HEALTH CANADA'S PROPOSED CHANGES TO THE REGULATION OF NATURAL HEALTH PRODUCTS

Confirms that the War Was Lost in 2004: We are Now Re-Negotiating the Terms of Our Surrender

Prepared by Shawn Buckley, LL.B., President of the Natural Health Products Protection Association on October 16, 2017. Latest revision on May 11, 2019.

SUMMARY: Gutting of the Natural Health Product Regulations & regulating natural products like chemical drugs – disaster looming!

- The *Natural Health Product Regulations* will be repealed or dramatically amended so that natural products are regulated in the same way as chemical non-prescription drugs;

- Claims will be restricted to minor conditions – conditions for which a person would not seek the advice of a health care practitioner licenced by a province such as a naturopathic doctor, a traditional Chinese medicine doctor, an Ayurvedic doctor, a nutritionist, a herbalist, etc. Anyone who thinks professional natural products will be around 4-5 years after the self-care framework is fully implemented is naive;

- Traditional use evidence will no longer be allowed to support all claims. Traditional use evidence will only be allowed to support claims for the most minor of conditions, claims for topical, periodontal or dental claims. ***For greater clarity, the main advantage of the NHP Regulations, the ability to use traditional use evidence for claims, is for the most part being taken away. This is a disaster for the natural health community;***

- The final phase of the self-care framework is to impose the same standards of evidence for chemical drugs on natural health products. This will be the death knell for any realistic truthful claims for natural products. It will be the death knell for innovation;

- Whereas now it is functionally illegal to treat serious health conditions with natural products, it will become functionally illegal to treat anything but the most minor of conditions with natural products;

- The powers and penalties we fought against in Bill C-51 in 2008 will be imposed on those in the natural product community. Fines will increase from a maximum of $5,000 an offence to $5,000,000 per day of an offence. Directors, officers and employees are also personally responsible for these $5,000,000 a day fines;

- Health Canada will get almost God-like powers. They can order you to take any "corrective action". Failure to comply can result in $5,000,000 a day fines;

- Cost recovery will be imposed. Unless the fee structure changes, the lowest fee for a licence application will be just under $20,000. For each licenced product there is a yearly fee of just under $2,000. A manufacturer of several products who also imports is looking at a site licencing fee of roughly $65,000 per building per year (see our Discussion Paper on this);

- Administrative penalties will be imposed. Expect fines for violations found during site licence inspections to pay for the increased inspections;

- The Good Manufacturing Practices for the chemical drug companies will be imposed on the natural health companies. This will further increase the costs on the NHP community;

- The compounding exemption for individual patients "may" be lost. Health Canada will not confirm or deny;

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- Censorship of truthful health information will increase through: the restriction of claims; increased fines and administrative penalties for telling the truth;

- Access to natural products will be reduced;

- Prices will increase;

- Small and medium manufacturers will go out of business reducing competition and access to innovative products;

- There is no scientific or political justification for these changes. They are being imposed by four bureaucrats, some of whom were involved in trade negotiations. The recommendations of the Standing Committee on Health are being discarded. For more read our Discussion Paper on the Origins of the Self Care Framework.

Changing time line for the drastic changes

When we released the first draft of this Discussion Paper in 2017, we predicted that Health Canada would wait until after the federal election before implementing the negative changes to the regulation of natural health products. This prediction has come true. On April 1, 2019 (April Fools Day!) Health Canada amended the time line as follows:

- spring of 2020 to bring in more labelling changes for natural products;

- spring of 2020 to bring in Self-Care Framework regulations for chemical non-prescription drugs, making it easier for them to be licenced and regulated despite disagreement with this new approach by the experts in managing non-prescription chemicals (the pharmacists);

- 2021, harmonizing the regulation of natural health products with the chemical non-prescription drugs including:

    - Limiting claims;

    - Losing the right to use traditional use evidence to support all but the most minor of claims;

    - Losing the right to use natural health products for conditions for which one would seek the advice of a health care practitioner licenced by a province (such as Naturopaths, TCM practitioners; Ayurvedic practitioners; Herbalists, Nutritionists, etc.);

    - Imposing the chemical drug standards of evidence on natural products;

    - Imposing chemical drug GMPs on the natural health community;

    - Imposing the chemical drug penalties on the natural health community, such as increasing fines from $5,000 an offence to $5,000,000 per day of an offence;

- Imposing new Health Canada powers such as the ability to order "corrective action" (whatever that means);

- Imposing administrative penalties to pay for increased inspections;
- Imposing cost recovery (licence application fees, yearly product licencing fees, and yearly site licencing fees);

- Perhaps taking away the compounding exemption.

Avoid being duped by the "not now" communications

To my astonishment, many in the natural health community are not feeling any urgency because Health Canada is delaying the implementation of the most unpopular parts of the changes until after the next election. Not acting now is committing to a strategy that is guaranteed to lose. Now is the time for action. After an election the citizen has no leverage. Unpopular changes are always put off to after an election on the understanding that years later, at the next election, the anger will have subsided.

Resources

This Discussion paper concerns Health Canada's proposed changes to the regulation of Natural Health Products ("NHPS"). The text of Health Canada's consultation document can be found at: http://tiny.cc/dbihoy. Photos of slides and a recording of the presentation taken at the June 29, 2017 Health Canada consultation session can be found at: http://tiny.cc/q3hhoy.

Details of Health Canada's time table for implementing these changes can be found at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/self-care-framework.html

Scope of this Discussion Paper

This Discussion Paper is the opinion of the author, Mr. Shawn Buckley. Although Mr. Buckley is the President of the Natural Health Product Protection Association, his opinion is not necessarily that of the NHPPA or of anyone connected with the NHPPA. As with all Discussion Papers published by the NHPPA we invite comment and further information.

Dramatically Changing the Natural Health Product Regulations just as the Natural Health Community has complied with them

In reaction to Health Canada removing natural products from the market because they did not comply with the chemical drug regulations, Canadians revolted. The pressure from the citizens was so great that the then Minister of Health, Allan Rock, asked the Standing Committee on Health to determine how natural products should be regulated. The Standing Committee held the broadest consultations in their history and came up with 53 recommendations. In response to these 53 recommendations, the *Natural Health Product* Regulations were drafted. These regulations came into force in 2004.

The *Natural Health Product* Regulations were drafted specifically for natural products in response to the recommendations of the Standing Committee on Health. It has been only 13 years since the Regulations came into force. It has taken almost all of those 13 years for the natural health community to come into compliance with the new Regulations

The *Natural Health Product Regulations* were much stricter than the Standing Committee on Health recommendations, but were much better than the chemical drug regulations. Now, after only 15 years Health Canada is planning on abolishing or dramatically changing the *Natural Health Product Regulations* and once again regulating natural products the same way as chemical drugs. The new proposed regulations might not be as strict as the previous ones, but will be much stricter than the current Regulations. I predict that the changes will be a disaster for our access to effective natural products.

I predict that the changes will be a disaster for the small and medium manufacturers and importers.

I also predict that most of the natural health industry will be lulled into a false sense of security by the Canadian Health Food Association until it is too late. Health Canada's proposed three-stage implementation of changes present a classic case of boiling the frog slowly. By the time standards of evidence become harmonized (see below), it will be too late.

All of the draconian enforcement measures that Canadians fought to avoid for natural health products that were in the infamous Bill C-51, will now be applied to natural products. If we allow the new changes to pass, the Bill C-51 fight that we had thought we had won will be lost. With these new powers Health Canada will take more products from the market.

Although the *Natural Health Product Regulations* do not preclude claims for serious health conditions, Health Canada has limited claims to structure function claims. This limitation and outright censorship of truthful information will increase under the new proposals.

Health Canada will bring in administrative monetary penalties. This will allow Health Canada to fine natural health companies without the involvement of Courts. There is a history with other regulatory agencies of using administrative penalties to pay for the wages of the inspectors. This puts pressure on the inspectors to "always" find some small violation for which a fine can be issued. This leads to increased inspection activity for revenue as opposed to real compliance concerns.

There will be fees for product licencing and the annual renewals of product licences. There will be yearly fees for site licencing. The last time Health Canada proposed cost recovery for natural products, it was clear that many companies could not survive the fees.

Increasing costs always leads to a reduction of products. We have prepared a Discussion Paper on Cost Recovery. The reality is that many smaller businesses will not survive cost recovery. I was in a conference call with manufactures where one in the call related that for about a third of their products, they either lose money or only break even. They continue to make the products available as they continue to get customer feed-back that many rely on the products. This manufacturer was grieved that with cost recovery they will simply have to drop the products that are not money makers. This will not be isolated. Many marginal products we rely on will disappear.

Canada will be moving further away from its largest trading partner, the United States. The U.S. has no licencing requirement for natural products. Canada's unnecessary licencing requirements are about to become more onerous and costly.

Context

For the past three years Health Canada has been in the process of a public relations campaign to groom Canadians for a change to how natural health products ("NHPs") are going to be regulated. The proposed changes have alarmed NHP manufacturers who have spent the last 15 years getting into compliance with the existing Regulations. They are now facing regulatory uncertainty. Consumers are concerned that the new changes may restrict their access to NHPs.

When I first reviewed Health Canada's new proposal for regulating NHPs, I found myself wanting to preserve the current NHP Regulations. That is when I knew the war for health freedom had been lost. The natural health community is now fighting to preserve a regulatory regime designed to censor truthful health information and to limit consumer access to NHPs for serious health conditions. We have accepted philosophical beliefs that we will come to regret.

The philosophical beliefs you accept define who you are and they define the outcome

Actions flow from our beliefs. If you do not like the actions, you must change the beliefs which cause the actions. Focussing on the actions will not solve the problem. Let me use our history of discrimination as an example.

Canada has a history of discrimination against both women and racial minorities. We have a history of discrimination because one group (males and/or Caucasians) *believed* they were superior to another group (women and/or minorities). The actions that flowed from the *belief* of superiority varied, such as exclusion from places and privileges, to head taxes. In all cases the actions were caused by the *beliefs*. Discrimination cannot be solved by attacking the actions. As long as the *belief* remains, the *belief* will continue to cause actions consistent with the belief.

We have made progress in reducing discrimination in Canada because we refuse to accept the *belief* that one group is superior to another group. **If we continued to *believe* that one group was superior to another group, we could not stop discrimination. It is the *belief* and not the actions flowing from the *belief* that matters.**

We have accepted a *belief* inconsistent with health freedom – we are now arguing about the actions that flow from this *belief*

The conflict concerning how to regulate natural products flows from a conflict in *beliefs*.

The *belief* supporting our current NHP Regulations and Health Canada's current proposals is that the individual (You) does not have the right to make personal health decisions. Rather the State (through its bureaucracy Health Canada) has the sole right to decide what treatments and information is available to you.

The health freedom *belief* is that the individual (You) has the right to make personal health decisions. The State has a role in ensuring you are given truthful information with which to make your decision. The State cannot, however, decide for you by restricting your access to information and to treatments.

Let me explain to you why I believe in health freedom. You and I are living in a body. As we grow and age we will have various health challenges. We will all eventually face death. Along the way most of us will have periods of intense suffering and pain. For many the suffering and pain will be so intense we will contemplate killing ourselves to end it. Some of us will end our suffering with suicide. Each journey is completely personal. No-one else can experience any of your pain and suffering. It is your pain and your suffering. It is for you alone to experience. Because our health journey is completely personal, I believe that each one of us has the right to decide how to manage our health. Indeed, it seems completely wrong to me that some politician or bureaucrat can be given the right to cause me personal suffering and/or death by restricting my access to a treatment (either through censorship and/or by laws making the treatment illegal).

The belief in health freedom is consistent with the State preventing fraud, and ensuring products are made safely. The belief in health freedom is inconsistent with the State:

- censoring truthful information, and
- making treatments not pre-approved by the State illegal.

Let me give you an example.

I like to use Truehope as an example, as almost everything I say is documented in Court files with evidence taken under oath. Truehope developed EMPowerplus to treat serious mental health conditions such as bi-polar disorder. As multi-ingredient NHPs go, there is probably more research on EMPowerplus then any other product in the world. All of this research is publically funded, usually by universities. A former director of the Natural Health Products Directorate told one of the principals of Truehope that Health Canada knows the product works but that they would never get approval to sell it to treat a serious mental health condition. I am not surprised that some at Health Canada know the product works. I recall one Health Canada expert changing her position during Court proceedings after

doing more research. However, at the beginning there was no research. There was only an idea and some desperate people who were finding relief.

When EMPowerplus was new, the people who decided to try it knew there was limited information. In effect, there was just anecdotal evidence (personal stories) of people claiming to have been helped. Symptoms and the progress of participants were being tracked to create further evidence, but all knew this was a novel product based on a then novel idea (that nutrition can assist with mental health). I have interviewed many of these people. Some of them I have called as witnesses in Court. Their story is the same. They had severe mental illness. They were in and out of psychiatric wards. They were not likely to survive long due to their suicide risk. They all got well. They became normal. They never went back into a psychiatric ward. Their lives were saved. I am not exaggerating this "their lives were saved" point. A Court found that it was legally necessary for Truehope to continue to make EMPowerplus available despite Health Canada demands that they stop selling. At the trial, the former President of the Alberta Branch of the Mental Health Association testified about attending funerals when some ran out of EMPowerplus.

A psychiatrist who was called as an expert witness was asked at the trial:

> Q. Okay. So, you can't tell us what you would choose for a patient but I'm going to ask you if you came down with bipolar what would you do after you got over your panic?

The answer is instructive on health freedom:

> A. And the reaction to your question? I actually probably would choose EMPower.
>
> Q. Okay.
>
> A. I know the trials aren't there but I've seen it and I think given the choice between committing myself to a lifetime of lesser stability and mental fogging I would first want to try EMPower.

When the psychiatrist says "I know the trials aren't there" the reference is to the clinical trials needed to get Health Canada drug approval. This psychiatrist would choose EMPowerplus as a personal treatment option based on anecdotal evidence.

Under our current regulatory scheme, companies like Truehope are not allowed to share anecdotal evidence with you. You are not allowed to be given things like this psychiatrist's Court testimony. You are currently only allowed to be told that the Health Canada approved claim for EMPowerplus is: "Nutritional support for mental and physical well-being". It is illegal for Truehope to give you copies of the published clinical research as that research goes beyond the approved Health Canada claim. In short, there is almost complete censorship of truthful health information. Without truthful information, you cannot make informed health decisions.

This Truehope story was given to make the point that the belief in health freedom is inconsistent with the State:

- censoring truthful information, and

- making treatments not pre-approved by the State illegal.

People are alive today because they were given truthful information (that information being the product is novel and has no research behind it but some are finding relief). People are alive today because Truehope sold the product despite it not having State pre-approval. In a situation like this, the State could have a positive role consistent with health freedom. For example:

- our law could be that instead of censorship, all information must be provided, along with information about how much weight to give certain types of information (such as self-reports can be exaggerated so be cautious) so that consumers are fully informed;
- for serious conditions such as mental health, cautions to seek medical advice could be mandatory;

- our current requirements to protect against adulteration and to ensure product purity could apply.

The point of this is that a belief in health freedom is not inconsistent with safe regulation. Conversely, the belief that the State has the right to censor truthful health information and to limit treatment options is not consistent with safe regulation.

Any reaction to the current Health Canada proposals should be based on an understanding that the real problem is the prevailing belief

An analysis of Health Canada's proposals follows. As alarming as they are, the proposals are simply another action flowing from the belief that you do not have the right to make personal health decisions. The real battle is to change the belief that is governing our health policy.

I still believe that the best answer is the *Charter of Health Freedom* (see www.charterofhealthfreedom.org). The *Charter* is intended to codify into law the belief that individuals have the right to make their own personal health decisions.

I give an outline of the *Charter* at the end of this Paper.

The political landscape has become more difficult with manufactured demand for stricter regulation

In the 1990s it was consumer action demanding increased access to NHPs that led to the Standing Committee on Health holding wide consultations.
In the 2000s it was consumer action demanding increased access to NHPs that led to: the defeat of Bill C-51; exemptions for NHPs from parts of the *Food and Drugs Act*, and a delay on cost recovery from manufacturers.

Until a couple of years ago, I had never heard an MP tell me that he/she gets letters from citizens asking for stricter regulations on NHPs. Now, it is common. Most MPs will tell you they now get letters asking for stricter regulations on NHPs. The last public forum I was at hosted by an MP had some people publicly asking for stricter regulations. When I asked them for specifics, such as what perceived problem exists for which there not already adequate laws to address, I was met with ignorance of the current law. I can certainly understand people getting upset about losing access to products they rely on. I have difficulty believing that citizens on their own decide there is a need for stricter regulation of NHPs. I have even more difficulty believing they will take action for this by writing letters and attending public meetings. My belief is further stretched when it becomes clear they do not understand the current regulatory powers they are complaining about. I become incredulous when I realize that this **new** trend to demand stricter regulation of NHPs comes after the NHP industry has complied with regulations bringing in good manufacturing practices and a licensing regime. That is, the **new** demands for stricter regulation come after stricter regulation, not before.

I am of the opinion that this is manufactured dissent, meant to undermine the traditional strength of the natural health community, which was a united message for increased access. Now MPs are getting two messages: (1) Canadians want increased access to NHPs, and (2) Canadians want stricter regulation of NHPs (which is inconsistent with increased access).

The "Facilitators" are hard at work undermining your freedom

The *Natural Health Product Regulations* which impose drug-style regulation on things we eat, and the coming Self-Care Framework that will make the regulations on natural products even stricter, are a classic exercise in what economists call "rent seeking". In the area of regulation, rent seeking involves the imposition of expensive and onerous regulations to limit competition and hence create a quasi-monopoly for the large companies that survive.

Investopedia describes this type of rent seeking as follows:

> **How Rent-Seeking Works**
>
> Politicians decide the laws and regulations that govern the industry and how government subsidies are distributed. If a firm succeeds in getting laws passed to limit their competition or create barriers to entry to others, the firm will increase its share of available wealth. Moreover, it has earned income without being productive or putting its capital at risk.

> Politicians decide the laws and regulations that govern the industry and how government subsidies are distributed. If a firm succeeds in getting laws passed to limit their competition or create barriers to entry to others, the firm will increase its share of available wealth. Moreover, it has earned income without being productive or putting its capital at risk.

When there are several companies in an industry that will go out of business with the imposition of stricter regulations, a "facilitator" is necessary to tell the victim companies that everything is okay. No small business will voluntarily sit still while unnecessary regulations are imposed that will drive them out of business *unless the trade or professional association they trust tells them that everything is okay*. The imposition of rent-seeking-regulations depends upon the trade association being co-opted by the larger companies that will benefit from the smaller companies going out of business. This is what is happening now with the Canadian Health Food Association and some professional organizations.

For example, when the first version of this Discussion Paper was released, the CHFA President sent out an email in an effort to calm its members down and to say there was no problem. This caused me to reply with a paper called: "*Canadian Health Food Association Competes with Montey Python's Flying Circus*". I admit that the title was unnecessarily cheeky but I was quite vexed with a clear attempt to calm the industry when there should be a red alert sounding. In that piece I challenged the CHFA President on the major problems with the self-care framework. There was of course, no truthful way to rebut my warnings.

Using a more recent example, last week a naturopathic doctor sent to me a one page document by Shawn O'Reilly of the Canadian Association of Naturopathic Doctors. This document was clearly intended to ensure that naturopathic doctors are unconcerned about the self-care framework. It began:

> Currently, self-care products, which consist of natural health products (NHPs), non-prescription drugs, and cosmetics, are regulated under three separate sets of regulations. Depending on the product use, its ingredients and/or the claim being made, a product could be found under any one or more of the above three categories.
>
> Under the Self-Care Framework, Health Canada is proposing a risk-based approach to aligning oversite of these three product categories and ensuring products have sufficient information on labels to assist consumers in making informed choices.
>
> The CAND is a member of the Natural and Non-prescription Health Products Directorate (NNHPD) Technical Working Group on the Self-Care Framework. Along with stakeholders representing industry, health care professionals, consumers, patient groups and academia, we provide input, insight and advice on the proposed framework. Regular technical sessions have been taking place since 2016 and are on going.
>
> Changes have been made to the proposed Framework as a result of the input the NNHPD has received from stakeholders and consumers.

> **The Director General of the NNHPD has clearly stated in meetings that they have no intention of repealing the Natural Health Product Regulations (NHPR). Natural health products will continue to be regulated under the NHPR…**
>
> (emphasis in original)

The last paragraph is in bold in the original, likely in response to the second version of this Discussion Paper where I was predicting that the NHP Regulations were going to be repealed. I was making this prediction because if the regulation of NHPs and chemical non-prescription drugs are going to be harmonized, the cleanest way is for there to be a single set of regulations.

If, however, because it will be politically unpopular to repeal the NHP Regulations in their entirety, then what will happen is that the NHP Regulations will be dramatically over-hauled so that NHPs and chemical non-prescription drugs are regulated the same way under two sets of regulations. ***This is a distinction without a difference***. What Ms. O'Reilly does not say, is that any of the significant changes that Health Canada has been consistent in telling Canadians are coming, are not coming. So, why didn't the communication tell naturopathic doctors:

- claims will be restricted to minor conditions, ***conditions for which a person would not seek the advice of a naturopath***
- that we will lose the right to use traditional use evidence to support almost all claims – this will lead to a loss of products;
- that the chemical drug standards of evidence will be imposed leading to a loss of products and claims;
- that it is naive to believe professional products will survive when "self-care" products are not intended for conditions for which a person would see a naturopath;
- that any naturopath that steps out of line, by say sharing truthful health information about a product, will be liable for $5,000,000 a day fines instead of the former $5,000 fines;
- that product lines will be lost as the marginal companies are pushed out of business;
- that prices will increase due to the increased costs to manufacturers with the new licencing fees, administrative penalties and increased GMP requirements.

And I ask Ms. O'Reilly:

1. what part of this is to the benefit of naturopathic doctors?
2. why is CAND not encouraging naturopathic doctors to take a stand like the NHPPA is?

The point of this is that the "facilitators" are at work which makes it vital that you educate yourself by reading the actual Health Canada documents and asking hard questions.

The Secrecy of the proposals – the devil is in the details and the details are not given

Despite several publications over several years, Health Canada has not revealed the details of the proposed changes. The public is being given a broad overview of proposed changes. The details are missing. The problem is that it is the details that will matter. A serious limitation in this discussion paper is that it is limited to comments on the deliberately vague information Health Canada has released.

Increased censorship – a reduction in allowed claims

In one of Health Canada's slides to promote the proposed changes they say:

> Benefits for Consumers...
>
> ✓ **Better information** to support informed decision-making.

This is referring to two main changes. They are planning on making changes to the facts and ingredients table on the label. They are also proposing that a URL be included on the outer label which would take the consumer to a website which would provide the following type of information:

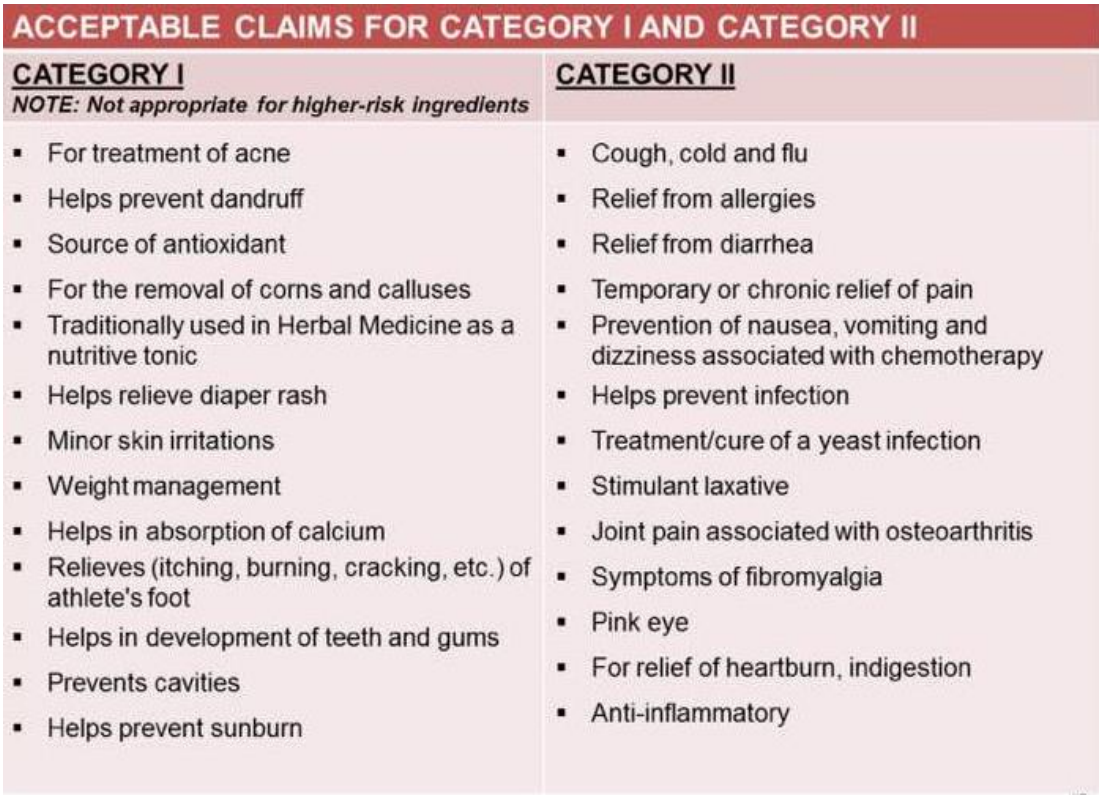
- the Health Facts table for the self-care product;
- information on the historical use or clinical evidence for the product. If the product is a traditional or homeopathic product, information relating to the paradigm or culture with which the product is associated, and
- information on regulatory activities impacting the regulated party within a defined period of time, such as adverse reactions, product recalls, site inspections.

This URL idea seems positive. For the very limited information that Health Canada will allow to be shared with consumers, a dedicated webpage is a positive way of sharing it.

The censorship problem with the new proposals is that we are going to further institutionalize limiting claims for natural products to soft structure function claims. A structure function claim is a claim about well-being or is a claim related to a nutritional deficiency. A structure function claim is not a treatment claim. For example, "vitamin C assists in the maintenance of bones" is a structure function claim. Because claims for non-prescription products will be limited to structure function claims, and because natural products do not have intellectual property rights to permit them to recover the cost of getting through the prescription drug process, the effect will be that natural products will not be allowed to treat anything but the most minor of health conditions.

The types of claims allowed under the new proposal

Under the new proposal there will be two categories of self-care products for which claims can be made. For both categories the claims will be limited to soft structure function claims. To illustrate this, I reproduce a photo of a Health Canada slide taken during one of their presentations in 2017. The list of "acceptable claims" clearly telegraphs that only soft structure function claims will be allowed.



ACCEPTABLE CLAIMS FOR CATEGORY I AND CATEGORY II

CATEGORY I *NOTE: Not appropriate for higher-risk ingredients*	CATEGORY II
▪ For treatment of acne	▪ Cough, cold and flu
▪ Helps prevent dandruff	▪ Relief from allergies
▪ Source of antioxidant	▪ Relief from diarrhea
▪ For the removal of corns and calluses	▪ Temporary or chronic relief of pain
▪ Traditionally used in Herbal Medicine as a nutritive tonic	▪ Prevention of nausea, vomiting and dizziness associated with chemotherapy
▪ Helps relieve diaper rash	▪ Helps prevent infection
▪ Minor skin irritations	▪ Treatment/cure of a yeast infection
▪ Weight management	▪ Stimulant laxative
▪ Helps in absorption of calcium	▪ Joint pain associated with osteoarthritis
▪ Relieves (itching, burning, cracking, etc.) of athlete's foot	▪ Symptoms of fibromyalgia
▪ Helps in development of teeth and gums	▪ Pink eye
▪ Prevents cavities	▪ For relief of heartburn, indigestion
▪ Helps prevent sunburn	▪ Anti-inflammatory

Truthful information about natural products treating serious and/or chronic health conditions will not be allowed

Our chemical drug model is deliberately allopathic. Allopathic means that it is designed to treat the symptoms of illness rather than the cause of illness. If someone can point out to me a chemical pharmaceutical drug that actually cures an illness, I would appreciate the update.

Our chemical drug model is also very dangerous in treating symptoms. Chemical drugs are one of the leading causes of death in Canada. Injury short of death is also common.

Even non-prescription drugs cause a number of deaths each year. If my understanding is correct, the common pain killer acetaminophen causes roughly 1 death per million people a year (so 36 a year in Canada). By way of contrast, my understanding is that Health Canada cannot point to a single death caused by a NHP in all of Canadian history. Many NHPs are

tremendously effective in treating serious health conditions. I have already spoken about Truehope, whose vitamin and mineral supplement treats serious mental health conditions such as bi-polar disorder. For those who simply could not be managed on the chemical psychiatric drugs, EMPowerplus was not simply a safer option, it was the only option.

I became passionate about defending our right to natural products when I defended the herbalist Jim Strauss. Jim was claiming to be able to cure heart disease with the Strauss Heart Drops. There was no clinical evidence to rely on but on the day of trial I had five middle class professional witnesses who:

- all had heart disease;
- all had experienced at least one open heart by-pass surgery;
- all continued to have heart disease as the reason their arteries were plugging up was not being addressed, and
- all needed another by-pass surgery to survive.

A couple of the witnesses were not strong enough to survive another by-pass surgery and so surgery was not an option for them. The other witnesses had experienced terrible complications from their first surgery and were not willing to go through another surgery. For all, the mainstream medical system was now a dead end. All were expected to die quickly. All had not been able to work for years. All then used the Strauss Heart Drops, got well and went back to work. At the time of the trial, I had the names, addresses and phone numbers of thousands who were alive because of the Heart Drops. For these, the Heart Drops were not simply a safer treatment option, they were the only option.

I have shared in earlier writing that my father can dance again because of Bell Shark Cartilage. His arthritis had progressed to the point where it was too painful to dance. The shark cartilage brought such relief that he was able to dance again. I know of another man who was disabled due to his arthritis and became well because of the shark cartilage. He became disabled while taking all of the chemical drugs his doctor prescribed. For him, shark cartilage was not "an" option, it was the only option for him. And yet it is illegal for the makers of Bell Shark Cartilage to tell you it can treat arthritis.

Every time I lecture members of the audience share with me that they have a serious health condition, the condition was being ineffectively managed with chemical drugs, and that they have found effective natural treatments. Many have shared they would not be alive without the natural treatments.

The point of this is not to say that natural treatments are better than chemical drugs. The point is many Canadians are alive solely because of natural treatments. Many more have a quality of life that they could not get with chemical drugs.

Because of the safety and effectiveness of many natural remedies, we cannot pretend that there is not a negative health consequence to censoring truthful information about them, and by creating a regulatory environment which will preclude most claims concerning the treatment of serious conditions.

The new Health Canada proposals will further institutionalize the censorship of truthful health information.

Risk for natural health practitioners and medical practitioners using NHPs

The proposed grouping of natural products into a "self-care product" umbrella with cosmetics and over the counter chemical drugs, combined with the significant limitations on claims, signals an intention to limit the use of NHP to structure function uses. Indeed, one of Health Canada's slides makes it clear that there can be no claim for a condition that would require health professional intervention, including follow up.

For greater clarity, natural products will not qualify as self-care products if meant for any health condition that will require the intervention of a health professional. If they do not qualify under the self-care product regulations, the only drug regulations they could be licenced under are the prescription drug regulations, which natural products generally cannot comply with. This would take us back to before the *Natural Health Product Regulations* when virtually all natural products were illegal. Only now it will be professional products manufactured to treat conditions requiring a doctor (be it medical, naturopathic, homeopathic or traditional like TCM practitioners) that will be illegal. Again, the devil will be in the details, but currently this is a significant concern based on the limited information Health Canada has disclosed.

The "branding" of NHPs as self-care products will have an effect on the public. It sends a clear message that they are not for serious conditions.

The "branding" within Health Canada of NHPs as self-care products will affect the types of claims permitted. It will also affect product composition. I am concerned that if in Health Canada's mind NHPs are not supposed to treat serious conditions, formulations for serious conditions will not be allowed. I am still haunted by a manufacturer of professional products for health care practitioners sharing with me that they were dropping one of their most effective products because Health Canada would not permit ingredients in the amounts needed to be effective. This company did not want to sell the product if it would not work. I am concerned that the branding of NHPs as self-care products will aggravate what I call the dumbing down of products to make them ineffective.

The federal regulatory environment also changes behavior at the provincial level. I will use health food stores as an example. Prior to 2004, virtually all products in health foods stores were illegal. I am guessing that as little as six years ago half were illegal. It once was very common for health food stores to have under the counter products that you had to ask for. These were the products they did not want a Health Canada inspector to see. It was almost a badge of honour for these stores to be providing such products because some consumers needed them. Now I do not even ask stores for such products as I do not expect them to have any under the counter products. Some stores will not carry NHPs that are not licenced. The "culture" has changed with the imposition of the *Natural Health Product Regulations*.

If the federal regulatory regime becomes more biased against the use of natural products to treat serious conditions, I am concerned that this will affect the populace. Provincial regulatory bodies may feel pressure to restrict the scope of practice of their members.

Uncertainty over the current compounding exemption

Under our current regulations, health care practitioners are free to prepare natural remedies for their patients on an individual basis. For example, if I visited a traditional Chinese doctor, that doctor could compound a remedy for me individually under the compounding exemption. It is not clear if this exemption will continue under the new proposals. In an email exchange I had with the Health Canada point person on the Self-Care Framework, Health Canada would not confirm or deny that the compounding exemption will survive.

"Protecting" You from products without proved efficacy – the scientific evidence censorship mechanism

One of the most significant changes in Health Canada's new proposals is the introduction of a new meme or belief. The new meme is that one of the risks of natural products is that a person may suffer if they do not work. This is referred to as "failed efficacy". I must say, that I find this new meme to be so truly Orwellian (saying the opposite of the truth), that I find it humorous. Let me explain.

When Health Canada speaks of "efficacy" they mean does the drug work. In the chemical drug world, and in the NHP world since 2004, products must be licenced to be sold. To be licenced they have to be shown to be relatively safe in comparison to the benefit that can be expected. The "benefit" must be proven. So if approval is being sought to treat scurvy, there must be evidence the drug treats scurvy. This is efficacy.

Most people assume that if a chemical drug is approved by Health Canada for a condition that it works for treating that condition. Most would be shocked if they understood how much uncertainty there is in the drug approval system. For example, in a Federal Court matter I was involved in, I cross examined an expert witness hired by Health Canada. This witness was an expert in designing and running clinical trials of psychiatric drugs. The witness made it clear that to get drug approval, two positive studies were needed, but that companies would be doing eight trials for anti-depressants so that they could come up with two positives. Specifically this expert testified:

> A. It is one of the factors. It means that you have to do many more studies to come up with the two positive ones. Instead of doing two, you now see companies are doing eight studies to make sure they have at least two positive.
> Q. Hmm.
> A. They obviously want more, but that's the way that the companies are doing it.
> Q. Right. Okay. So just so that I understand, so there is a kind of an industry standard or I guess to get approval from the regulatory body, at least for a chemical antidepressant, you have to have at least two –
> A. Positive –
> Q. -- quality studies showing a statistical significance over placebo.
> A. Yes.
> Q. And you can have some failed studies in there, but you have [to] have at least two showing this statistical significance over placebo.
> A. Yes. Yes.
>
> (Cross-examination of Dr. Silverstone, Federal Court File T-880-03 Applicant's Record pp. 7730-7731)

So that there is no misunderstanding, this expert was explaining that there could be six studies that showed the anti-depressant did not work any better than sugar pills, but as long as there were two studies showing the drug did work better then sugar pills, the drug would be approved by the regulatory body.

Adding uncertainty to the approval of drugs is that the clinical trials themselves can be designed to unfairly get the result the drug company wants. For example, on January 1, 2015, the New York Review of Books, Vol. 56 No. 1, reviewed *Drug Companies & Doctors: A Story of Corruption* by Marcia Angell. She is a medical doctor who had spent over 20 years as an editor of the New England Journal of Medicine. The review outlined the ways in which clinical trials into psychiatric drugs are manipulated to get a positive result. Dr. Angell is then quoted as follows:

> The problems I've discussed are not limited to psychiatry, although they reach their most florid form there. Similar conflicts of interest and biases exist in virtually every field of medicine, particularly those that rely heavily on drugs and devices. It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine.

My point is that when Health Canada says that a chemical drug has "efficacy" (i.e. that it "works"), there is, to be polite as possible, room for healthy skepticism. It is in light of the frailty of chemical drug "efficacy" that this new meme about "failed efficacy" needs to be assessed. Health Canada is signalling that a new risk of NHPs is that of "failed efficacy" meaning there is a risk of people taking them for a serious condition and them not working. It flows from this new Health Canada meme that people will need to be protected from taking NHPs for serious conditions so that they take the chemical drugs with proven "efficacy". Health Canada will not be factoring into their risk analysis the very serious side effects of the chemical drugs. Nor will Health Canada be factoring into their risk analysis the risk of preventing people from taking natural products that are effective.

How the scientific censorship mechanism works – the absence of intellectual property rights

By mandating that there must be double-blind clinical trial evidence to get approval to treat serious health conditions, Health Canada is declaring that no natural product can be used to treat serious health conditions. This is because of our intellectual property right laws. It has been several years since I was involved in Court proceedings in which the cost of the chemical drug approval process was relevant. At that time the cost was around a billion dollars. Chemical drug companies can tolerate this cost because they have intellectual property rights on new chemical compounds. If a new drug gets Health Canada approval, they have a monopoly until their patent runs out. Because of the monopoly they can charge high prices for the drug during the monopoly period to recover the cost of getting Health Canada approval.

There are no corresponding intellectual property rights for natural products. Consequently, the cost of the chemical drug approval process (the only process that will exist for making health claims for serious conditions) cannot be recovered. In effect, by limiting the type of evidence that must be used to get approval to treat serious conditions, natural products are automatically excluded.

For greater clarity, the proposed changes will move us into a regulatory environment designed to ensure that natural treatments are not used for serious health conditions.

Health Canada's reasons for requiring double blind clinical trials for serious health conditions should not be "assumed" to be correct

Health Canada's Consultation paper applies some rather seductive logic to make the case that NHPs should be regulated in the same way as chemical drugs. The Consultation paper explains that cosmetics, natural remedies and chemical drugs are all regulated differently. At the same time, they may appear together on store shelves. According to Health Canada consumers may be misled into thinking that the three types of products are equally effective, when they may not be. For example, the Consultation paper includes:

> When shopping for a self-care product, you will often see various options grouped together on store shelves based on the condition for which they are intended to be used. For example, a wide variety of products for skin care may be grouped together or a number of different products for headache relief may sit next to each other on the shelf. Many of the products you see might make the same or similar claims about what they do and they may have packaging that looks alike. These similarities may lead a consumer to believe that these products are equally effective and have had to follow the same rules and oversight to be allowed to be sold, but this may not be the case.

Health Canada's proposed solution to this "problem" is to subject all products to "scientific proof".

I cannot say whether this "problem" the Consultation paper discusses is real or manufactured to push a specific agenda. However, if there is a real problem of consumers being misled by different types of evidence backing different types of products, there are likely several solutions. The solution may not be forcing different types of products into one approval mechanism. The solution may be better labeling or education.

It should be noted, however, that the Consultation paper ignores a very real debate about scientific evidence. One of the reasons why the chemical drug approval process is so expensive, is the need for double blind clinical trials to show efficacy. Health Canada assumes that this is the best evidence to show efficacy. My understanding from my dealings with experts on this subject, is that this "assumption" is very much open to question. Other less expensive types of evidence can lead to more accurate results. It will be lost on most people reading the Consultation paper that it may be very dangerous for a regulatory body to limit the types of evidence that are acceptable for us to access remedies of our choice.

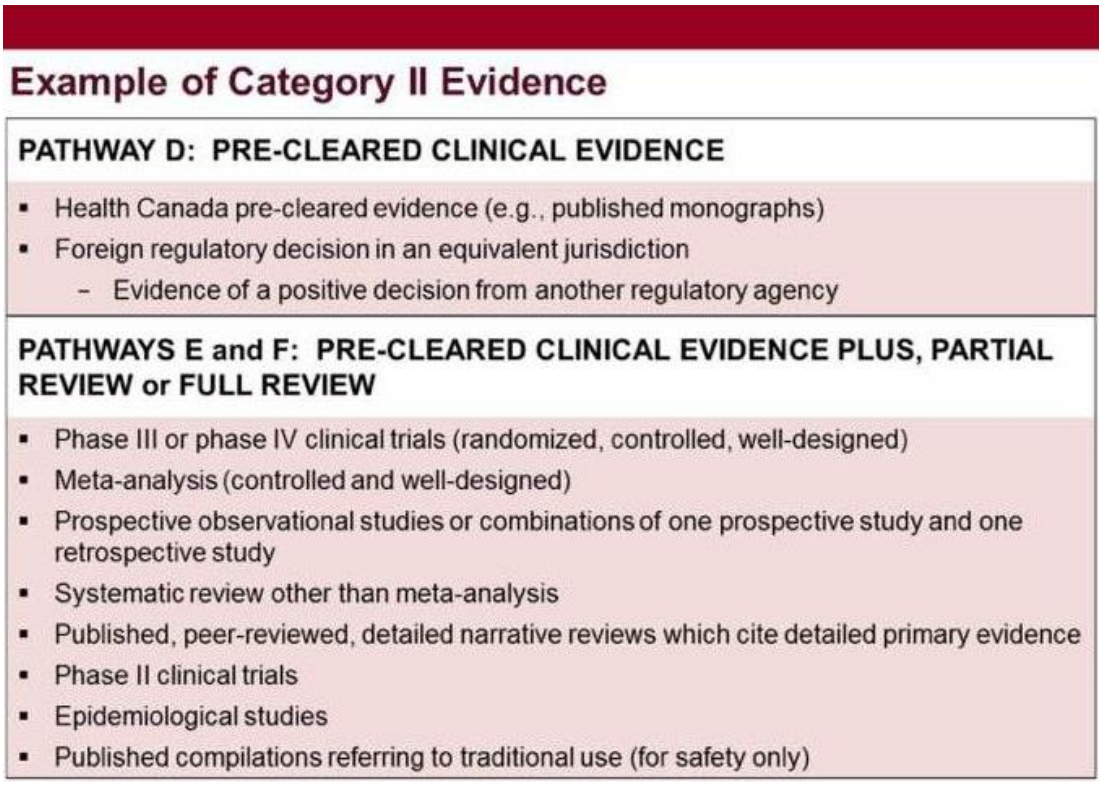
If other types of evidence that may lead to similar or more reliable results than the types of evidence Health Canada wants to privilege are ignored, all of us will suffer. We will lose access to evidence and products that may be more safe and effective than those that can afford to obtain the type of evidence Health Canada wants to privilege. This can lead to poor health outcomes. We cannot assume without serious inquiry that the evidence standards that Health Canada will want to impose will lead to better health outcomes. Indeed, they may lead to worse health outcomes. Any debate on changing the regulatory structure for any health product should include a realistic analysis of the strengths and weaknesses of

the different types of evidence. Any such debate should also take into account the health risk of losing products that may not meet any new evidence standards.

Specifics on the Evidence changes – loss of traditional use evidence for Category II claims

The current *Natural Health Product Regulations* includes homeopathic and traditional medicines as Natural Health Products. Because of this, traditional medicines can be licensed by using evidence of their traditional use to show both efficacy and safety. This will change under the proposed changes. Health Canada has made it clear that traditional use evidence will now only be allowed to show safety, but not efficacy for Category II products. This will likely severely restrict the licencing of traditional medicines such as First Nations, Traditional Chinese, Ayurvedic, or Traditional Herbal.

Below is a copy of Health Canada's slide concerning the evidence that will be required for the limited Category II structure function claims listed in the table above called "Acceptable Claims for Category I and Category II".



The current *Natural Health Product Regulations* do not specifically set out the evidence that is required for product licencing. The details are found in Health Canada's policy documents. Most likely this will be the case with the proposed changes, the details of which are not released. However, based on the above slide, it appears that the types of evidence Health Canada will be requiring for self-care products is more limited than the types of evidence allowed for natural health products. If this is the case, we can expect fewer natural health products to survive under the new regulations.

Indeed, in a different slide Health Canada writes:

- Claim must be supported by clinical evidence, with similar claims requiring an established level of evidence.

If this is correct, and a large pharmaceutical company runs a series of expensive double blind clinical trials to support a claim, such as a cold or flu claim, then every product wanting to make a similar claim may have to provide similar evidence. We do not have the details so this may not be correct. It is clear, however, that evidence requirements will be tightened to the detriment of natural products.

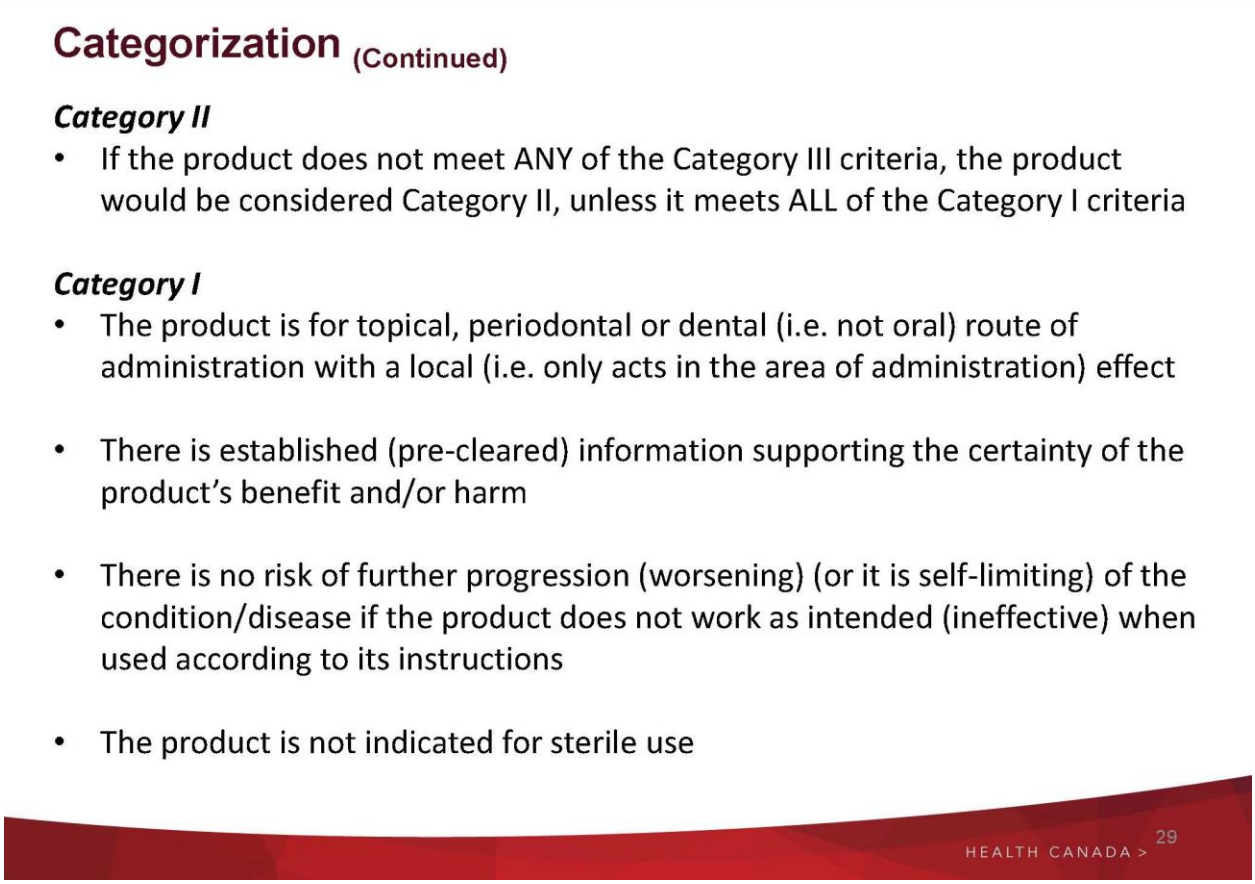
The Category I uses for which traditional use evidence can be used appears to have been reduced

As set out above, the types of claims allowed for self-care products will be for only the most minor of conditions. In Health Canada's 2017 cross-Canada tour they set this out in the following slide.

ACCEPTABLE CLAIMS FOR CATEGORY I AND CATEGORY II

CATEGORY I *NOTE: Not appropriate for higher-risk ingredients*	CATEGORY II
▪ For treatment of acne	▪ Cough, cold and flu
▪ Helps prevent dandruff	▪ Relief from allergies
▪ Source of antioxidant	▪ Relief from diarrhea
▪ For the removal of corns and calluses	▪ Temporary or chronic relief of pain
▪ Traditionally used in Herbal Medicine as a nutritive tonic	▪ Prevention of nausea, vomiting and dizziness associated with chemotherapy
▪ Helps relieve diaper rash	▪ Helps prevent infection
▪ Minor skin irritations	▪ Treatment/cure of a yeast infection
▪ Weight management	▪ Stimulant laxative
▪ Helps in absorption of calcium	▪ Joint pain associated with osteoarthritis
▪ Relieves (itching, burning, cracking, etc.) of athlete's foot	▪ Symptoms of fibromyalgia
▪ Helps in development of teeth and gums	▪ Pink eye
▪ Prevents cavities	▪ For relief of heartburn, indigestion
▪ Helps prevent sunburn	▪ Anti-inflammatory

On February 21, 2019, Health Canada did a presentation at the CHFA West show which included the following slide on classifying a product as a Category I or II.



This recent slide makes it clear that Category I products will be limited to products that are ***topical, periodontal or dental***. In other words, ***the only products for which traditional use evidence can be used to support efficacy claims are topical, periodontal or dental products***. For all practical purposes, the use of traditional use evidence is over. This is a significant change.

Which monographs will survive the loss of traditional use evidence?

We were the first in publically predicting that an extensive monograph system would develop under the NHP Regulations.

We now query which monographs will survive the transition to the Self-Care Framework. Traditional use evidence will only be allowed to support claims for topical, periodontal or dental products. Many current NHP monographs are based on traditional use evidence. These are clearly at risk once the Self-Care Framework is implemented.

Losing innovative products

Before the *Natural Health Product Regulations* came into force in 2004, products for serious conditions such as Truehope's EMPowerplus or the Strauss Heart Drops were developed and marketed. Many lives were saved. One of my major criticisms of the *Natural Health Product Regulations* was that they would stifle innovation. Because there are no intellectual property rights for natural products, innovation would be stifled because clinical research would be needed and the cost could not be recovered. Some will say this is positive, that we do not want products on the market for serious conditions for which there is no research. The problem with this is that Canada has a proven track record of developing natural products that save lives. There is a health cost to stopping this innovation. A more balanced risk approach would involve mandating full disclosure of the lack of evidence so that consumers and health practitioners are fully informed.

The new proposals will further stifle innovation. They will further restrict claims allowed for products preventing them from being sold for what they are for. They will require the same type of evidence for innovation as is required for chemical drugs, taking away the discretion permitted under the current regulations for different types of evidence.

Increased ability to cancel product licences

Under the current regulations, once a licence has been issued, Health Canada can cancel a licence at any time if it is necessary to prevent injury. Absent the risk of injury a licence can only be cancelled for violating the law or if it is discovered the licence application was fraudulent. In both of these cases, the license holder must be notified before the cancellation and is given the opportunity to rectify any problem.

Under the new proposal Health Canada will be able to refuse or cancel a licence under "reasonable grounds". It is completely unclear what "reasonable grounds" are. I suspect Health Canada will be given more discretion to remove products.

It should be noted that when Health Canada removes natural products from the market for perceived contraventions, a risk analysis of removing the product from the market is never done. Health Canada has made it clear in Court that its role is <u>not</u> to protect the health of Canadians. Rather its role is to enforce the law (the *Food and Drugs Act* and *Regulations*).

Administrative penalties

The new proposals would subject natural health companies to administrative monetary penalties or AMPs. This is a scheme to penalize manufacturers, distributors, and retailers without the procedural safeguards of the Court process. AMP fines are always smaller then the fines a Court could order. This is done so that the public will accept being penalized without the presumption of innocence and without due process rather than face Court proceedings that have these safeguards but which also have larger penalties.

A significant problem with AMPs is that they are often used to finance the inspectors that issue them. This is no different then what occurs in some third world countries where the police will set up road-blocks to extort money from motorists on the road. The police manning the road-block get income from their inspection role. When it comes to AMPs, the money from the fines do not go "directly" to the inspector, but it does go "indirectly" to the inspector. Many agencies with AMPs use the estimated fine revenue to set their inspection

budgets. The idea being that the AMPs will pay for the inspectors. It is a dishonest form of cost recovery. It puts pressure on the inspectors to issue an AMP at most inspections for minor infractions to cover the cost of the inspections. As with the cost recovery issue discussed below, this will further add an administrative burden that does not now currently exist.

If there is any doubt that AMPs will be used to finance inspections, it should be noted that in Health Canada's slide on site licensing, compliance & enforcement, and vigilance they write:

> "Increase proactive verification of compliance, including inspections".

These inspections will be paid for by AMPs or by direct fees brought in for such inspections.

Administrative penalties to increase censorship

Health Canada is considering the use of administrative monetary penalties to enforce the advertising standards that Health Canada sets. This means that as a censorship tool, Health Canada can keep fining any person who shares truthful information contrary to Health Canada's wishes. As discussed above, the censorship of truthful information does not lead to positive health outcomes. This is one of the most troubling changes being proposed.

Putting natural health practitioners and companies at such risk that they would have to comply with Health Canada directions even if complying would lead to harm or death

As indicated above, Health Canada has been unable to identify to me a single death caused by a NHP, since confederation in 1867. Risk is always relative. It is misleading to say there is danger and risk, without comparing the risk to other risks. For example, peanuts and shellfish cause numerous deaths a year in Canada due to food allergies. It is then a statistical fact that the entire NHP industry which has never caused a single death, is dramatically safer than peanut butter, or scallops.

If Health Canada was saying that it was necessary to impose draconian sanctions on sellers of peanut butter or scallops due to the significant risk they pose, Canadians would likely not take them seriously. However, when Health Canada uses terms such as "drugs", and

"scientific evidence", to convince us to accept draconian penalties concerning NHPs, they are taken seriously, despite this being more ridiculous then imposing high penalties for peanut butter and shellfish.

Currently, the offence structure in the *Food and Drugs Act* reflects the different levels of risk posed by the products regulated under the Act. For example:

- the lowest risk products, NHPs and cosmetics are subject to a maximum fine of $5,000 and/or up to 3 years in jail for violating the Act or Regulations;
- food, is considered higher risk because of deaths caused by allergies and bacterial contamination. Violations concerning food can be punished by fines of $250,000 and/or up to 3 years in jail;

- chemical drugs, even over the counter ones such as pain relievers and cough medicines, cause numerous deaths each year. Prescription drugs as a group carry such a high risk that they must be managed by doctors and pharmacists. Despite this management, my understanding is that prescription drugs are still one of the leading causes of death in Canada. Due to their high risk, most violations concerning chemical drugs can be punished by fines of $5,000,000 and/or imprisonment of 2 years. It is indeed curious that single violations concerning chemical drugs face less potential jail then violations for NHPs, cosmetics, or food;
- for chemical drugs every calendar day there is a violation is considered a separate violation;
- for the offence of making misleading statements to the Minister concerning chemical drugs, fines can be unlimited and there can be jail of up to 5 years;
- because of the significant risk posed by chemical drugs, directors, officers, and employees that are involved in any violations can be personally prosecuted and subject to the $5,000,000 fines and/or 2 years of jail provisions. This is the case even if the company itself is not charged.

  In addition to the high penalties for chemical drugs, due to the significant risk they present, Health Canada has powers that currently only apply to them. For example, for chemical drugs:

- Health Canada can order recalls. It is a separate offence each calendar day a recall is not followed;
- Health Canada can order a person or company to do anything it considers to be "corrective action". It is a separate offence each calendar day such an order is not followed;
- it is an offence to continue to sell if there is a recall order;
- Health Canada can order an injunction;
- Health Canada can order clinical trials and any other testing, even if it would bankrupt the person or company and even if the product is withdrawn from the market.

  For NHPs, cosmetics, and food, Health Canada has significant power if it feels that there is a safety risk or wants to prevent a suspected offence regardless of whether there is a risk. For example:

- Health Canada can apply to a Court for an injunction against selling or doing anything that would be a violation. In this case, the Court would also have the opportunity to consider the risk of removing a product from the market if such a risk existed;
- Health Canada could get a search warrant and seize product and/or manufacturing facilities;
- Health Canada can seize without a warrant anything, including product their inspectors believe is connected with a violation;
- Health Canada can revoke the product's licence, and any site licences, rendering the continued manufacture and sale illegal;
- Health Canada can issue public advisories.

Health Canada is wanting to change the current structure where the penalties and powers reflect the risk involved. **They want to subject NHPs to the same penalties and powers that apply to chemical drugs.** For example, in the Consultation document they write:

> **There are inconsistencies and gaps in post-market powers.** Although self-care products are generally considered to be of lower risk, safety concerns can still arise when companies do not follow the regulations. The law provides Health Canada with powers to take action on products that are already on the market. At this time, Health Canada does not have the authority to order a recall or a label change for natural health products or cosmetics. Instead, Health Canada must work with a company to encourage it to remove a product from the market or change its label. In contrast, for non-prescription drugs, Health Canada has the power to demand a
>
> recall or a label change exists. Further, for those who break the laws for natural health products and cosmetics, the maximum fine is $5, 000 compared to fines in excess of $5,000,000 for non-prescription drugs.
>
> [Emphasis and grammatical error in the original].

Obvious misleading statements in the above Health Canada text include:

- the implication that Health Canada is helpless to take actions against NHPs or cosmetics when, as outlined above, Health Canada has significant powers to take action, and
- the statement that Health Canada must work with a company for a recall or label change when Health Canada has significant powers to stop the sale of a product, including a Court injunction which could include a recall.

I have come across several situations where Health Canada was demanding that a natural product be removed from the market. In some cases there was a danger in doing so. In cases such as that, it is a criminal offence under the *Criminal Code* to follow Health Canada's direction. In Canada a person cannot put a remedy on the market, allow people to become dependent on it, and then remove it from the market without warning. If death or harm ensues there can be charges of criminal negligence. In the case of death the maximum penalty is life imprisonment. So using the Truehope example, where the Court found it was legally necessary for Truehope to keep the product on the market to prevent harm, Truehope would have been guilty of criminal negligence if they had listened to Health Canada.

Under the current penalty scheme, persons can resist Health Canada directions where it would be unsafe to do so. Persons can generally survive $5000 fines for each offence. Most practitioners and companies in the natural health field cannot survive fines of $5,000,000 a day for each offence. The potential penalties for non-compliance would become so large that in effect resistance becomes futile, regardless of the health consequences.

Recalls without Court supervision are dangerous

In the area of chemical drugs which carry a very high risk profile, it may be more defensible to permit Health Canada to order a recall without Court supervision. I say "it may be more defensible", as in the area of products which persons may rely upon for their lives or for serious health conditions, it is always dangerous to allow a regulator the only say. Mistakes can cost lives and there is no downside to having a Court supervise the process to ensure people are not harmed.

Concerning NHPs, although there has never been a death caused by an NHP, I am confident that there have been deaths caused by Health Canada removing NHPs from the market. I have already spoken about the Truehope example, where the President of the Alberta branch of the Canadian Mental Health Association testified of deaths caused by this restriction. There was other evidence I relied on to invite the Court to find Health Canada had caused deaths.

If Health Canada could have ordered a recall backed by penalties that would have been certain to destroy the company, its directors and employees, I am confident that there would have been many more deaths. As it was, it came out during the trial that many deaths were prevented only because law-abiding Canadians became smugglers to protect their lives or the lives of their loved ones.

To further illustrate the danger of giving Health Canada the power to recall NHPs without Court supervision, I would like to share the example of a company I was assisting when Health Canada took nattokinase off of the market. At the time Health Canada directed every company that had submitted a licence application for nattokinase to perform a full recall. On behalf of the company I hired a medical doctor to perform an analysis of the risk of following Health Canada's direction. The doctor determined that because Canadians were relying on nattokinase for serious medical conditions, often under the direction of medical doctors, that it would be irresponsible to perform an immediate recall. People relying on nattokinase needed time to find alternative sources or to transition to other treatments. What the company did, was to stop selling any further nattokinase, but to let stores sell their existing stock. The company also advised stores and customers that individuals could legally access nattokinase by purchasing from U.S. companies for personal importation. My understanding is that this was the only company that did not do a recall as demanded by Health Canada. I found their actions laudable as they took steps to mitigate the risk of nattokinase being taken away, and there was zero financial gain for themselves. The irony in our law is that Health Canada can tell Canadian retailers and manufacturers they cannot sell a product like nattokinase, but Canadians can legally purchase from other countries.

As the law currently exists, because the penalties in the Act concerning NHPs reflects their low risk, companies can act responsibly, as in the nattokinase and EMPowerplus examples, to ensure that no-one is harmed, or that harm is minimized. NHP companies that defy Health Canada in order to minimize risk can still be punished but not destroyed. However, if the chemical drug powers and penalties are applied to NHPs, as Health Canada is now wanting, no company could withstand defying Health Canada to comply with their *Criminal Code* obligations and to comply with their ethical obligations as human beings. I do not know of any NHP company that could survive five million dollar a day fines for any non-compliance. When you add the fact that every director, officer or employee involved can also be charged and face five million dollar a day fines, non-compliance is unrealistic.

Considering there has never been a death caused by NHPs and that companies have a responsibility to take the risk of removing a product from the market into account, the

powers Health Canada is signaling they want are excessive. As outlined above, Health Canada currently has significant powers to protect Canadians from any supposed risk concerning an NHP. **Matters like recalls should be supervised by the Courts so that the risk of removing a product from the market can be properly managed.**

Cost Recovery and Access to NHPs

Health Canada has made it clear that once natural health products are regulated in the same way as chemical non-prescription drugs, that natural health companies will be charged fees for licencing (i.e. there will be cost recovery). Health Canada's rational is that they cannot continue to charge the chemical drug companies fees, and not charge natural health companies fees, when both are under identical regulatory requirements for licensing.

In fact, once the *Natural Health Product Regulations* are repealed or dramatically revised, Health Canada may have no choice but to charge the fees found in the *Fees in Respect of Drugs and Medical Devices Regulations*. Natural health products are exempted from the Fee Regulations. Once natural health products are "self care" products, the Fee Regulations will likely apply.

No one can say for certain what the cost recovery fees will be. However, **it may be naive to think that Health Canada is going to reduce the fees for the chemical pharmaceutical companies once the Self Care Framework is in place**. If Health Canada does not reduce the current fee structure for the chemical pharmaceutical companies, then the current fee structure is an accurate guide for what natural health companies will have to pay once the Self Care Framework is implemented.

For a detailed analysis of the current fees see our Cost Recovery Discussion Paper. As set out in that paper, we could expect the following:

> **fees for the processing of product licences**. The fees range significantly from $355,579 to $19,921. The smallest fee of $19,921 is for applications based on published data only;
>
> **yearly licencing fees** of $1,200 per licenced product;
>
> **yearly establishment licence fees per building** of:
>
> > **$65,422** for a typical **manufacturer** who both imports and distributes. This is reduced to $48,564 if the manufacturer distributes but does not import. It is reduced to $31,706 if there is no importing or distributing;
> >
> > **$54,888** for a **packager or labeller** who both imports and distributes but does not manufacture. This is reduced to $38,030 if there is no importation. This is reduced to $21,172 if there is no importation or distributing
> >
> > **$16,858** for an **importer** who only imports;
> >
> > **$16,858** for a **distributor** who only distributes products, at least one of which the distributor holds the product licence for.

More strict standards

Despite the fact that Health Canada cannot point to a single death in Canadian history caused by a natural health product, good manufacturing standards were imposed upon the products in 2004. I am not aware of a realistic concern that the current standards are too lax. Now Health Canada is signalling they will become stricter. For example, in one of their slides they include:

- Require **site licences** for Categories 1B and II, including licensing for testers;

- Create a **baseline quality manufacturing standard** that is consistent across all product lines [meaning chemical product lines and natural product lines], with increased requirements for Categories 1B and II.

In another slide Health Canada states:

- A common quality standard would be applied as a baseline for all self-care products, including Places, People, Processes and Products.

In imposing this solution (stricter requirements) when there is no problem (the current standards are fine), Health Canada is pursuing classic rent seeking. Rent seeking is where the regulatory body imposes ever stricter standards that makes the cost of pursuing the regulated activity prohibitive except for very large companies. The large companies which can afford the regulatory burden, including the licencing and inspection fees that support the regulator, support the strict regulations as they create a quasi-monopoly. The regulatory body supports the ever stricter regulations as that is the regulator's business, and it allows the regulator to grow by charging fees for their service.

The increased regulatory burden will drive more natural health companies out of business, further reducing access to products.

A solution without a problem? – There is no need to subject the natural health community to chemical drug penalties and powers

In my law practice I defend and am consulted by natural health companies and practitioners facing Health Canada demands and charges. As President of the NHPPA I am briefed by others facing Health Canada demands and charges. I am not aware of a single instance where the current powers Health Canada has concerning natural health products was not

sufficient for their role of enforcing the *Food and Drugs Act* and *Regulations*. I challenge Health Canada to point out a single instance where their powers were inadequate for their enforcement mandate.

The natural health community is being asked to accept being subjected to dramatic penalties and powers when there is no need. If we accept that nothing happens in government without a purpose, then why is Health Canada wanting these changes?

Trojan Horse timeline & NHPPA predictions coming to pass

(1) The difference between amending Acts and changing Regulations

For changes to the *Food and Drugs Act* to be passed, the government must pass an Act. To do this, the Act has to go through three readings in both the House of Commons and the Senate. This takes months as usually after second reading Acts go into committee for study before being brought forward for third reading. The obvious benefit of this for persons concerned about any changes, is that it gives citizens time to petition their MPs to oppose the Act.

In contrast, Regulations are not subject to any vote by MPs. Regulations get passed by the government publishing them in the Canada Gazette, waiting for comments, and then publishing them a second time in the Canada Gazette. This can happen in a matter of weeks. MPs do not vote on regulations, and so in addition to their being little time to oppose regulations, MPs do not have the option of opposing them with their vote. Indeed, opposition MPs have literally no clout under this process.

(2) The gaming of the natural health community with Bill C-17

In 2008, when the NHPPA and other groups across Canada worked together to fight the infamous Bill C-51, the CHFA was on the opposite side supporting Bill C-51. Thankfully the CHFA was unsuccessful, and Bill C-51 was defeated. Canadians had produced so much pressure on MPs during the Bill C-51 fight that some told us their offices were literally shut down with phone calls and letters. I was told during a meeting at the Prime Minister's Office that there was so much mail to the Minister of Health that it was delivered by wheel barrow. Health Canada learned from this that they could not re-introduce Bill C-51.

To get around the opposition in the natural health community to Bill C-51, Health Canada came out with Bill C-17 in December, 2013. Bill C-17 was specifically designed to game the natural health community. It was drafted to subject natural health products to most of the provisions of Bill C-51 at a later date without the *Food and Drugs Act* having to be amended.

Bill C-17 misled and gamed the natural health community by:

- creating a new category of "therapeutic product";
- subjecting "therapeutic products" to the harsh measures in Bill C-51 that were opposed by the natural health community, and
- defining "therapeutic product" as excluding natural health products as defined in the *Natural Health Products Regulations*.

This gamed the natural health community as on its face, Bill C-17 did not subject natural health products to the harsh penalties and powers that would apply to "therapeutic products". At the same time, Bill C-17 was structured so that at a later date, Health Canada could subject natural health products to the provisions that apply to "therapeutic products" without having to pass an Act in Parliament. Rather, all Health Canada had to do was to abolish the *Natural Health Products Regulations*.

Bill C-17 was a clear Trojan Horse designed to fool the natural health community. Indeed, in the NHPPA discussion paper on Bill C-17 we wrote:

> **"Whether this Bill affects natural health products depends upon the "therapeutic product" definition.** The definition does not currently apply to natural health products, but the way it is written leaves a back door, like that in a Trojan Horse, that could come back to haunt us. This back door would be closed if Bill C-17:
>
> 1. added the current definition of natural health product into the *Food and Drugs Act*, and
> 2. defined "therapeutic product" as:
>
> > "therapeutic product" means a drug or device or any combination of drugs and devices, but does not include a natural health product"
>
> If the definition of natural health product was put into the Act, the definition could not be changed without an amendment to the Act. In that way, if the Government wanted to change the law to make the strong powers and harsh penalties in Bill C-17 apply to natural health products, they would have to amend the Act. This would require three readings in the House of Commons and three readings in the Senate.
>
> There would be ample opportunity for citizens to communicate to the law makers that they do not want these changes. That was the protection that stopped Bill C-51.
>
> If Bill C-17 passes, we do not have the protection of the Government having to change an Act to affect natural health products. Rather, all they have to do is change a regulation.
>
> The definition of "natural health product" referred to in the "therapeutic product" definition, is only a regulation. Regulations can be changed by simply publishing the change twice in the *Canada Gazette*. There are no votes by either the House of Commons or the Senate to regulation changes. Even an unpopular minority government can change regulations with impunity.
>
> The potential danger of Bill C-17 is that Canadians will not take any notice because the return of the Bill C-51 powers and penalties it represents do not appear to apply to natural health products. The Bill could easily pass because the public does not care. Later even a minority government can apply the Bill C-17 provisions to natural health products by simply changing or abolishing the natural health product definition in the regulations."

This prediction that Bill C-17 was a Trojan Horse is coming to pass. **The exact threat that we predicted, i.e. that the harsh penalties and powers in Bill C-17 would be applied to natural health products by simple regulatory change, will occur in the next two years.** Health Canada has now given us a timeline that by 2021, the *Natural Health Product Regulations* will be either repealed or drastically revised so that natural health products will be regulated the same way as chemical non-prescription drugs.

It is important to note that in 2013, the NHPPA pointed out to the CHFA the exact problem with Bill C-17. The CHFA ignored the correct NHPPA analysis and supported Bill C-17. We are still at a loss as to how the CHFA could have viewed Bill C-17 as in the interests of the natural health community. Now the door of the Trojan Horse the CHFA supported is being opened.

(3) The new Trojan Horse timeline

Health Canada is planning on implementing the changes outlined above in a three phase timeline. This timeline is masterful political manipulation. It is a classic boil the frog slowly implementation of dramatic change. The timeline is as follows:

- in the spring of 2020, amend the labelling provisions of the *Natural Health Products Regulations*. These are not significant. In the boiling of the frog analogy, the water is comfortably warm at this stage. The frog is not concerned about these changes which helps the frog to be comfortable with the coming changes;

- in the spring of 2020, begin harmonizing the regulation of non-prescription chemical drugs and natural health products. New regulations for chemical non-prescription drugs will be introduced. Despite the concerns by pharmacists, it will become easier for these drugs to be approved. This will not yet impact the natural health product industry as the introduction of the framework that will later be imposed on natural products is not yet imposed on them. In the boiling of the frog analogy, the water is now getting uncomfortably warm, but the frog thinks it can tolerate it;

- in 2021, harmonize the regulation of natural health products with the chemical non-prescription drugs. This is when the changes discussed above are implemented such as the restriction of claims, the loss of traditional use evidence, the imposition of $5,000,000 a day fines, the phasing in of the chemical drug standards of evidence. I predict this will not be the standards that will be eventually introduced (i.e. the final standards will arrive later). The *Natural Health Product Regulations* will be completely repealed or dramatically changed. In the boiling of the frog analogy, the water is now clearly too hot but the frog has nowhere to jump to. The frog did not do anything when harmonization of the regulation of chemical drugs and natural health products began. Now with the repeal or re-writing of the *Natural Health Product Regulations* the frog has nowhere to jump to.

- the standards of evidence and regulatory requirements are increased. Frog legs are served.

There is no scientific or political reason for these changes

In a separate Discussion Paper I outline:

- the significant expertise that went into the development of the current NHP Regulations including the Standing Committee on Health Report and recommendations that natural products should not be regulated in the same way as chemical drugs and that the chemical drug standards of evidence should not be imposed on natural products;

- that four bureaucrats came up with the self-care framework literally out of thin air, and

- that the natural health community was not consulted on the significant changes before being told they were going to be imposed as non-negotiable.

The experts in managing the risk of chemical non-prescription drugs disagree with the self-care framework

Pharmacists are experts in managing the risk of chemical drugs, both prescription and non-prescription. In giving comment to Health Canada on the self-care framework pharmacists were clear that the approval process for chemical non-prescription drugs should not be made less onerous, one of the main goals of the Self-Care Framework. Indeed, the National Association of Pharmacy Regulatory Authorities made submissions to Health Canada on the Self-Care Framework which included:

> We thank you for the opportunity to contribute and wish to share our feedback with you. In general, NAPRA does not disagree with Health Canada's proposal to separate the regulation of prescription and non-prescription drugs by creating a new set of regulations for non-prescription drugs. ***However, we caution that this should not result in less stringent regulatory requirements for non-prescription drugs.*** We do not agree with the assumption that seems to permeate this framework that the level of risk of all non-prescription drugs is similar and is more closely aligned to that of natural health products than to that of prescription drugs. In addition, we feel that the framework should address Health Canada's role in ensuring the appropriate scheduling of consumer health products based on their inherent level of risk.
>
> **Level of risk**
>
> The level of risk for non-prescription products can vary, just as the level of risk for prescription or natural health products (NHPs) can vary. An example of higher-risk non-prescription drugs are products that were recently switched from prescription to over the counter (OTC) status (Rx to OTC switches). The risks of prescription drugs can be mitigated through prescriber intervention and monitoring. However, when a drug is switched from Rx to OTC status, the risks that led to it originally requiring a prescription do not completely disappear. In fact, the risks may even be greater since prescriber intervention and monitoring will no longer occur and the ability of consumers to safely use the drug in the absence of supervision is unknown. We noted that Rx to OTC switches seem to have increased in frequency each year and are concerned that this framework will lessen the regulatory controls for these and other higher-risk OTC products.
>
> (emphasis added).

The NARPA's letter can be found in the materials disclosed by Health Canada to support the self care framework at: http://nhppa.org/wp-content/uploads/2019/02/Health-Canada-Response-to-Mr-Parkes-ATI-246-pages.pdf?fbclid=IwAR1mjLjJD2FMgp6h7yb_5KvLJUL8rtJA2wg6Qoqri5fCvxyuxI5Kt3Y2F4U

Wake-up call for those in the natural health community

Everyone in the natural health community should answer the following questions to determine whether they support the upcoming changes:

- is it in your interest for your company to be liable for $5,000,000 a day fines for any violation of the Act or Regulations instead of the current $5,000 fine per offence (where an offence subject to the $5,000 fine limit can occur over weeks or months);
- is it in your interest to be personally liable for $5,000,000 a day fines (any director, officer or employee involved in a violation of the Act or Regulations becomes personally liable for the $5,000,000 a day fines) as opposed to $5,000 fines;
- is it in your interest for Health Canada to be given the power to order you or your company to take any "corrective action", regardless of how unnecessary or even dangerous it may be? Is it in your interest to be liable for $5,000,000 fines for every day you do not comply with any corrective action order;
- is it in your interest for Health Canada to be given the power to order you or your company to conduct clinical trials or any other testing, even if the cost of the trials or testing will bankrupt you and even if you are not selling the product? Is it in your interest to be liable for $5,000,000 fines for every day you do not comply with the order to conduct the trials or testing;
- is it in your interest to be subject to Administrative Penalties that you are not now subject to? Is it in your interest to have more inspections as the Administrative Penalties will be used to pay for increased inspections;
- is it in your interest to be subject to Administrative Penalties for not complying with Health Canada's advertising guidelines which are not law, and which you are not currently subject to any liability for not following;
- currently there has to be a health risk for Health Canada to cancel one of your product licences. Is it in your interest for Health Canada to be able to cancel your product licences for any reason, even if the reason has nothing to do with safety? It is in your interest to then be liable to $5,000,000 a day fines if you sell after your licence is cancelled;
- is it in your interest for the NHP licences you have worked hard to obtain, to be cancelled and for you to have to comply with a new set of licensing regulations;
- is it in your interests for stricter site licencing and manufacturing standards to be imposed so that natural products and chemical drugs share the same standards;
- is it in your interest for Health Canada to be able to order you to recall a product without any court supervision. Is it in your interest to be subject to $5,000,000 a day fines for each day you do not fully comply with a recall order. Is it in your interest for this change, when in the case of a product people rely on for serious health conditions, you could be subject to long prison sentences under the *Criminal Code* if you comply with the recall order;
- is it in your interest for Health Canada to be able to issue an injunction without court supervision prohibiting you from continuing to sell a product. Is it in your interest to be subject to $5,000,000 a day fines for each day you do not fully comply with the injunction order. Is it in your interest for this change when, in the case of a product

people rely on for serious health conditions, you could be subject to long prison sentences under the *Criminal Code* if you comply with the injunction order;

- is it in your interest for there to be cost recovery, including yearly licencing fees, in the same amounts set for chemical non-prescription drugs;
- is it in your interest to increase censorship of truthful information concerning natural health products;
- is it in your interest to ensure that natural products cannot be used for serious health conditions;
- is it in your interest for a culture to be created where natural products are not considered appropriate of treating serious conditions;
- is it in your interest for a culture to be created where the scope of practice for natural practitioners is curtailed;
- is it in your interest for the individual compounding exemption to be taken away;
- is it in your interest for a "failed efficacy" standard to be implemented to ensure that natural products are not used for serious health conditions;
- is it in your interests for the standards of evidence used for chemical drugs to be imposed on natural products;
- is it in your interest to lose traditional use evidence as a support for efficacy claims;
- is it in your interest to accept for your children and grandchildren a system that denies them the right to choose which remedies they will access? This is the most important question listed.

Offering a solution instead of just reacting: *The Charter of Health Freedom*

The current concern caused by Health Canada's Consultation document is like déjà vu. It appears that time after time Health Canada proposes changes that endanger our access to NHPs. The natural health community reacts to stop the changes. The reaction is not always successful.

As discussed above, in the early 1990s there was a tremendous public backlash against Health Canada applying the chemical drug regulations to NHPs. The backlash caused the then Minister of Health, Allan Rock to refer the issue to the Standing Committee on Health. After extensive consultations the Standing Committee came out with 53 recommendations.

Health Canada was then tasked with drafting regulations for NHPs in response to the 53 recommendations. It can be fairly said that the NHP Regulations are not what many in the natural health community expected in response to the 53 recommendations.

For greater clarity, many felt that Health Canada could not be trusted to accurately draft laws that reflected what Canadians wanted concerning the regulation of natural remedies.

The next large public backlash was public reaction to what was then called Bill C-51 which proposed changes to the *Food and Drugs Act*, including some of the changes discussed in Health Canada's current Consultation document. This public reaction was largely successful.

Some of the parts of Bill C-51 were later incorporated into the *Food and Drugs Act*, but they did not apply to NHPs.

Following the Bill C-51 campaign, the NHPPA hosted groups, practitioners, consumers and companies from across Canada in a series of meetings. It was apparent that a solution to protect against constant government encroachment into personal health choices was needed. It was also felt that Health Canada could not be trusted to draft any laws to protect health freedom. Rather, the exact law wanted, word for word, needed to be drafted. Various ideas were debated and there was give and take until a consensus of how to solve on-going government encroachment was reached.

What came out of these meetings was the *Charter of Health Freedom* (the "Charter"). The Charter is a standalone Act with several key features. For example, the Charter:

- guarantees the right to make personal health decisions;
- guarantees the right to any treatment unless there is substantial and compelling evidence that the treatment poses a significant health risk, and that interfering with access to the treatment will not create a more significant health risk;
- sets out key principles such as each person being the best source of information concerning whether a treatment is effective for them, and privileging traditional healing traditions;
- creates the Ministry of Wellness that cannot have the same Minister as the Health Ministry and which cannot regulate chemical drugs. The purpose here is to separate the Ministry of Wellness from pharmaceutical lobbying and influence;
- ensures non-chemical and non-invasive treatments cannot be removed from the market without a balanced risk analysis which also takes into account the risk of taking a treatment away;
- ensures that regulations governing small and medium businesses must be reasonable for them;
- creates a Health Ombudsman with jurisdiction over all federal government departments to ensure that the rights and principles in the Charter are respected. Currently when the government is interfering with fundamental health decisions, there is no meaningful way short of expensive Court proceedings to seek a reasonable compromise with the government, and
- gives the Ministry of Wellness significant powers to restrict access when necessary, such as where there is fraud, adulteration, or unreasonable risk.

To learn about the Charter and to get a copy, visit the *Charter of Health Freedom* website at: http://www.charterofhealthfreedom.org/.

If the *Charter of Health Freedom* was law, Health Canada would not have jurisdiction over NHPs, and the current Health Canada proposals would not threaten any access to NHPs.

I would recommend that everyone concerned with Health Canada's ongoing efforts to over-regulate NHPs consider the Charter as a solution. Efforts to stop Health Canada's current initiative, even if successful, will simply put off the inevitable unless fundamental changes to the law, such as the Charter, are made. The Charter would not prevent regulation of NHPs such as is found in the current NHP Regulations. It would, however, ensure the protections set out above. It would also prevent over-regulation going forward.

Amending the Food and Drugs Act to un-do Bill C-17

A solution to having some of the proposed changes applied to natural products without the supervision of Parliament is to have the *Food and Drugs Act* amended to solve the problems created by Bill C-17. This solution will not prevent unwanted changes. It will, however, ensure that many of the unwanted changes cannot come about without Parliament scrutinizing them.

This initiative will need to occur relatively quickly, so that it can be accomplished before an election is called.

Call to action and support

The NHPPA has been quite consistent over the nine years since the Bill C-51 scare that Health Canada was not satisfied with the status quo and changes such as those currently being proposed were to be expected. We are now facing what we predicted would occur. We need you to work with us in the upcoming fight and in pushing for the Charter as a solution. We need your funding. We are inviting people to contact us at info@nhppa.org for setting up financial support. Alternately visit the donation page of our website at www.nhppa.org. We need your email address so that we can alert you to needed action. Please visit our website (www.nhppa.org) and provide us with your email address.

For more materials on the Self-Care Framework visit: http://www.nhppa.org/stophc