WHY CANADA NEEDS A NATURAL HEALTH PRODUCTS ACT

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Position Paper

About the Author

From 1997 to 2004, J.William LaValley MD was appointed to and actively participated in three major federally appointed natural health product advisory bodies (the Advisory Panel on Natural Health Products, the Office of Natural Health Products Transition Team and the NHPD Expert Advisory Committee). Dr. LaValley is the founder and Chair (since 1994) of the Complementary Medicine Section of Doctors Nova Scotia within the Canadian Medical Association. Dr. LaValley is a fully licensed phy sician in the US and in Canada for over 20 years. Dr. LaValley practices Integrative and Complementary Medicine in Chester, Nova Scotia and Austin, Texas. He is a physician and researcher whose current work includes emphasis on molecular biological evidence-based integration of conventional medicine and complementary medicine in the treatment of patients with various cancers and other major chronic diseases.

NHPs- A Canadian Solution

Amend the Bill. Kill the Bill. Canadian consumers and manufacturers o f natural health products (NHPs) are greatly concerned about a recently proposed piece of legislation titled Bill C -51. Bill C-51 would create significant changes to the existing Food & Drug Act, which in turn may affect future access to NHPs in Canada. Within the NHP industry there is mounting concern over government's perceived inability to deal with a massive backlog of unlicensed products thereby threatening greater consumer access to safe NHPs. Concurrently, debate is raging about government -imposed requirements for NHPs standards of evidence to in -effect "pharmaceuticalize" NHPs, requirements which far exceed what Canadians originally asked for - and expected - when supporting the NHP regulatory process from 1998 until recently.

Bill C-51 places NHP's in the ill-suited and ambiguous position of being regulated as "therapeutic products" under the exact same legislative umbrella as "drugs". Canadians do not want NHPs to be regulated the same as pharmaceuticals. No provision is made to accommodate t he important, unique requirements of NHP regulation. No attention is given to the significant differences recognized by Canadians that make separate *legislation* for NHPs mandatory in Canada.

In addition, if Bill C-51 were to be adopted, a significant po rtion of NHP's may in future fall under the Codex designation of "Nutrition and Foods for Special Dietary Uses" [1]. This Codex committee's recommendations will lead to the imposition of globally harmonized standards of restrictions on availability of NHP's dosages and dosage forms.

Fortunately there exists a reasonable and appropriate solution that permanently ensures NHP product safety and provides greater access to NHP's for Canadian consumers. This solution permits Canada to continue to push forward on the current (Bill C-51) type of legislation for the numerous non -NHP associated reasons that it is really needed. Additionally, where it is appropriate, Canada can further its commitments to 'harmonizing' its Food regulations with other countries and trad e organizations around the world.

NHPs are neither Food nor Drugs

Canadians need a separate Natural Health Products Act (NHP Act). The NHP Act will be separate from the current Food and Drug Act. The new NHP Act will create a separate category *in Legislation* defining NHPs as neither Foods, nor Drugs, nor any category designated in Bill C -51 under the umbrella term of "therapeutic products". Foods and Drugs can remain within Bill C -51. The obvious exception is that all NHPs, as described within the new NHP Act, are removed from Bill C -51, and instead are wholly

governed by the NHP ACT. Ample precedence already exists for removing a category of products from the Food and Drug Act and from Bill C-51 in order to provide separate Legislation for that category of products. Since 1997, the Tobacco Act has specifically governed that category of products by separate legislation. The Tobacco Act is specifically referenced in Bill C-51 as being exempt from the governance of Bill C-51. This interesting precedence provides ample evidence of separate legislating a separate class of products otherwise appropriately included in Bill C-51.

There is another significant reason to remove NHPs from the Food and Drug Act and from Bill C-51.

Codex Alimentarius covers Food standards and "Foods for Special Dietary Uses"

Canada participates in the global Codex Alimentarius Commission that began in the 1960's in order to bring about better safety standards for the world's food supply. Canada has an active national delegation, appointed by government, representing Canada within the Codex Alimentarius Commission. Within this "Codex" organization, there exists a relevant committee with the long-sounding title of '*Codex Committee on Nutrition and Foods for Special Dietary Uses* (CCNFSDU). It is within this CCNFSDU ("Special Dietary Uses Committee") that specific worldwide guidelines are being set for the purpose of harmonizing Food regulations around the world. Interestingly, by the definitions adopted in this committee, certain NHPs in Canada would be recognized as "food supplements" and subject to Codex restrictions.

So, on one hand, NHPs are inappropriately regulated the same as pharmaceuticals. NHPs are even designated the same under the umbrella term "therapeutic products" which specifically includes Drugs. On the other hand, NHPs are included within the Codex Committee designation under the "Nutrition and Foods for Special Dietary Uses" as "food supplements". For clarity it is important that NHPs are defined by separate Legislation as neither Foods (or "food supplements") nor Drugs (as in Bill C-51's "therapeutic products").

Canadians have already recognized this distinction and made extensive recommendations for NHPs.

"Natural Health Products: A New Vision" 53 Recommendations Report in 1998

In 1998, after extensive public and industry stakeholder consultations, the federal Parliamentary Standing Committee on Health produced its long-awaited Report entitled "Natural Health Products: A New Vision". Canadians spoke clearly and with strong agreement. The NHP Report produced 53 Recommendations for the development and maintenance of appropriate, separate Regulation of Natural Health Products. The clear message was heard across Canada – NHPs are neither Foods nor Drugs – and NHPs must be regulated differently, separately and appropriately. The 53 Recommendations were specifically and unanimously adopted across all political parties.

The 53 Recommendation Report provides the framework for the necessary NHP Act legislation. Years of cooperative work developing definitions and standards for regulating NHPs are immediately available for adoption under this new NHP Act legislation. A minor reorganization within Health Canada is necessary to separate and promote the Natural Health Product Directorate (NHPD) to its own separately legislated organization within Health Canada. The Canadian Food Inspection Agency (CFIA) oversees the regulation of food in Canada. The Therapeutic Products Directorate (TPD) can continue to oversee the regulation of "therapeutic products" - except products designated as Natural Health Products in the NHP Act. NHPs will be regulated by an independently legislated NHPD.

The appropriate implementation of the NHP Act will include a rigorous regulatory framework to establish highest standards of Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) within the NHP industry. At the same time it will establish appropriate standards of evidence requirements that recognize and support the unique nature of NHPs. Much of this work has

already been done in the existing NHP Regulations. The most notable exception includes the particular development of a risk-based matrix for standards of evidence requirements appropriate to provide safety and greater access to NHPs for Canadians. Previous NHP committees found hard-won consensus and produced recommendations for appropriate standard of evidence requirements, which were later quietly – and inexplicably - removed from the regulatory framework. The documentation of the risk-based matrix for standards of evidence from these working consensus agreements remains available and can be restored into the NHP Regulatory framework quickly. Canada does not need to reinvent a new framework for the NHP Act. The 53 Recommendation Report remains the foundation for the development of a sound approach to separate legislation for NHPs and will serve as the well-vetted and immediately available template for the NHP Act Legislation and its subsequently developed NHP Regulations.

Why move NHPs out of the Food & Drug Act at all?

The Canadian Food and Drug Act, written in 1953, did not anticipate the needs for separate NHP regulations and thus, by legislative requirement, NHPs have remained technically classified as a subset of Drugs. Recently, a set of regulations was established specifically for NHPs – even though the technical classification as Drugs remains. The 53 Recommendations were to serve as a guide for transitioning from the old status quo of regulating NHPs as pharmaceutical drugs to developing the new, appropriate regulatory framework based on a separate and distinct status of NHPs as neither Foods nor Drugs.

In preparation for implementing the NHP Regulations in 2000 the government established the NHPD within Health Canada. The NHPD has its own budget and staff within Health Canada. From 2000 until 2004, an Expert Advisory Committee (EAC) was appointed to the NHPD to provide guidance and policy recommendations for implementation of the Natural Health Product Regulations.

The work was extensive and diligent. The development of a risk-based matrix model of NHP regulation - categorizing NHPs by degree of safety, by type of health claim, and integrating an appropriate broad spectrum of evidence standards emerged. Rigorous recommendations for implementing Good Manufacturing Practices (GMPs) through development and maintenance of appropriate Standard Operating Procedures (SOPs) were adopted. Canada sought to develop a world-leading role in its comprehensive approach to providing higher safety of and greater access to Natural Health Products. The beginning of a reasonable NHP regulatory system began to take shape.

Unfortunately, progress has been too slow. Far fewer than half of the NHP Report's 53 Recommendations have ever been implemented. Woefully underfunded, understaffed and overworked, the NHPD within Health Canada has labored to implement the NHP Regulations. Generally, the NHP industry has remained supportive of the new regulatory framework despite the inconsistent and slow roll out. However, due to multiple bureaucratic, political and technical reasons, the key issue of adopting reasonable evidence standards appropriate to NHPs has deteriorated into a seemingly insurmountable quagmire. Canadian consumers suffer the result of this bureaucratic morass that now stifles greater access to NHPs and threatens the NHP industry with overwhelming regulatory restrictions – the de facto 'pharmaceuticalization' of NHPs.

Fortunately, a robust, viable legislative solution exists – create a separate NHP Act. Reasonable regulatory options exist in the current appropriate Natural Health Product Regulations. Canada must create a separate Natural Health Products Act based on the 53 Recommendations, providing requirements for GMPs, SOPs, and reasonable evidentiary criteria for the diverse health claims appropriate to the nature of natural health products.

The impediment of ambiguous and contentious "evidence standards" has been bubblin g in the background since the very first discussions in 1997 about designating NHPs within the Food and Drug Act. This issue is unlikely to be solved within the current drug -regulating paradigm. As long as NHPs are viewed through the same lens as pharma ceutical type drugs, the government will have an almost impossible task accepting them as scientifically valid and licensing them. This is due in part to an entrenched mind set on the part of regulators who appear adverse to change and intolerant of broad er, necessary guidelines of evidence that are not limited only to conventional randomized clinical human trials.

The problem seems to be that the current regulators have little familiarity with the NHP evidence base and/or are disinclined to accept the fact that NHPs are already widely available, have been widely available – and have a far superior record of safety when compared to pharmaceutical drug adverse reactions. It is important to provide appropriate standards of evidence to adequately support claims made for NHPs. This evidence base should, and does, range from double -blind placebo-controlled crossover randomized clinical trial all the way to traditional claims within culturally based healing systems. A large evidence base for NHPs does in fa ct exist. Being unfamiliar with an evidence base does not excuse dismissal or rejection of it. Merely because regulators don't know about or weren't trained in those perspectives does not mean that those regulators have the right to dismiss those evidence standards. This wide spectrum of evidence -based claims cannot be appropriately managed under the Food and Drug Act, or under Bill C -51 or its derivatives.

A Separate NHP Act Provides Better Safety, Greater Access and Improved Information

A separate NHP Act will accommodate all the necessary requirements for appropriate evidence standards providing Canadians with the necessary and appropriate safety of, access to, and information about, NHPs. A separate NHP Act provides the necessary basis for prov iding safe NHPs to Canadians by providing rational and reasonable guidelines based on the relative risk of various NHPs. A separate NHP Act will provide for the appropriate integration and management of the various applicable NHP evidence-base standards to provide Canadians reasonable, appropriate health claim information. A separate NHP Act will provide greater access to NHPs for Canadians through more appropriate and efficient implementation of regulations designed specifically for NHPs. Greater access to safe NHPs provided with reasonable, appropriate information will improve the wellbeing of Canadians who will have greater ability to engage greater responsibility to participate in their own self -care decisions.

In a separate NHP Act, NHPs are perman ently removed from the designation as drugs or as any sub -class of drugs. This allows for the emergence of new approaches in managing NHPs because NHPs are a new, distinct, separate legislatively recognized category of products that are neither Foods nor Drugs, nor conventional "therapeutic products" as in Bill C -51.

Bill C-51 includes all products that make "disease claims" or "treatment claims". Bill C -51 also includes all products that make "structure/function claims". The majority of claims made f or NHPs are in the "structure/function claims" area. Under Bill C -51, NHPs and Drugs are lumped together for any "structure/function claims". This 'pharmaceutical -ization' of NHPs is precisely the reason that Canadians sought new regulations for NHPs ove r a decade ago. In a new, separate NHP Act, Canada can make its own regulations and policies for NHPs that truly reflect the distinct and unique nature of these products. New legislation provides the necessary foundation to establish appropriate natural health product recognition and regulation. Doing so will make Canada a leader in this emerging field.

Under Codex, any product designated as a food or "food supplement" is subject to worldwide harmonization. This harmonized approach will limit access t o products and dosages not approved by the Codex Committee on 'Special Dietary Uses' yet which are already available to consumers for years.

The separate NHP Act will clearly define NHPs as non-foods and thus not "food supplements" and therefore not subject to the Codex Alimentarius Commission's externally imposed limitations.

It is important that representatives of the Canadian natural health food industry be appointed to the Canadian delegation to the Codex Alimentarius Commission. Health food industry participation in the Canadian Delegation in Codex will help ensure the most harmonious management of the boundaries between Codex's "Nutrition and Foods for Special Dietary Uses" and Canada's NHP's. Presently, non-governmental participation from within Canada appears to be limited to the dairy industry. Surely the natural food industry has a relevant stake in direct participation in Canada's Codex Delegation.

Finally, creating this Act will give NHPs a home in Canadian legislation that is acceptable to both consumers and industry and will put to rest fundamental concerns about the future of this sector. Canadian consumers can then rely on reasonable assurances of greater access instead of the current stalled and tangled system. Bill C-51 can go ahead with the specific provision of removing NHPs and being non-applicable to NHPs – the same as it is non-applicable to Tobacco. A separate NHP Act recognizes that the vast majority of Canadians consumes NHPs and supports the development of a responsible, empowered NHP industry.

How Will the NHP Act relate to Bill C-51 or similar legislation proposed in future?

The new Bill C-51 type legislation can continue to define 'therapeutic product' as proposed with the significant exclusion of Natural Health Products as defined in the NHP Act. As referenced above, there exists ample precedent for creating a separate Legislative Act for a specific, designated class of product(s). The Tobacco Act in Canada designates separate legislative recognition for tobacco. NHP products similarly need to be recognized as a unique product class. It is interesting how tobacco is treated in Bill C-51. It underlines the simplicity with which an entire product class can be written out of the legislation.

Within Bill C-51 exist the following clauses:

> TOBACCO ACT
>
> 72. The definition "tobacco product" in section 2 of the *Tobacco Act* is replaced by the following:
>
> > "tobacco product" means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes and filters but does not include any food or therapeutic product that contains nicotine to which the *Food and Drugs Act* applies.

In a similar fashion, NHP's could reasonably be designated in a separate NHP Act. Reference to NHP's within Bill C-51 could be included within any such similar bill in a manner as to designate 'therapeutic product' as:

> Section 3. (6) Definition of "therapeutic product"
>
> "therapeutic product" means

(*a*) a drug,

(*b*) a device,

(*c*) cells, tissues or organs that are distributed or represented for use in

(i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, or

(ii) restoring, correcting or modifying the body structure of human beings or animals or the functioning of parts of the bodies of human beings or animals, or

(*d*) a combination of two or more of the things referred to in paragraphs (*a*) to (*c*);

(e) except as defined as a natural health product in the Natural Health Product Act (NHP Act).

The definition of "natural health product" already exists as designated within the current Natural Health Product Regulations. Appropriate NHP Regulations can be continued under the new NHP Act.

Moving Forward

There are two ways to introduce potential new legislation. One is through the current government's direct introduction and the other is through a private member's bill. Either will do. There are certainly individual MPs who have in the past and would again take up this issue. Election results will likely have significant bearing on this matter. The creation of this NHP Act will be a boost in the status of the current NHPD raising them to a legislated existence. Therefore one would assume the bureaucratic officials involved would be supportive of such a move. A guarantee of support for an NHP Act would likely end the public outcry against Bill C-51. As we head into an election, various interested Parties may see the value in supporting this easily implemented legislation. Everyone wins: NHPs are under a separate NHP Act, Bill C-51 proceeds – albeit without NHPs, and Canadians obtain greater access to safer products for generations to come.

At the end of the day the NHP Act should be created because it is the will of the Canadian people and the best solution to the problem. No issue has moved this country more in recent decades than the issue of the regulation of natural health products. Canadians deserve to know that the safety of and access to NHPs are guaranteed. If killer tobacco can have its own legislation, certainly Natural Health Products deserve at minimum the same level of recognition.

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Ref: (1) Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).