

Perspectives on the Natural Health Product Regulations and Licensing Crisis

For Members of Parliament delivered on behalf of concerned Canadians in all 308 Federal ridings. This report is a preparation for conversations with local constituents who are asking to have the current Natural Health Product Regulations suspended, reviewed and revised.

April 2011

This report does not pertain to Bill C-36, now Canada's Consumer Product Safety Act. The CCPSA excludes the Food & Drugs Act; and therefore does not apply to Natural Health Products.

Stephen Harper on regulating Natural Health Products

On page 9 of Stephen Harper's 2004 healthcare platform, "One Conservative Voice" he states the following promise to Canadians, regarding the treatment of Natural Health Products, if he is elected leader of the Conservative party:

Canadians voluntarily spend \$1.6 billion on natural health products to promote personal health. Yet Health Canada continues to remove effective Natural Health Products from the marketplace and shut down research into Natural Health Products because they are regulated under drug-style rather than food-style regulatory regime.

Natural Health Products would benefit from moving towards a more "food-style" regulatory regime as outlined in Dr. James Lunney's Private Members Bill C420. This would make regulating Natural Health Products more in line with the safety record and non-patentable nature of these products. Regulation will be required to ensure Good Manufacturing Practises, inspections, product testing and quality assessment of health claims that will afford Canadians both the assurances and the access they have been seeking.

Stephen Harper will pass Dr. James Lunney's Bill C-420 in order to regulate Natural Health Products as "food-style" rather than "drug-style" products.

Stephen Harper will increase federal research into Natural Health Products.

Stephen Harper on federal control over Natural Health Products

Excerpted from the same 2004 campaign, Stephen Harper confirms that health care should not be placed in the hands of the federal government and must remain under provincial jurisdiction. Stephen Harper asserts:

When it comes to health care, I have some fairly straightforward guiding principles. The first is that all Canadians should have reasonable access to timely, quality health care services regardless of ability to pay. The second is that health care is a provincial jurisdiction, and that means the federal government has to work with, not dictate to, the provinces when it comes to health care.

These guiding principles led me, as leader of the opposition, to support the Health Accord signed between the provinces and Jean Chretian last year. I supported that Accord because it reflected a number of my own priorities.

- It restored funding for core health care services that Paul Martin had cut;
- It provided flexibility to provinces in the areas of primary care reform, home care and catastrophic drug coverage
- It created a dedicated Health Transfer from Ottawa to the Provinces
- It allowed for flexibility of delivery options within the public health care system without compromising the principle of quality service regardless of ability to pay; and
- Most importantly, because addressing health care is not just a matter of spending more money, the Accord provided an accountability framework that would allow Canadians to hold provincial and federal governments accountable for the pledges made in the Health Accord.

A Report on the Natural Health Product Regulations in Canada: Facts supporting the case for suspension

This report has been prepared to provide Members of Parliament with a recent history of the Natural Health Product Regulations (NHPR), the issues behind the current regulatory environment as seen by some sectors of the Natural Health Products (NHPs) industry and consumers, and facts unavailable from Health Canada.

This report shows that Health Canada has not implemented the expectations of the Standing Committee on Health. It demonstrates how the classing of NHPs as a subset of drugs has negatively impacted the NHP industry and the Canadian consumers who use them; and it argues the legal and constitutional case for suspending, reviewing and revising the 2004 NHP Regulations.

Executive Summary: The Problem

Many Canadians are rattled at the increasing number of NHPs unavailable due to the 2004 NHPR. Health Canada denies that the industry is being downsized, however their last quarterly report ending December 31 2010 shows that 45% (21,383) of the Product License Applications submitted since 2004 have failed the licensing process, resulting in refusals of Natural Product Numbers (NPNS). Licensing failures are only part of the measurement of lost products. Retailers have lost access to over 20,000 products which are freely available in other countries such as the U.S. There are also a large number of products that either have been or will be removed without trying to get through the licensing process because it is too cumbersome. These lost products will not show up in the licensing failure statistics.

Health Canada has repeatedly stated that their foremost consideration for the regulations is consumer safety. However, less than 5% of the refusals have been based on safety. This means that NHPs rarely fail the licensing process due to safety concerns. A comprehensive statistical analysis of information from Health Canada, the Canadian government, and NGOs, found that the relative risk/chance of dying from an NHP was less than one in ten million (see Appendix 1). Health Canada cannot support policy or rationalize outcomes of the current regulations based on safety concerns.

In 1998, the Standing Committee on Health endorsed the wishes of Canadians to enjoy increased access to NHPs. Instead of enjoying increased access, we face a crisis consequent upon the regulation of NHPs as a subset of drugs. Drug-style regulations are reducing our access. These regulations deem all NHPs to be illegal. Assumed to be unsafe and fraudulent, only those NHPs which meet onerous conditions can remain on the market. There is no mechanism to prevent Health Canada from making the conditions more onerous.

Since health is a provincial jurisdiction, neither can the agency rightfully claim legal authority over NHPs. Each province has autonomous authority over health care unless a risk becomes sufficiently significant to be regulated under criminal legislation. At that point only, can a health issue be controlled at the federal level. The onus is on Health Canada to demonstrate potentially criminal levels of risk. No such risks exist for NHPs.

The Government of Canada has not done a single risk-analysis to determine the risk of removing tens of thousands of NHPs, *safely accessible for years*, from Canadians who rely upon them, by personal choice, for the maintenance of health. In short, the NHP community is being dismantled by drug-style regulations designed to restrict access to NHPs.

The central problem with Health Canada is that the agency enforces the same legislation that it creates, while being in relationship with many of world's wealthiest corporations. The inadvisability of creating a situation where conflicts of interest are not only possible but likely is the reason we do not ask the police to write our laws. Many Canadians also see a disconnect in Court decisions allowing access to 'unlicensed products'. We have no right to treatments of our choice, if Health Canada ignores the spirit of our Court decisions guaranteeing personal choice.

With this in mind, since the provisions of the NHPR are demonstrably disproportionate to the need for protection, Health Canada's basis for control fails to meet the criteria necessary to justify pre-empting Canadians' rights to life, liberty, and security, guaranteed in Section 7 of the Canadian Charter of Rights and Freedom.

Recommendation: Due to sustained nation-wide opposition from the NHP industry and consumer sectors we ask that enforcement of full compliance of the NHPR be suspended, pending review by the Standing Committee on Health.

For all intents and purposes, NHPs were unregulated until 2004. Even now, most of the products Canadians regularly purchase in health food stores are illegal and non-compliant with the current regulations. Suspending the NHPR would not suddenly create an unregulated environment. Indeed, there would not be much of a change at all. All that would change is that the NHPs Canadians have been relying on for decades would stop disappearing pending a review. Health Canada would be in the same position as it was prior to 2004. It could take targeted action against products where there was a legitimate health risk.

Rationales:

The NHPR were never intended to take their current form.

The Standards of Evidence that Health Canada is using to reject NHP license applications are invalid.

The NHPR undermine our personal freedoms and are unconstitutional.

The NHPR are harmful to Canadian citizens, both physically and economically.

Primary Legislative Change:

Remove NHPs as a subset of drugs and create a distinct third category.

Possible Regulatory Solutions:

Define NHPs according to what they are and their relative levels of risk, rather than what they are intended for.

Within the distinct third category, make claims voluntary. If an NHP displays an official claim, then it may have to be substantiated with appropriate levels of evidence. Product labels can carry disclaimers, allowing the consumer to decide.

Use presumption of safety as the guiding principle for NHPs, allowing them to remain on the market, with a general discussion of ingredients on the label to inform consumers of their purpose. Let consumers make informed decisions.

Remove the possibility of conflicts of interest by the pharmaceutical lobby or chemical drug model by creating a distinct third category with a new minister and ombudsman as a part of the mechanism for reviewing regulatory actions.

Create a balanced regulatory environment where our individual right to make fundamental health decisions is honoured, while enabling the state to address legitimate safety concerns.

It is erroneous to believe that this crisis can be solved by 'tweaking' the current Natural Health Product Regulations.

We can end the regulatory crisis by enacting the Charter of Health Freedom: a proposed legal framework under which regulations would be passed. (page 12)

The exact form of appropriate regulations cannot be finalized until this new statutory framework is put in place.

The Natural Health Product Regulations were never intended to take their current form.

As currently administered by Health Canada, the regulations have taken a drastically different direction, producing outcomes opposite to the demands of the Canadian public, supported by the Standing Committee on Health in 1998.

After the largest citizen movement in Canadian history, directed at increasing our access to NHPs, Canadians should be enjoying increasing access.

Unfortunately, we are facing a crisis where we are losing access to over half of our NHPs. The Standing Committee on Health (*Natural Health Products: A New Vision*, November 1998, containing the 53 recommendations accepted by the then Health Minister) and the Office of Natural Health Products Transition Team (*A Fresh Start – Final Report of the ONHP Transition Team*, March 31, 2000) gave directions intended to increase access to natural health products.

Despite these directions, Health Canada has imposed inappropriate drug-style regulations on the NHP industry.

When Health Canada tried to pass the Establishment Licensing Act in 1997, Canadians protested that they did not want Natural Health Products regulated as drugs. The largest petition ever at the time, called *Our Foods are Not Drugs* gathered over 150,000 signatures. The Act was halted, and a lengthy review by the Standing Committee on Health culminated in 53 recommendations to Parliament. All of which were accepted.

Excerpted from the 1998 *New Vision* study:

“These witnesses recommended that a ‘new’ or ‘separate’ or ‘third’ category of products be established for NHPs.”

“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.”

This was to provide a category for NHPs, distinct from either Foods or Drugs, to recognize their low risk nature.

Had they done this, the Food and Drugs Act, in essence, would have become the “Food, Drugs, and Natural Health Products Act”. Instead, Health Canada created a separate directorate and a new set of regulations for NHPs, placing them as a subset of drugs.

The purpose and design of these regulations, the starting assumption for every license application, is that the product is dangerous until proven safe.

The drug assessment model currently being applied to NHPs was developed and used for decades to assess pharmaceuticals. This is not using a process ‘detached from’ pharmaceuticals as was recommended. Since, as with drugs, NHPs are presumed dangerous until proven safe, this model fails to recognize their high safety levels, repeatedly referred to by the Committee.

The intention to create regulations that acknowledge the low risk nature of NHPs was also apparent in the *Final Report of the ONHP Transition Team*, established to ensure that the regulations arrived at were fair and balanced.

Health Canada has obscured the situation from Members of Parliament and the public by advising them that *“Natural Health Products and drugs are regulated separately, and have been since 2004”*. In this statement the word “drugs” is automatically assumed to mean pharmaceuticals, but this wording is deceptive and inaccurate. The accurate way to state the fact is: Though NHPs and pharmaceuticals are regulated separately, **both are regulated under drugs** in the Food and Drugs Act.

This means that both must meet ‘drug’ standards. These standards were developed to regulate man-made compounds made in a laboratory. Chemical pharmaceutical drugs, which as a group are responsible for a very large number of deaths, can only be approved if there are randomized, controlled trials showing that their benefit outweighs their risk.

In order to gain market approval, drugs, and now all NHPs, are *forced* to make a claim as to their intended use. That claim must then be proven *in humans*. Yet, until 2004, the majority of NHPs were classified as foods. Studies proving efficacy in humans were seldom done, since there was no financial or legal incentive to do so.

Though there may be countless other forms of evidence for a given natural ingredient, because of their expense, human trials are uncommon. For thousands of NHPs, and an even greater number of herbal and traditional remedies *official evidence proving benefits in humans is not pre-existing*. Therefore, the NHPs' mechanisms of healing cannot be included in 'the broad range of evidence' Health Canada claims to accept.

NHPs contain natural ingredients which cannot be patented. When the evidence for an NHP does not meet Health Canada's standards of evidence, the agency frequently demands double-blind human trials. Such trials are extremely expensive and provide no patent protection at their conclusion. Any competitor can simply copy the product in question and use the study results, without incurring the costs. The sponsoring company is practically guaranteed to lose money, so such studies are rarely performed. Because of this, it is exceptional for a study to be done on an NHP. Imposing randomized clinical trials on NHPs is the same as banning NHPs and/or banning truthful claims that NHPs can treat mild and serious health conditions.

With this imposition, many NHPs are being forced off the Canadian market. The drug model has created a 'rock and a hard place' scenario for proving claims in humans. On one hand, the necessary evidence to prove their claims often doesn't exist, and on the other, it is not financially feasible to create it, because NHPs cannot be patented.

This is presumably why Health Canada wanted NHPs in the drug category. They tried in 1997 and despite all the public protests and government directives against it ended up doing it anyway in 2004.

Excerpted from the 1998 *New Vision* study:

"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."

The outcome of regulating NHPs as drugs is seeing Canadians' access to over 70,000 NHPs fall to near 30,000. That difference of 40,000 NHPs represents 40,000 instances of Canadians promoting healthier lives on a daily basis, at their own expense, through natural means.

These products have been pushed off the market by the NHPR and are no longer available for domestic purchase. This includes over 20,000 documented U.S. imports that retailers used to be able to order and sell in their stores (see appendix 2), and in excess of 21,000 product license application failures, representing 45% of the applications submitted.

As of the last quarterly report ending December 31, 2010 -- seven years after the Regulations began -- Health Canada awarded only 25,919 Natural Product Numbers (NPNS), representing just a 55% approval rate.

This total does not include duplicated products that simply put a different label on a product that is already licensed. Health Canada commonly includes these in their totals to inflate their stated numbers. Despite the actual 25,000+ licenses, the most recent claim by Scott Sawler --the new Director General of the NHPD, is that there are over 43,000 NHPs on the Canadian market. This figure is deceptive since it does not refer to individual licenses.

As of the same date, 8169 NHPs were still in the queue, having been given Exemption Numbers (ENs) while waiting to have their applications processed. This merely allows the product temporary exemption indicating the product has been received by Health Canada for consideration. This EN does not guarantee that the product will remain on the market. *Many have had their applications submitted for five or more years.* If the ratio of approved to unapproved products continues, 5000 or less of these NHPs will be approved, bringing the total to approximately 30,000...just over 40% of available products in 2004.

How do eliminating 60% of our choices achieve Health Canada's stated intention of increasing Canadians' access to NHPs? Losing 60% is already a disaster that has and will continue to have serious and long-term health consequences for millions of Canadians (the additional constitutional issues regarding loss of individual freedom will be discussed later in this document).

Since the NHPR began virtually all Canadian NHP manufacturers, distributors and producers have voluntarily reduced the number of products they offer due to the cost of compliance, and/or the likelihood of license refusals. These are losses that cannot even be reflected in the stats provided earlier. At first, slow sellers were discontinued, followed by multiple ingredient products. They have been eliminated, not because they are unsafe or unpopular, but simply because they cannot meet Health Canada's onerous burden of proof for efficacy in humans, designed for drugs.

Health Canada commonly decides that in order to meet regulatory requirements and remain on the market, long-standing effective herbal combinations need to be withdrawn and reformulated. However, when they return, they are *rarely, if ever*, as effective as the original formula. Their sales decline.

To compound the problems, a number of U.S. companies that were operating in Canada in 2004, either with their own warehouses or through distributors have simply stopped doing business in Canada, taking their products with them. Many had been sold in Canada for decades with no problems or issues. The most recent of many examples is EAS, a sports nutrition icon, trading in Canada since the 1980s. As of January 2011, they pulled all of their operations out of Canada. These companies simply can no longer justify the expense or hassle of doing business here.

Health Canada maintains that safety is their utmost priority for the regulations, yet less than 5% of licenses were denied due to safety concerns. This includes a dried parsley product. The agency doesn't specify how small this category actually is because several causes are lumped together, as being "...refused due to quality, safety, and/or efficacy issues..." i.e. safety could actually account for less than 1% of license refusals.

Even this would not necessarily mean these products weren't safe, rather it often just indicates a paperwork deficiency. If an application fails to prove safety, it gets refused, even if other products with identical ingredients received approval on their applications. Such was the case with the parsley refusal.

One might think that this would apply to products that don't work, but in fact, often the opposite is true. When a product produces beneficial results in the health of a consumer, it is also likely to be refused.

Excerpted from the 1998 *New Vision* study:

"The Members of the Committee acknowledge that the current definitions of a food and a drug in the Foods and Drugs Act do not adequately accommodate NHPs."

"Any new regulatory framework for NHPs must take into account the well being of consumers"

When Health Canada refuses a product license for a product you have been relying on, that product is taken away.

In effect Health Canada is making health decisions for us by taking away our treatment choices. This is offensive from a personal freedom perspective because it takes away your freedom to choose, based on the assumption that only Health Canada is qualified to decide which treatments you can access when you are suffering. We are moving to a place where the only treatments you can access are those approved of by Health Canada. This raises the question as to whether you should have the right to choose to take a treatment that is not approved of by Health Canada.

With all the references to a distinct category, and low risk levels in both the final reports, along with Health Canada's own announcements of what Canadians asked for, there is ample evidence that, regarding the NHPR, Health Canada has acted against the will of the Canadian people and Parliament.

The Standards of Evidence Health Canada uses to fail NHP license applications are invalid.

These standards come from a pre-existing drug model template, originally designed for assessing single-molecule pharmaceuticals. In contrast, many NHPs are extremely complex. Ginseng, for example, contains over 80 identified constituents. Ginger contains over 400. They can have multiple effects on multiple systems in the human body. With over 88,000 identified substances in the human food chain, there is simply no way Health Canada can account for all the potential benefits of NHPs, or the reasons people may use them, with the current drug assessment model.

Yet, Health Canada *can* control the direction of future innovations and discoveries. Considering that NHPs are non-patentable, and given the expense of proving NHP claims in human trials, any future discoveries are now for the most part the domain of large pharmaceutical/transnational corporations. Very few NHP manufacturers or small to mid-sized producers can afford such trials. These are the same NHP manufacturers that have been on the forefront of leading the NHP industry into some of the greatest natural discoveries in existence today. And the same herbalists and traditional medicine producers who have given us trusted remedies used by millions of individuals, for generations.

Consequently, the NHPR have ground product innovation in the NHP industry to a virtual standstill. By stifling future discoveries and innovations, the regulations are exerting control over Canadian consumers' health options and preventing an untold number of NHP benefits from ever reaching the public.

With the popularity of NHPs, an argument can be made that what Health Canada is attempting with the NHPR is to collar the direction and development of the NHP market. There are many indications that the market is being pruned, simplified, and made less effective overall. Small companies making effective, specialized and innovative products, are forced off the market, while what remains on store shelves are simpler, more mainstream commodity products.

We need to ask whether blind acceptance of randomized clinical studies as the apex of 'good science' is correct.

The first product awarded an NHP license by Health Canada was the sugar and caffeine-rich stimulant drink, *Red Bull*, produced by an Austrian transnational. According to lead researcher Scott Willoughby, Red Bull can impair proper blood vessel function, raise risk of blood clots, and be deadly if the person consuming it is stressed or has high blood pressure. (Source: Mercola.com)

Conversely, in several instances, where an NHP has worked too well, and has supplied too much evidence indicating that it is extremely effective for a serious health issue, the therapy gets usurped by the medical/pharmaceutical industries.

An excellent example of this is an anti-inflammatory enzyme NHP called Serrapeptase. Since entering the market in the late 1990s, it has been used with great success for pain relief, and to clear arterial plaque by slowly digesting proteins that hold the plaques together. After more than 5 years of submitting ever more evidence to answer Health Canada's Information Request Notices, the NHP applications for the two highest strength products in the most popular brand were denied. Within six weeks of this occurring, CBC news announced that a new medical procedure had been approved by Health Canada for injecting proteolytic enzymes into the arteries to clear plaque. This would seem to be more than just coincidence.

It is also relevant to note that even though NHPs themselves are not patentable, if an identified constituent in a botanical can be isolated, and a unique use identified for it, *that use can be patented*.

Bayer reportedly owns several hundred of these patents on such isolated constituents from botanicals, and this is to become the new frontier in drug development. Yet such drugs would be much less marketable, if the whole plant form, from which the isolated constituent is derived, remains widely available as an NHP. Bayer, along with other pharmaceutical companies, is a member of the Program Advisory Committee for the NHP Regulations.

In the regulation of NHPs there needs to be a mechanism in place where claims are not mandatory, and/or if claims for a product are disallowed, it is still allowed market access with a general discussion as to its purpose, and a name that simply identifies what it contains. This way Canadians can still get products that they need, or that they consider they were getting benefits from. Due to the complexity inherent in many NHPs, Health Canada cannot account for all of the reasons a person may use it or why it may benefit them. If the product does not work people will stop buying it and it will be culled by free market pressures. It will eventually disappear from store shelves.

The NHPR undermine our personal freedoms and are unconstitutional.

The rights our courts have ruled that we have.

Section 7 of The Canadian Charter of Rights and Freedoms guarantees the right of Canadians to life, liberty, and security of the person. By restricting access to NHPs that Canadians require for their health, the NHPR interferes with the right to life.

This interference is amplified when, after losing access to a natural product previously used for a health problem, Canadians substitute a chemical pharmaceutical for the NHP they no longer have access to. Since pharmaceuticals have a much higher risk level associated with them, this makes adverse side effects, including death, more likely. This interferes with the right to life, and is unconstitutional.

In Canada, according to poison control statistics, pharmaceuticals are responsible for thousands of deaths each year, versus zero recorded deaths ever for all NHPs.

When the NHPR force an NHP off the market, it should only happen if and when the question of who it will harm has been addressed. Health Canada has carried out no analyses, regarding the risks of blocking or eliminating access to any of these NHPs. In some circumstances, consumers have tried every possible treatment for serious health concerns and found that the only effective treatment for improving and/or maintaining their wellness is an NHP. If Health Canada then restricts access to this NHP, once again, they make illness, pain, and/or death more likely.

The question needs to be asked: *"By making natural health products unavailable to Canadians, and forcing them to use higher risk treatments, how many deaths will the regulations cause?"*

Canadians are turning to natural health.

This question becomes all the more relevant when the extremely small risk/benefit ratio of NHPs is considered, i.e. their relative risks are very small, and they can provide meaningful benefit in a wide range of situations.

NHPs' low risk levels are evidenced by their safety record. In Canada, according to poison control statistics, the total number of Canadian deaths on record as being caused by an NHP is zero. As mentioned, a comprehensive statistical analysis of information from Health Canada, the Canadian government, and NGOs, found that the relative risk/chance of dying from an NHP was less than one in ten million (see Appendix 1).

Why then are so many NHPs being eliminated in the face of such overwhelming evidence that they are indeed extremely safe? Is it really because they don't work? And if so, why are they so popular and continuing to grow in popularity?

If the NHPR are as reasonable as Health Canada claims, why are so many people upset about losing access to NHPs?

As evidenced by the increase in Canadians turning to NHPs for their health, and the two million peer reviewed papers being published on them annually around the globe, it is likely that most NHPs work for the people who use them...but just can't prove efficacy in their current classification as drugs.

For products sold while waiting years for approval, or that were eliminated after decades on the market: if an NHP is safe enough to be on the market for years without problems, and is effective enough to survive market pressures, what valid rationale is there for eliminating it?

NHPs are not criminal: The question of provincial jurisdiction.

In order for the federal government to exercise authority, a matter must be criminal. To be considered criminal, it is necessary for a matter to exceed a threshold of risk. With zero Canadian deaths on record where an NHP is listed as being the cause, NHPs do not reach this threshold. Therefore Health Canada is out of its jurisdiction.

Every year Canadians die from anaphylactic reactions to nuts. Anaphylactic reactions to shellfish and various other foods also occur, and according to CBC News, one in nine Canadian emergency room visits are due to side effects from prescription drugs. It is well established that pharmaceuticals account for thousands of Canadian deaths each year.

Being on record as having caused zero Canadian deaths, it can be established that NHPs as a group are safer than either foods or drugs and do not pose enough of a risk to be governed by criminal legislation at a federal level.

Health Canada may wish to engage in a process of 'bureaucratic creep', where they expand their actions into an increasing number of areas, however they do not have jurisdiction.

Health Canada states in their Regulatory Impact Analysis Statement (Canada Gazette, Part I, Dec 22, 2001, Pg. 4914) that: "*The Regulations are not aimed at regulating the activities of retailers of NHPs.*" Yet they have several times provided deadlines after which retailers should not sell an NHP that does not have either an NPN or an EN. It has been made clear to all retailers that Health Canada will launch full enforcement, where inspectors go to health food stores across the country to remove products from shelves that they deem to be non-compliant and illegal.

Who should decide which treatments work for you?

Because natural health practitioners are a provincial jurisdiction, a practitioner can compound any natural formulation they wish for someone they are advising, (NHPR Regulatory Impact Statement, pp. 4913-4914). Why is Health Canada blocking hundreds of U.S. imports that practitioners were formerly using in their practices, and refusing to grant NPNs to products when the company only sells to health professionals? By overriding the practitioners' decisions about whether or not these products are needed, is Health Canada not *practicing medicine without a license*? Are the bureaucrats making these decisions trained in the appropriate areas, and who is being put at risk?

The individuals processing NHP applications are bureaucrats with no expertise in the field of natural health. Leading up to the NHPR, another change in policy direction that was repeatedly identified as necessary by all involved groups was to have people with expertise in the field making the decisions (See Chapter 4 of the Standing Committee Report.) But this is no longer being adhered to.

Inconsistency also exists regarding personal importation of NHPs. As long as an NHP is not banned, or provided only by prescription in Canada, a person can import a three month personal supply of any NHP from the U.S. or abroad. Yet, when it comes to importing that same product for resale, Health Canada claims jurisdiction, and blocks the import, saying that the product must have an NPN. If the NHP in question was safe enough for any individual to import privately and use, why does Health Canada's jurisdiction over safety and fraud, kick in when it comes to importing the exact same product for resale?

Health Canada has also recently claimed jurisdiction over NHP exports to other countries, stating that with the exception of the U.S. (due to NAFTA), any exported product must have an NPN, even when the country of destination does not require it. It is again very questionable whether or not this is within their legal authority.

It appears that Health Canada is controlling NHP commerce, rather than remaining in their area of jurisdiction over fraud, adulteration, and risks worthy of criminal legislation.

Health is the jurisdiction of the provinces, and as their title assigned by Health Canada indicates, NHPs are most commonly used for maintaining wellness and prevention or for treating concerns before they require medical attention. Given their safety, and their potential to save millions in healthcare expenditures, NHPs should be regulated at a provincial level.

The Regulation of intention

When applied to NHPs, which pose relatively very low levels of risk, the "use based" definition of a drug is unconstitutional, because it regulates the intended use of a substance, instead of the substance itself.

When it comes to products that are established as being safe, this amounts to censoring an individual's actions. It is unwarranted State control that serves no benefit, and can be detrimental. We cannot prove beyond all doubt that Health Canada is biased in its approach to natural health products. We can, however, point to several issues that suggest that Health Canada appears biased, which raises the question as to whether you should trust them to be the sole decider of which treatments you may take.

If there is even a hint of a safety risk concerning a natural health product, Health Canada almost invariably demands the product be taken off of the market through a recall. The same cannot be said for chemical drugs. Many examples exist of Health Canada dragging its feet over recalls of products from pharmaceutical companies, e.g. the range of children's liquid medications recalled by McNeil Consumer Healthcare during 2010 (Source: Globe and Mail, May 4, 2010).

For a banned street drug like crystal meth, it doesn't matter whether it is in powder or capsules, it is still treated the same, i.e. the substance itself is regulated. But when it comes to turmeric, cinnamon, or parsley for example, if you use one of them in cooking, Health Canada considers them foods. If you put any of these same substances in capsules and

swallow them for their health benefits, they are considered drugs. What changed was the intended use or your intention. *But you were going to ingest it one way or another, so regulating your intention serves no rational purpose.*

They are the same substances, considered safe one moment but considered 'dangerous until proven safe' the next.

This is unconstitutional because it isn't the State's business why you are putting a safe substance in your body.

With pharmaceuticals there are risks involved, which can be used to rationalize control. But for NHPs, with zero deaths in Canada, regulating your intention cannot be rationalized.

NHPs need to be regulated according to what they are, and their safety level, rather than what they are intended to be used for. The creation of a distinct third category, apart from drugs, is necessary if fairness to consumers is to be maintained.

The NHP Regulations are harmful to Canadians, both physically and economically.

The NHPR are having many damaging effects at every level of the NHP supply chain.

Consumers are frustrated at the loss of products they want and need. Products they have used successfully for everything from headaches to life-threatening diseases are disappearing. Due to the strict demands of the NHPR, prices for NHPs have been driven up. The net effect, whether products are unavailable or unaffordable is still reduced access.

Natural Health Practitioners are being hobbled professionally and financially by no longer being able to source the products they used to create effective therapeutic protocols for their clients' health and wellness. Skilled professionals are being dictated to by untrained and inexperienced bureaucrats.

Retailers are losing all manner of unique specialty products. As even more of these products disappear, the selection in health food stores increasingly becomes the same as mass market stores. The character and the quality of many NHPs are changing. The NHPR are removing many innovative and specialty NHPs from the marketplace.

Distributors are unable to plan or trade, as all manner of products are blocked at the Canadian border. These are technical barriers to trade that are undermining our economic growth. This has put many respected suppliers of superior international products in a tenuous business situation, questioning the survival of their business.

Manufacturers are having all manner of safe, effective and reputable products eliminated due to license application failures. Today, once robust and thriving Canadian NHP manufacturers are in a waiting game to find out which of their products will be restricted next.

Health Canada's campaign against NHPs directly harms the economic welfare of the large number of Canadians whose livelihood is invested in this growing business sector. A lot of jobs are at stake. Health Canada is not applying the NHPR based on what is good for Canadians or for the economy. They are taking natural substances which have been part of the global food chain for millennia and, with regulations inappropriate to the levels of risk involved, they are driving up costs and putting at risk many quality businesses.

Growers, manufacturers, distributors, retailers, health professionals and researchers will all suffer when Health Canada's full enforcement and compliance takes place. MPs must support the development of a healthy NHP industry which is rich in entrepreneurial vitality instead of allowing Health Canada to dismantle it.

The greatest crisis facing Canadians in our healthcare system is the growing tension between constantly rising costs and declining outcomes. When Canadians use NHPs, they ease the burden. With costs of adverse effects from prescription drug use going through the roof, and publically funded health care bankrupting the nation, how do we justify the expense of Health Canada's large-scale campaign against ultra-safe NHPs?

NHPs are effective; their preventative properties benefit consumers and this reduces the demand on high priced taxpayer-funded conventional medicine. They are largely used by people who have actively taken control of their health. Dollar against dollar, measure against measure—be the focus on benefits, adverse effects or compliance—NHPs deliver a better return on investment than drugs. It should be the case that the widest possible use of NHPs is formally promoted as public policy.

If, as the Globe and Mail on Feb. 27, 2011 states: "*Health care costs could eventually swallow all levels of government if left unchecked*", then why aren't we increasing our access to these products? Canadians are paying the wages of Health Canada bureaucrats to filter their health options. Eventually, we will face cost recovery.

Many MPs respond to their constituents who voice concerns about the NHPR as if their inquiries are about Bill C-36. It is important that MPs know the difference. Many other MPs respond with letters containing platitudes written for them by Health Canada. Citizens affected by this crisis know that there is another side to the issue. MPs must come to the aid of their constituents who take responsibility for their own health and do so because they are intelligent, capable and living in a country where they should be permitted to exercise the freedom to choose.

Legislative and Regulatory Solution

Contrary to the portrayal presented by many in the NHP industry, media and Health Canada, NHP stakeholders and consumers opposing the current regulatory environment, *want* regulations.

They want confidence and acknowledgement from the public and government that they are following good manufacturing practices, high standards for testing, and other forms of quality assurance to ensure that what is on the label, is in the bottle. They want the current regulatory model of the NHPR to be suspended, reviewed and revised.

There are many aspects of the NHPR that are workable and reasonable, if administered properly. The parts ‘that work’, such as mandatory good manufacturing practices and testing, could be used to good effect. The fundamental issue in arriving at a fair regulatory environment (when considering enforcement and definitions of claims, efficacy, testing or ‘approval’ symbols) is the *statutory framework*, which the regulations are passed. Regulations are confined to implementing the purposes and intentions of their parent statute. Until NHPs are ‘regulated’ under a statute with an appropriate legal framework, such as a presumption of safety, they are at risk of being over-regulated.

It is for this reason that it is essential to have the Charter of Health Freedom enacted.

The Charter of Health Freedom creates a separate, independent category for Natural Health Products.

It contains key safeguards, such as a presumption of safety and a balanced risk analysis, before removing products. At the same time it gives the government broader powers than are currently in the Food and Drugs Act when a legitimate safety concern needs to be addressed. It is a law that is drafted as complete legislation to be enacted as it is written.

Many Canadians see a disconnect between Court decisions allowing access to unlicensed products where there is genuine need, and Health Canada’s actions in restricting our access to NHPs. We have no right to the treatments of our choice if Health Canada ignores the spirit of our Court decisions, guaranteeing that choice.

The Charter of Health Freedom was written to overcome these problems. It does not create any new rights. Rather, the Charter codifies the rights our Courts have already ruled that we have. The Charter compels the Government to honour our current rights.

The Charter creates a specific legal environment to ensure that NHPs are regulated fairly. All of the mechanisms that regulatory bodies in Canada, the UK and the US use to over-regulate NHPs have been examined. As drafted, the Charter should prevent the removal of any NHP due to over-regulation where there is not a legitimate health concern.

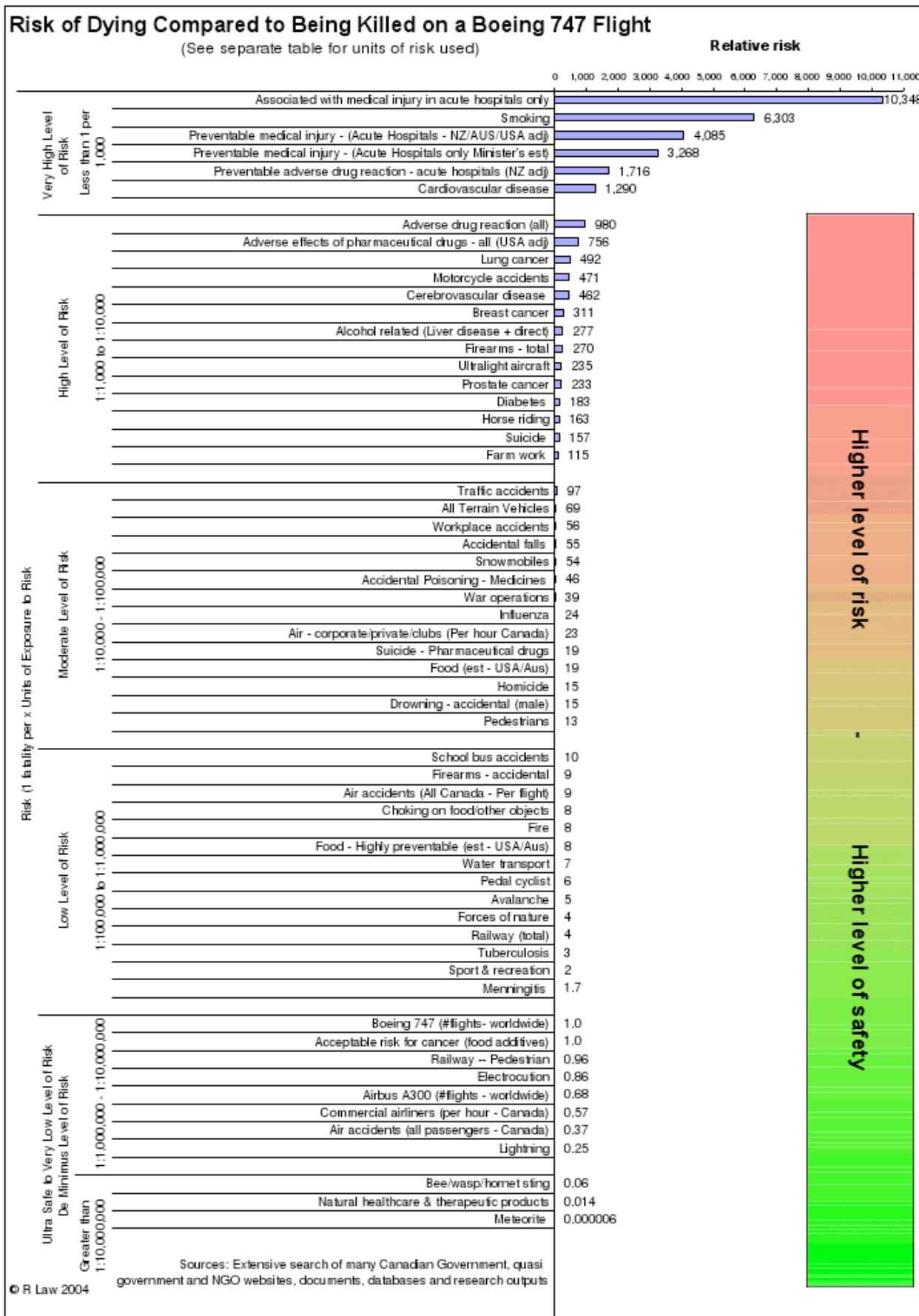
The Charter protects Canadians by ensuring that no NHP can be taken away if the risk of removing that NHP exceeds the risk of leaving it on the market. This will ensure that the NHPs Canadians rely on for preventative or serious health conditions will not continue to be taken away over regulatory issues unconnected to safety.

The Charter also takes the regulation of NHPs away from Health Canada which has a ‘drug’ regulation culture. Under the Charter, NHPs are moved to a Ministry of Wellness, charged with protecting and promoting access to treatment options such as NHPs. The Ministry of Wellness is also charged with promoting the rights set out in the Charter. Because the Minister of Wellness and the Minister of Health cannot be the same person, the Charter would protect NHP regulatory policy from being overly influenced by either the pharmaceutical lobby or the chemical drug model.

The Charter also creates the Health Freedom Ombudsman. Currently there is no review mechanism for persons whose health is threatened by unreasonable regulatory actions. The only possible redress is through the Courts. Most do not have the time or resources for Court actions, especially when in a health crisis. For the first time, the Charter creates an independent review mechanism to ensure our current rights are respected.

See www.charterofhealthfreedom.org and www.nhppa.org for details on the Charter of Health Freedom

APPENDIX 1



APPENDIX 2

Since 2004 Health Canada's NHPR have forced over 20,000 U.S. imports off the Canadian Market: below is a partial list of companies whose products used to be sold in Canada prior to the 2004 implementation of the NHPR. The following breakout was prepared and distributed by a Canadian NHP retailer in 2008.

- 1. Solaray, Kal, and all other products produced by Nutraceutical Inc. – Over 5000 products** offered in their US pricelist. Sold in Canada for more than ten years when discontinued – complied with everything Health Canada asked for 4 years before having their site license denied.
- 2. HerbPharm** – producer of **100s of herbal tinctures** – sold in Canada for over ten years, discontinued due to NHPR.
- 3. Gaia Herbals** – producers of **100s of herbal tinctures** – sold in Canada for over ten years, discontinued due to NHPR.
- 4. Allergy Research Products** – **over 650** extremely high quality natural products of all sorts – sold in Canada for more than ten years when discontinued.
- 5. Country Life** – **100s** of quality products in tablets/capsules – sold for more than ten years in Canada when discontinued.
- 6. Source Naturals** – **2300 products** in two lines representing a full range of nutraceuticals. Will no longer ship to Canada because of shipments being held at the border.
- 7. Vitamin Research Products** – **400 plus innovative**, well researched products – no longer available.
- 8. Jarrow products** – **600 plus** well researched, high quality products – no longer available.
- 9. Herbasway** – producers of green tea products – no longer available.
- 10. Yogi Teas** – these are herbal teas – no longer available.
- 11. Sweet Wheat** – high quality wheat grass products – no longer available.
- 12. Bernard Jensen Products** – **200 plus** products available in Canada since the 1970s – no longer sold due to the NHPR.
- 13. Organic Essentials** – organic tampons – disallowed: their applicator was considered a medical device by Health Canada.
- 14. Zand Herbals** – hundreds of herbal products sold in Canada since the 1980s – pulled out of Canada after the NHPR.
- 15. Life Extension Products** – hundreds of well researched NHPs no longer allowed into Canada for commercial sale.
- 16. Dr. Christophers** – **200 plus** herbal formulas sold in Canada since the 1970s. No longer sold due to NHPR.
- 17. Vaxa vaxa** – no longer allowed across the border.
- 18. Robert Grey Cleansing products** – sold in Canada since the 1980s – have pulled out of Canada due to the NHPR.
- 19. Natrol** – over 1000 products. Sold in Canada until the NHPR came into effect.

This is just a **partial list** of the products stores can no longer provide for consumers who rely on them. Today, across Canada, there are dozens of long standing Canadian NHP distributors experiencing great economic hardship, because Health Canada is stopping their shipments at the Canada – U.S. Border.

SUPPLEMENTAL

What is Health Canada's number one concern?

Here are a few things to consider as we anticipate what some people say could ruin the health food retail business and many suppliers' business. (We realize there are those in our industry, primarily large companies who will benefit from the bankruptcy of competitors, who see the regulations as a good thing so they need not read any further.) The following list was prepared by a Canadian NHP distributor *in 2011*.

Health Canada states their #1 concern is the safety of Canadians.

Remember this statement.

- Health Canada will still allow cigarettes to be sold after full enforcement of the NHP Regulations.
- Health Canada will still allow alcohol to be sold after full enforcement.
- Health Canada will still allow GMO foods to be sold after full enforcement, even though the science is questionable, the safety is unproven and they do not require GMO foods to be mentioned on the label.
- Health Canada will still allow prescription drugs to be sold after full enforcement, although they are proven to have caused deaths. Now, some do save lives. However, they are also the number three killer of Canadians.
- Health Canada will still promote flu shots after full enforcement, even though there is evidence showing the flu shot does not work. Why is HC promoting products anyway?
- Health Canada will still allow artificial sweeteners—considered to have side-effects—to be used indiscriminately after full enforcement.
- Health Canada told a prominent Toronto health food store that it is 'illegal' to sell baked goods made with Stevia.
- Health Canada will still allow 'junk food' after full enforcement, and allow the epidemic of obesity and diabetes caused by junk food to flourish.
- Health Canada will still not allow Kava, Ephedra or Tryptophan to be sold after full enforcement, even though the 'concerns' over safety were very suspect and they have since been proven to be safe and effective. Yes, as stated above, prescription drugs proven to cause death are still being prescribed daily.
- Health Canada will still allow Canadians to buy 'illegal' NHPs for their personal use on-line or through over border shopping. Support Canadian economy...shop in the USA!
- In spite of many questions about the safety of fluoride, mercury, irradiation etc. these will still be allowed after full enforcement.
- Toxic chemicals will still be used on crops after full enforcement of the NHP Regulations.