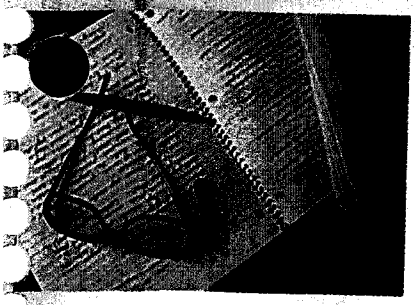
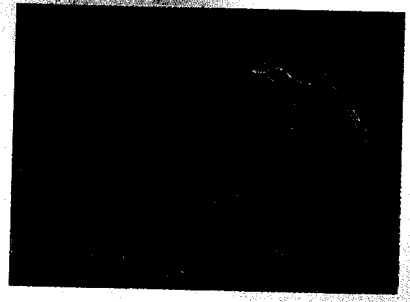
A Fresh Start

Final Report of the ONHP Transition Team

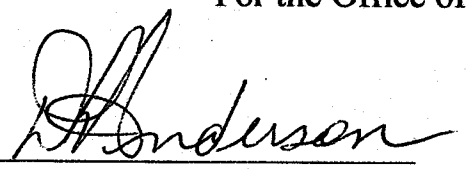

A Fresh Start:
Final Report of the ONHP Transition Team

Presented to
The Honourable Allan Rock, PC, MP
Minister of Health
Government of Canada

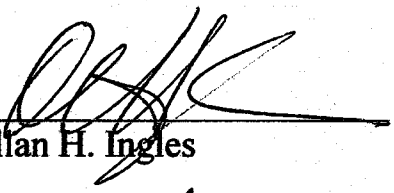
Presented by
The Transition Team
Office of Natural Health Products

March 31, 2000

Respectfully submitted by the Transition Team
For the Office of Natural Health Products

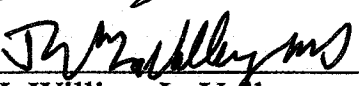


Mr. Del Anderson

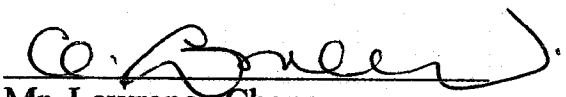


Mr. Allan H. Ingles

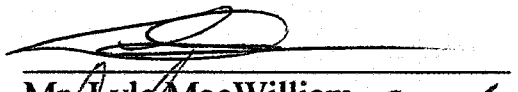
Dr. Peter Chan



Dr. J. William LaValley

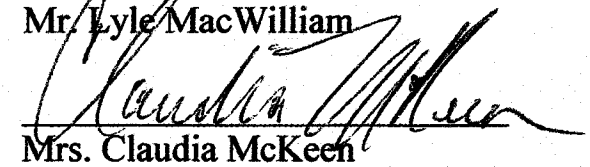


Mr. Lawrence Cheng

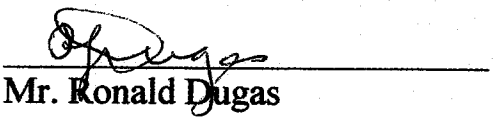


Mr. Lyle MacWilliam

Ms. Valerie Dugale

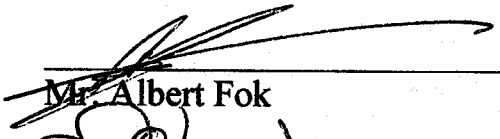


Mrs. Claudia McKeen

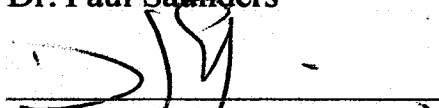


Mr. Ronald Dugas

Dr. Paul Saunders, PhD, ND, DNANP



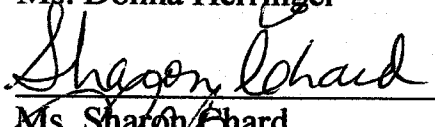
Mr. Albert Fok



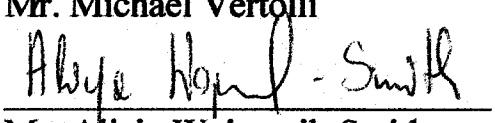
Mr. David Skinner

Ms. Donna Herringer

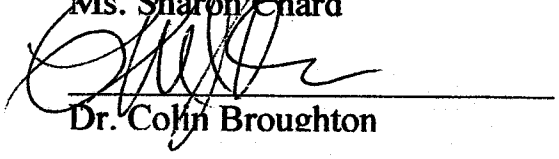
Mr. Michael Vertolli



Ms. Sharon Chard



Ms. Alicja Wojewnik-Smith



Dr. Colin Broughton

March 31 2000

Executive Summary

On March 26, 1999, the Minister of Health, the Honourable Allan Rock, announced the Government's acceptance of all 53 recommendations made by the Standing Committee on Health in its 1998 report on natural health products.[1] In accordance with the Standing Committee's report, the Minister acted to initiate the creation of a new Office of Natural Health Products (ONHP) under the direction of the Assistant Deputy Minister, Health Protection Branch. In addition, the Minister announced the creation of an ONHP Transition Team to ensure an appropriate process to build public confidence in a new approach to the regulation of natural health products (NHPs).

The mandate of the ONHP Transition Team was to structure an administrative and regulatory framework and identify broad policy directions to assist Health Canada in implementing the 53 recommendations made by the Standing Committee on Health in its landmark report.

Since its inception, the Team has made substantive progress in conceptualizing and delineating an operational framework for the newly created office. During the process, the Team moved forward on a number of fronts. The task has been both provocative and rewarding. Throughout the process, the Team has been guided by the 53 recommendations as presented by the Parliamentary Standing Committee on Health and accepted by the Government.

The following recommendations are the embodiment of almost ten months of creative effort of the ONHP Transition Team, submitted for the Minister's consideration. They lay the foundation for a fresh start in the regulation of natural health products in Canada. Hopefully, they also will act as a catalyst in helping to move Canada toward a more pro-active, holistic health care paradigm.

Creating the Vision

1. **Mission Statement:** The mission of the Office of Natural Health Products is to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

2. **Vision Statement:** The new Office of Natural Health Products shall be:

    a) acknowledged as the national authority for the regulation of natural health products used in Canada;
    b) recognized worldwide as a leader in natural health product regulation;
    c) a leading national and international partner in the management of natural health products; and,

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1 *Natural Health Products: A New Vision.* Report of the Standing Committee on Health, November 1998.

d) the vehicle for Health Canada to create and maintain an innovative regulatory environment, based on a wellness model that will set a global standard in natural health product regulation.

Organizational Structure

3. **Organizational Structure:** The organizational structure of the ONHP, including the Executive Director, Director of Policy and Regulatory Affairs, Director of Research and Development, Director of Outreach and Communications, and Director of Product Regulation, as outlined in Sections 2.1 to 2.5 of the report, be accepted as proposed.

4. **Field Inspectors:** The ONHP should ensure that field inspectors carrying out the duties of the Office are trained and knowledgeable about NHPs and that inspection duties are performed consistently and on a regular basis to ensure uniform enforcement of regulations across the country.

5. **Expert Advisory Committee:** The mandate and structure of the Expert Advisory Committee (EAC), as outlined in Section 2.6 of the report, be accepted as proposed.

6. **Transition Advisory Team:** A sub-group of four to five ONHP Transition Team members, with a quorum being three members, should be retained on an interim basis to serve as a Transition Advisory Team (TAT). The TAT should be assembled at the call of, and report to, the Executive Director. The TAT should provide ongoing advice and counsel to help ensure that the vision and intent of the Standing Committee and ONHP Transition Team recommendations continue to be reflected in the new Office and operational framework. While travel and accommodation expenses should be paid, members should not receive any remuneration for their counsel.

7. **Ongoing Consumer Representation:** Upon the winding down of the TAT, the Executive Director should ensure that a consumer representative, having strong knowledge in and experience with NHPs, be appointed to the EAC.

8. **Management of NHPs within HPB:** The Assistant Deputy Minister, Health Protection Branch (HPB), should:

    a) play a strong role in coordinating the policy and regulatory activities of the Branch's various regulatory units with respect to NHPs;
    b) ensure that such policy and regulatory activities do not result in duplication and/or inconsistent regulation; and,
    c) immediately begin to coordinate regulatory activities based on the leadership provided by the ONHP.

9. **Interim Management Strategy:** In the interim and until such time as the regulatory framework is fully implemented, Health Protection Branch (HPB) immediately implement an Interim Management Policy for the current regulation of NHPs. This policy should include the following:

a) the ONHP Executive Director should be the level of interim management contact and decision making;
b) all matters of regulatory action on NHPs (or those products deemed NHPs under the ONHP's working definition) proposed by any HPB Directorate or other branch of Health Canada should be undertaken through the ONHP; and,
c) all regulatory decisions and actions should be conducted in an open manner and reported with full explanatory communications to all stakeholders and the Canadian public in a timely fashion.

Regulatory Framework

10. **Working Definition of a Natural Health Product:** The ONHP and Health Canada should work toward appropriate legislative or regulatory change to ensure that the legal interpretation of natural health products (NHPs) clearly differentiates these products from foods and pharmaceuticals.

11. **Site Licensing:** The specified criteria deemed essential for an effective ONHP site licensing program, as outlined in Section 3.2.1 of the report, be adopted as proposed.

12. **Importation for Personal Use:** The ONHP, in conjunction with Health Canada's Legislative Renewal Initiative, develop a regulatory provision which clarifies the reasonable grounds respecting the importation of NHPs for personal use.

13. **Product Licensing – Guiding Principles:** The Guiding Principles for developing a product licensing system, as outlined in Section 3.2.2(a) of this report, be adopted as proposed.

14. **Product Licensing – Establishing Safety, Quality and Claim:** The ONHP should adopt a process for product licensing which relies on two basic methods for establishing the safety, quality and claim of products:

    a) the use of available evidence, including non-attestable monographs, on a product-by-product review and assessment process; and,
    b) the use of ONHP-approved attestable monographs against which lower risk product applications can be audited.

15. **Product Licensing – Monographs:** Monographs should be subject to a process of regular review, update, revision and assessment of risk.

16. **Lower Risk Products with Attestable Monographs:** The ONHP should adopt an approach to optimizing the use of ONHP-approved attestable monographs which has, as its initial approach, a pre-market audit process with a 45 calendar day limit on government response to the application.

17. **Lower Risk Products – Post-Market Notification Trial Project:** Within three years of the coming into force of the new regulations, the ONHP should move to further optimize the monograph system. Specifically, a trial project utilizing a post-marketing notification

approach to product registration should be implemented and evaluated for a limited number of ONHP-approved attestable monographs. If successful, the ONHP could further expand the use of such a post-market system.

18. **Lower Risk Products without Attestable Monographs:** For lower risk products without ONHP-approved attestable monographs, the provision of acceptable evidence, consistent with the margin of safety of the product, should be required for assessment of the product by ONHP.

19. **Higher Risk Products:** For higher risk products, performance standards for the review and assessment of submissions should be set in consultation with stakeholders.

20. **Cancellation of Product License:** The conditions under which the Executive Director may cancel licenses need to be set out in regulations. Product recall, product seizure and other compliance activities should be available to the Director and subject to a timely appeal process by the marketer.

21. **Public Registry:** A public registry of all ONHP registered products, that is easily accessible by the public and stakeholders, should be established; the registry should include the product name, active ingredients, registration number and company name for each product.

22. **Electronic Submissions:** An electronic submission system should be established for all product reviews, and in the case of products for which there is an ONHP-approved attestable monograph, an electronic submission and review system for abbreviated assessments (or audits) should be developed.

23. **Good Manufacturing Processes:** The ONHP begin consultation with manufacturers, packagers and importers to develop the specific regulatory requirements and guidelines for good manufacturing practices (GMPs) of natural health products, which will assist inspection and compliance to GMP regulations.

24. **Standards of Evidence:**

    a) The evidence to support the safety and claim of a product must not be limited to double blind clinical trials, but may also include other types of evidence, such as generally accepted and traditional references, published monographs, expert opinion reports, other types of clinical trials and other clinical or scientific evidence;
    b) the ONHP, with the assistance of the EAC, should establish a list of acceptable references, develop the criteria for ONHP-approved monographs and develop criteria for linking levels of evidence to health claim validity; and,
    c) claim approval by the ONHP, on the basis of scientific evidence, should be allowed to be applied to other products, with supportive scientific evidence of at least an equal level of claim assessment.

25. **Administrative Lists:** The ONHP develop an administrative list of NHP categories based on the proposed working definition. The list should include broad categories of products, such as those set out in the working definition, and there should be flexibility in the inclusion of products in the list and a means to amend such a list. Monographs for products