miller, Bill
Norris, Victor
Punt, Lesley
Rainier, Alexandra
Reynolds, William

Monday, April 20, 1998

Salem, Ann

Simpson, Sandy

Spratt, Herb

Whitehead, Jane

Acupuncture and Traditional Chinese Medicine Associated — Wednesday, April 22, 1998

Terry Duff, Patient

Ted Gould, Patient

Ollie Ferda, Patient

Lynn Holmes, Patient

Subzali Janmohamed, Patient

Ming Shing, Patient

Stanley Shyu, M.D., Traditional Chinese Medicine Practitioner

Helma Trass, Patient

Advisory Board for Functional Foods and Nutritional Initiative, Department of Western Diversification

Larry Milligan, M.D., Vice-President (Research) and Former Chair

Boehringer Inglheim

Nancy Baines

Bracebridge Muskoka Hospital

Michelle Boivin, Traditional Chinese Medicine Student

Canadian Academy of Chinese Traditional Health Science, Shanghaï University of Traditional Chinese Medicine

Jai Li, M.D.

Peng Li

Chinese Medicine and Acupuncture Association of Canada — Wednesday, April 22, 1998

Cedric Cheung, President

Healing Arts Centre

James Fitzpatrick

Homewood Health Centre Inc.

William Wilkerson, Patient

Institute of Traditional Chinese Herbal Medicine

David Bray, M.D.

Marilou's Health and Bulk Foods

Walter Sawchuk

National Coalition for Health Freedom

Miriam Hawkins

Natural Affairs Action Group

Robert McMaster, Executive Director

Ontario College of Family Physicians

Ralph Masi, President

Thuna Herbals

Roger Lewis

Toronto Hospital

Richard Johnson, Registered Nurse

Toronto School of Traditional Chinese Medicine

Mohammad Javaherian, Instructor

Jeff McMackin, Traditional Chinese Medicine Student

Mary Wu, Director

As Individuals

Green, Jerry

Holmes, Barry

Lender, Ted

Leung, Kevin

Lofquist, Bruce — Wednesday, April 22, 1998

Luheng, Han, M.D., Traditional Chinese Medicine Practitioner

Association de médecine chinoise et d'acupuncture du Québec — Monday, April 27, 1998

Xie Zhi Ang, Executive Director

Yu Guang Sheng, Vice-President

Stephen Hui Chun Kee, President

Wong Shi Wing, Vice-President

Association des diplômés en naturopathie

Nicole Renaud, President and Naturopath

Association of Quebec Chinese Herbalists

Mieu Tu Huynh

Shao Li Ping

Ing Dan Tran, President

Robert Wong

Eel River Bar

Gordon LaBillois, Band Manager

Gilles Soucy, Coordinator — Heritage Gardens

Immunotec Research Ltd.

G. Bounous

Chuck Roberts, President

Institut de pharmacopée chinoise

Arlette Rouleau, President and Acupunctor

Luc Martineau, Vice-President and Acupunctor

Mannatech Incorporated

Mark Perlstein

National Health Products Association

André Aubé, President, *Les produits naturels Magistral Inc.*

Guy Bohémier, Naturopath and Consultant

André Gagnon, President (ANPS) & Executive Vice-President, *Santé naturelle (AG) Inc.*

André Lavallée, Executive Director, *Le naturiste JMB Inc.*

Lise Lefebvre, Director, Yves Ponroy Canada Inc.

Denise Poirier, President, *Robert et Fils Inc.*

Roger St-Laurent, President, *Laboratoire du St-Laurent E.H. Ltée*

Monday, April 27, 1998

Syndicat professionnel des acupuncteurs et acupunctrices du Québec

Luc Martineau, Vice-President, Information/Training

Luce Prévost, Treasurer

Syndicat professionnel des homéopathes du Québec

Claudine Larocque, President and Homeopath

Florent Tremblay, Vice-President and Homeopath

As Individual

Yves Roy

Advisory Panel on Natural Health Products — Wednesday, May 13, 1998

Frank Chandler, M.D., Chair

André Gagnon, Member, National Association for Natural Health Products

William LaValley, M.D., Founding President, Canadian Complementary Medical Association

Mary Wu, M.D., Director, Toronto School of Traditional Chinese Medicine

Chemicals and Non-Prescription Drug Branch (Australia) — Thursday, May 14, 1998

Laurayne Bowler, Acting Director

Health Canada

Ron Burke, Acting Director, Bureau of Food Regulatory, Interagency and Intergovernmental Affairs, Food Directorate

Margaret Cheney, Chief, Nutrition Evaluation Division, Food Directorate

Harry Conacher, Acting Director, Bureau of Chemical Safety, Food Directorate

Dann Michols, Director General, Therapeutic Products Program

Medicines Control Agency (United Kingdom)

Richard Woodfield, Group Manager

Federal Institute for Drugs and Medical Devices (Germany) — Thursday, May 14, 1998

Konstantin Keller, Director

APPENDIX B
LIST OF BRIEFS

Agence du Médicament, Mission des Affaires Européennes et Internationales, France
Brunitière, J. R., Director

Ahmadiyya Movement in Islam, Canada
Mahdi, Naseem

Bioforce Canada Inc.
Grieb, B. Sc., Victoria, Product Manager, Regulatory Affairs

European Agency for the Evaluation of Medicinal Products (EMEA), United Kingdom
Harvey, Martin, Administrator

Heart Productions
Ellingson, Cori

Medical Products Agency, Sweden
Finne Grahnén, Anita, Director of Operations

Nova Scotia Herbalist Association
Taylor, Mark, Acting Secretary

Ordre professionnel des diététistes du Québec
Gougeon, Réjeanne, President and Committee Member in the Treatment of Obesity

Quebec Consumer Protection Bureau
Fontaine, Nicole, President

Toronto School of Homeopathic Medicine
Edge, Raymond, School Director

Viv-Herbes
Forget, Alain

Working Party on Chinese Medicine, Hong Kong

As Individuals
Ainsworth, Larry
Anderson, Jill
Baxter, Lance
Bédard, M.
Bishop, Roy
Bourdon-Lussier, Carmen

Brummet, Lillian
Cloutier, Geneviève
Corcoran, Susan
Couture, Bernadette
Davidson, Micheline
Dietrich, Bill
Dietrich, Cindy
Greve, Sharon
Haddy, Ann
Hanson, Ann
Helsing, Fran
Klein, Esther
L'Espérance, Gisèle
Laporte, Christine
Lauser, Marla
Laval, Celia
Lexow, Kjell
McCutcheon, M.D., A.R.
McLaughlin, Nora
Michon, Sébastien
Nosel, Miloslav
Perrin, Carol
Quinn, Frank
Rea, M.D., Rev. R.E.
Rona, M.D., Zoltan
Schneider, Anny
Scott, Tammy
Sheils, Louise
Shellian-Frey, S.
Smith, Carole
Steckle, Paul, M.P.

LIST OF RECOMMENDATIONS

Definitions

1) Health Canada, in conjunction with a new separate NHP Expert Advisory Committee, set out an appropriate definition of NHPs and amend the Food and Drugs Act accordingly.
2) Health Canada, in conjunction with the new NHP Expert Advisory Committee, examine the status of bulk herbs for legislative purposes.

Expertise and Regulatory Structure

3) The Government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch.
4) The structure for this new regulatory authority be established within the next six months and be permanently staffed by individuals with expertise and experience in the field of NHPs.
5) The selection of personnel be agreeable to both government and NHP stakeholders.
6) When necessary, working groups reflecting the various segments that make up the NHP category be set up to advise the new regulatory authority.
7) All relevant inspection personnel be provided with training specific to NHPs.
8) The necessary process to amend the Food and Drugs Act not delay in any way the implementation of the regulatory and administrative changes that can proceed at this time.
9) An Expert Advisory Committee be established immediately to assist Health Canada in the general and specific tasks necessary to design a new NHP regulatory environment.
10) This Expert Advisory Committee review the re-establishment options for an NHP section with research and laboratory capacities and report its findings to Health Canada.
11) The selection of members for the Expert Advisory Committee be agreeable to both NHP stakeholders and Health Canada.

Safety

12) The new regulatory authority assume primary responsibility for assessing safety of products.
13) General safety protocols be developed by the Expert Advisory Committee based on EAC judgements of reasonable evidence.
14) When necessary, this regulatory authority establish appropriate working groups to assess the safety of specific products.

Quality/Good Manufacturing Practices

15) Health Canada, in collaboration with the NHP industry, establish appropriate GMP guidelines reflective of the different nature of NHPs.
16) GMP standards for NHPs include specific quality control and testing for herbal products.
17) Manufacturers, packagers, importers and distributors of NHPs, whether located in Canada or abroad, be obliged to hold valid establishment licenses.

18) Inspection activities be performed consistently and on a regular basis by inspectors knowledgeable about the products.

Efficacy

19) NHPs be allowed to make health claims, including structure-function claims, risk-reduction claims and treatment claims.
20) Claims be assessed to ensure that there is reasonable evidence supporting the claim.
21) The evidence not be limited to double blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence.
22) The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims.
23) The label indicates clearly the type of evidence used to support the claim.

Product Licensing

24) The new product licensing framework be based on a risk management approach that emphasizes the margin of safety associated with a particular product.
25) Health Canada, in conjunction with the Expert Advisory Committee, establish categories within the NHP class to determine what level of regulation is appropriate for a particular product.
26) A product licensing system based on monographs be used when they are available. Such a system should rely on a pre-market approval process and the regulator should have a short period of time (for example, 30 days) to review the application.
27) Health Canada, in conjunction with the Expert Advisory Committee, establish procedures to create new Canadian monographs based on work already accomplished in other countries.
28) Manufacturers of products that do not have monographs be required to provide evidence to Health Canada before a product is marketed. The level of evidence would be consistent with the margin of safety associated with the product.
29) The level of post-market monitoring be based on the margin of safety associated with the product and include an NHP adverse event reporting system for industry and an adverse reaction hotline for practitioners and the general public.
30) Certain lower safety products be made available to consumers with appropriate warnings and other lower safety products only be made available with practitioner intervention.
31) The new framework be phased in over a period of months to allow sufficient time for the stakeholders and the regulator to review the current DIN system and conform to the new regulations.

Labelling

32) Health Canada consult with its new separate NHP Expert Advisory Committee to determine what information is to be included on the labelling, consisting of, at a minimum, the items recommended by the Advisory Panel on Natural Health Products.
33) NHP labelling provide consumers with all relevant information needed to make informed choices.

34) NHP labelling be standardized to provide clear and consistent product information.

Section 3 and Schedule A of the Food and Drugs Act

35) Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulation from the broad terms found in Schedule A.
36) Health Canada, subsequently, conduct a study with the participation of representatives from consumer groups, the food, natural health products and pharmaceutical industries, and health practitioners to determine whether subsections 3(1) and (2) of the Food and Drugs Act or all of the diseases listed in Schedule A should be deleted.

Importation of Human-Use Drugs for Personal Use

37) When the new regulatory framework is implemented, the personal importation policy be reviewed by Health Canada and the Expert Advisory Committee to determine if it is still appropriate and to outline permissible changes.

Cost Recovery

38) Health Canada conduct a review analysing the impact of the overall cost recovery policy on the different segments of the NHP industry.
39) The NHP industry stakeholders be consulted in the establishment of the most appropriate fee structure and amount.
40) As a result of this review, the existing fee levels be re-examined if necessary.

Appeal Process

41) As part of the immediate process for NHPs, Health Canada work with stakeholders to establish appropriate, accessible and effective appeal processes for relevant policies and possible inclusion into a revised regulatory and legislative framework.

Informed Choice

42) Health Canada immediately utilise existing formats and forums for more open and transparent communication on NHPs with the broader public and practitioners.
43) Communication efforts include details about decisions and actions regarding NHP products (removal from market, change of status, etc.).
44) Relevant consumer, industry and practitioner groups be consulted on a regular basis about the nature of the required information.
45) The federal government research bodies, including Health Canada, begin immediately to encourage research on NHPs. This could include studies focusing on the interactions of herbal products with conventional medications as well as studies that explore different uses by various groups in Canada.

46) Health Canada undertake, through its various established avenues, the dissemination of the resulting information to health care professionals and consumers.

NHP Practitioners

47) Health Canada inform its provincial and territorial counterparts of the regulatory changes with regard to NHPs and of the concerns raised by practitioners.

Enforcement

48) The new regulatory framework for NHPs be enforced in a regular and consistent manner and done in conjunction with education.
49) Sufficient resources be provided for enforcement activities.

Aboriginal Healers

50) If a product that is extemporaneously compounded for a particular person is not exempted from the regulatory framework, that such a product be exempted.

Plant Conservation

51) Health Canada work with Foreign Affairs and International Trade to ensure that existing International Agreements that currently protect biological diversity are not violated and that additional strategies are developed if needed to prevent depletion of these valuable health resources.

Transition

52) The interim enforcement policy regarding NHPs continue to be applied until the new framework is in place.
53) The Minister appoint, immediately, a transition team responsible for ensuring that the new framework is established quickly.

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the Government provide a comprehensive response to this Report.

A copy of the relevant Minutes of Proceedings of the Standing Committee on Health (Meetings Nos. 5 to 51 which includes this Report) is tabled.

Respectfully submitted,

Joseph Volpe,
Chair

MINORITY REPORT TO THE HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH

The Reform Party of Canada
Official Opposition

Grant Hill, MP
(Macleod)

Reed Elley, MP
(Nanaimo-Cowichan)

Maurice Vellacott, MP
(Wanuskewin)

October 27, 1998

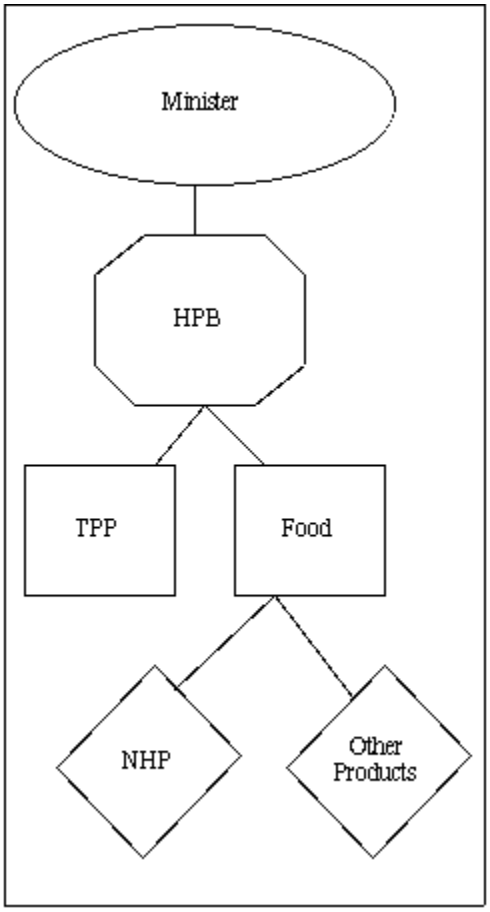
The Reform Party of Canada wishes to thank everybody who participated in the Standing Committee on Health's review of natural health products (NHPs). As a consistent national political voice for the millions of Canadians demanding freedom of choice over NHPs, the Reform party has been fully supportive of this standing committee initiative. However, while buoyed to some degree by some positive aspects of the standing committee's Final Report, as a result of the inadequate degree to which the central issue of Canadians' freedom of choice is addressed, Reform was compelled to submit this committee Minority Report.

Notwithstanding Reform's inability to support the Final Report, there are a number of key positive recommendations that Reform feels deserve attention:

- Creation of an NHP Advisory Panel to allow input from experts who are professionally involved with NHPs
- Recognition of the need for improved labelling of products
- Recognition of the need to question the existence of FDA Schedule `A'
- Creation of an open, accountable appeals process
- Training of inspectors/enforcement officers on NHPs

In the final analysis, however, the committee's overall report recommends a continuation of the existing situation of a paternal federal government that must protect Canadians from the unknown evils of NHPs. This is inconsistent with Canadians' experience that shows overwhelmingly an incredibly safe historical pattern of use of NHPs. As for the introduction of new, untried products, Reform believes regulators have a higher duty to review the data that the product sponsor brings forth. But regulators should only be refusing to grant compliance for products based on sound scientific reasons - reasons that should be clearly demonstrated. And let not partisan rhetoric take away from Reform's overriding concern: **public safety must always be the first priority**.

Canadians universally recognize NHPs as basically foods - certainly not as drugs - especially when consumed in the dosage and form recommended. The existingoveremphasis on government control, licensing and regulation of mostly benign consumer products could be greatly simplified.



In fact, Reform recommends an organization structure for regulating NHPs such as that protrayed in the adjacent model. By regulating NHPs under the purview of Health Canada's Food Directorate, Reform believes we could ensure that these substances are viewed within the culture most familiar to them and thereby never again fall victim to the intimidating practises and procedures of the Drugs Directorate (TPP). And while it has been suggested that such a structure would lend NHPs to potential policy conflict with CODEX Alimentarius, Reform firmly disagrees. Regardless of CODEX policy, Canadian domestic law (such as the Food and Drugs Act and Regulations) reigns supreme over international policy recommendations. Further, while Reform has not been supportive of numerous Codex proposals dealing with NHPs, the debate over Codex must take place as a separate issue.

Consistent with the paternal theme in the Final Report is the committee's recommendation for more resources for NHP enforcement purposes. Recommending that existing enforcement personnel receive adequate NHP training is laudable. But recommending more enforcement personnel for NHPs simply contradicts every principle Canadians demanding this NHP review have articulated. Like most Canadians, Reform frankly believes there are already too many enforcement personnel barging into mom and pop health food stores with RCMP escort, seizing computers and raiding store shelves for packets of harmless melatonin or stevia (an herb traditionally used as a natural sweetener). Surely the Government of Canada has more important things on which to spend taxpayer's money. Yet, under cost recovery for the new NHP products, the government will extract more taxpayer money. Inevitably, with such a committee recommendation, NHP consumers will sadly end up paying more for their products.

Finally, a policy which has always been very confusing and frustrating, particularly to consumers and businesses, is what is commonly referred to as the personal importation policy. It says that while Canadians can not buy or

sell NHPs that are not approved in Canada, they can nonetheless go to the US, buy enough for personal use from US businesses and import the product back to Canada. Such a policy clearly fails any rational analysis. As such, Reform would repeal this so that all NHPs that are available by importation would necessarily be available for purchase in Canada.

The Standing Committee on Health's review of NHPs was long overdue. Evidence of that is the mountain of mail Members of Parliament received from angry constituents. In the Reform party's view, Canadians were expressing their disdain for the shackles of Ottawa bureaucracy, arbitrarily, irrationally impeding their access to safe, harmless preventive health products which also happened to be growing exponentially in demand. The answer Canadians were looking for from the standing committee's review is that the federal government must assure consumer's freedom of choice. While Reform is optimistic the recommendations contained in the Final Report move in the right direction, Reform still believes Canadians deserve, and will continue to demand, much more freedom of choice over NHPs. ***Reform believes an informed Canadian consumer will always be a better judge of what is best for them and their loved ones than some distant bureaucrat in Ottawa.***

NATURAL HEALTH PRODUCTS: A TIME FOR ACTION

MINORITY REPORT - NEW DEMOCRATIC PARTY SUBMITTED BY JUDY WASYLYCIA-LEIS, M.P. - WINNIPEG NORTH CENTRE

The response by Canadians to the parliamentary study on natural health products has been overwhelming. The NDP is deeply grateful to the hundreds of individuals and organizations who took the time and effort to make their views known. Together, the input, advice and feedback constitute an important body of research for pursuing wellness, disease prevention and holistic approaches to health care. Underlying it is a clear sense of responsibility for individual and community well-being and a positive force for change.

The NDP is committed to reasonable access to herbal products and natural health care alternatives. In the last Parliament we spoke out strongly against the Liberal government's moves to reclassify many herbs as drugs, to implement cost-recovery programs which impose huge fee increases on natural health products, and against international attempts at the Codex Commission to restrict access to nutritional supplements. We joined with concerned citizens and succeeded in achieving a moratorium on those restrictions.

Canadians want access to natural health products at affordable prices. They want their government to play a pro-active role to ensure safety and quality and in advancing research and knowledge about natural health alternatives. After a year of consultations and citizen participation, this report falls short of Canadians' expectations and leaves many unanswered questions. Many important issues have been left to an Expert Advisory Committee in conjunction with Health Canada, including such basic matters as the definition of natural health products, the criteria by which products will be judged, and whether an in-house research laboratory will be re-established. It is equally disturbing that the matter of regulating natural health products has been included in the three-year review of the Health Protection Branch and the 11 pieces of legislation which relate to this government function.

A central issue to the development of an appropriate regulatory framework was the Health Protection Branch itself. Time and time again, participants expressed lack of confidence in the ability of this branch to regulate in a fair and balanced way. The concerns expressed include:

- the loss of the NHP Research Laboratory;
- elimination of the Drug Research Bureau;
- attempts to gut the Food Research Lab;
- threats and intimidation of scientists;
- the cost-recovery policy;
- influence of the pharmaceutical industry;
- a double standard for drugs and natural health products;
- a general lack of openness, consistency and accountability.

Such widespread and deeply felt lack of trust in the very branch of government that must implement the regulation of natural health products makes it difficult - if not impossible - to move forward. Establishing a new regulatory authority to handle natural health products and opening up the Food and Drug Act in the midst of this crisis is potentially dangerous and could further jeopardize Canada's already troubled health protection system. Measures must be taken immediately to address the crisis of confidence in the Health Protection Branch and to respect the expressed wishes of Canadians concerned about freedom of choice and access to natural health products.

The NDP makes the following recommendations for immediate action:

1. Public investigation into the Health Protection Branch

There is a long and growing litany of damaging and questionable practices at the Health Protection Branch:

- breast implants and blood safety are both under criminal investigation;
- 70% of the drug approval process is paid for by the pharmaceutical industry;
- sworn testimony from scientists about gag orders and pressure to approve bovine growth hormone;
- a pattern of inconsistency and secrecy in the treatment of natural health products.

Because of deep and extensive cuts and increased reliance on data and funds provided by the pharmaceutical industry, the Health Protection Branch may no longer have the resources or the independence to regulate in a fair and balanced way. A full, independent, public investigation into the branch is needed in order to ensure the critical role of health protection is restored, and the foundation in place for open and meaningful approaches to natural health products.

2. Immediate re-establishment of a natural products research laboratory

The government must immediately address the overriding concern of Canadians for quality and safety of natural health products. The cancellation in 1991 of research and laboratory capacity in natural health products has destroyed our reputation as one of the most progressive and scientifically informed countries in the world. All efforts to ensure the identity and quality of herbal products on the market have stopped. No program for assessment of commercial plant products exists, nor is there now an experienced and knowledgeable body of scientists to do the work of assurance of botanical identity, purity, quality and strength. An in-house capacity for independent research must be re-established to assure Canadians that the products have not been contaminated with pesticides, adulterated with other herbs, subject to substitution with an inferior species of herb, or simply lack the active ingredient.

3. Ensure what's on the label is what's in the bottle

Complimentary to the establishment of a natural health products laboratory is the enforcement of provisions which currently exist in the Food and Drug Act. Section 4 of the Act makes it an offence to sell any food that is poisonous, harmful, adulterated, unfit for human consumption or prepared under unsanitary conditions. Section 5 makes it an offence to label, package, process, sell or advertise any food in a manner that is false, misleading or deceptive. A pro-active and constructive role by the Health Protection Branch should include the random testing of natural health products at the wholesale level on an organized basis, enforcing measures that already exist in law.

4. Information, education and recognition

Overwhelmingly, participants in the Health Committee consultations were interested in sharing the knowledge they had gained through personal struggle with illness and disease or their pursuit of a more holistic approach to

well-being based on the importance of body, mind and spirit in health. In the spirit of this conviction, we recommend:

- A National Institute on Alternative Health Care to conduct in-depth research into the benefits of alternative health care and the integration of traditional and non-traditional approaches to wellness and disease prevention;
- Acknowledgement of the contribution and experience of health care professionals including homeopaths, naturopaths, herbalists, traditional Chinese and Ayurvedic practitioners, and Aboriginal healers and initiate discussions with the provinces and territories about professional recognition and educational possibilities;
- Leadership internationally to ensure the development and marketing of natural health products based on rights of indigenous peoples and environmental standards.

MINUTES OF PROCEEDINGS

TUESDAY, OCTOBER 27, 1998
(Meeting No. 50)

[Text]

The Standing Committee on Health met *in camera* at 9:10 a.m. this day, in Room 371, West Block, the Chair, Joseph Volpe, presiding.

Members of the Committee present: Elinor Caplan, Aileen Carroll, Reed Elley, Grant Hill, Ovid Jackson, Maria Minna, Robert D. Nault, Pauline Picard, Judy Wasylycia-Leis.

Acting Member present: Lynn Myers for Rose-Marie Ur.

In attendance: From the Parliamentary Research Branch: Nancy Miller Chenier and Gérald Lafrenière, Research Officers.

Pursuant to Standing Order 108(2), the Committee resumed consideration of natural health products. (*See Minutes of Proceedings dated Thursday, November 20, 1997*.)

The Committee continued its consideration of a draft report.

At 10:25 o'clock a.m. the sitting was suspended.

At 10:35 o'clock a.m. the sitting resumed.

It was agreed, - That, pursuant to Standing Order 108(1)(*a*), the Committee authorize the printing of dissenting opinions of the Reform and New Democratic parties in this Report immediately after the signature of the Chair, that they be limited to not more than three pages, and delivered in both official languages, to the Clerk of the Committee by 5:00 o'clock p.m. on Thursday, October 29, 1998.

At 11:45 a.m., the Committee adjourned to the call of the Chair.

WEDNESDAY, OCTOBER 28, 1998
(Meeting No. 51)

The Standing Committee on Health met *in camera* at 3:40 p.m. this day, in Room 701, La Promenade Building, the Chair, Joseph Volpe, presiding.

Members of the Committee present: Elinor Caplan, Aileen Carroll, Grant Hill, Dan McTeague, Robert D. Nault, Denis Paradis, Pauline Picard, Joseph Volpe, Judy Wasylycia-Leis.

In attendance: From the Parliamentary Research Branch: Nancy Miller Chenier and Gérald Lafrenière, Research Officers.

Pursuant to Standing Order 108(2), the Committee resumed consideration of natural health products. (*See Minutes of Proceedings dated Thursday, November 20, 1997*.)

The Committee continued its consideration of a draft Report.

It was agreed, - That the draft Report, as amended, be adopted as the Committee's Second Report to the House and that the Chairman be instructed to present it to the House.

It was agreed, - That the title of the Report be "Natural Health Products: A New Vision".

It was agreed, - That the Chair be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the draft Report.

It was agreed, - That the Committee print 2,500 copies of its Second Report in tumble bilingual format with a distinctive cover.

It was agreed, - That, pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to the Report within one hundred and fifty (150) days.

It was agreed, - That members would have until 5:00 o'clock p.m. on Thursday October 29, 1998 to submit their editorial changes to the Report to the Clerk of the Committee.

At 3:55 the Committee proceeded to consider its future business.

It was agreed, - That the Committee would begin consideration of Bill C-42, An Act to amend the Tobacco Act, on Thursday October 29, 1998.

At 4:10 p.m., the Committee adjourned to the call of the Chair.

Marie Danielle Vachon
Clerk of the Committee