Discussion Paper on Health Canada's September 7, 2016 "Consultation" Paper on the Regulation of Self-Care Products in Canada

Scope of this Discussion Paper

This Discussion Paper, is the opinion of the author, Shawn Buckley, drafted October 23, 2016. 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.

Threat level - High

Health Canada is proposing changes to the regulation of Natural Health Products.

In my opinion it is likely that these changes will pose a significant threat to your access to Natural Health Products.

Timing – When to take action

As discussed below, the actual changes proposed by Health Canada have been kept secret. It could be that parts of the proposed changes are positive or neutral, such as permitting structure function claims or monograph products without licencing. The point being, is that it is difficult to appropriately direct public action when the target is not known.

It has also been the NHPPA's considered experience that there are clear diminishing returns in calling for public action. What I mean is that we can motivate people to take some action once asked. If, within a short period of time we seek to motivate the same people to take action a second time, the second response is generally smaller. Subsequent attempts in short periods of time yield smaller and smaller results. A cardinal rule of public campaigns is not to call for action too soon.

We have not yet put out a call for action and do not anticipate doing so until the proposed changes are released and we can assess them. This Discussion Paper will be released when Health Canada's call for public comment has ended. We are asking our networks not to jump the gun and exhaust the efforts of the networks until we know what we are facing. If, as discussed later in this paper, we are properly funded, we will once again provide our networks with the tools necessary to enable individuals to take meaningful action.

An unfair consultation process on specific changes Health Canada wants to make to the law governing the regulation of Natural Health Products

Health Canada is signaling that they want to change how Natural Health Products ("NHPs") are regulated. They have published a document called "Consulting Canadians on the Regulation of Self-Care Products in Canada".

A copy of this can be found at: http://tiny.cc/h518fy

So that there is no misunderstanding about the purpose of this "Consulting" document, it is not to ask you how you would like products to be regulated. Health Canada will have already drafted the exact changes they want made to the law. The "Consulting" document is merely a public relations exercise to justify the changes Health Canada has already drafted. For greater clarity, specific changes are in the works. We are all being asked to comment on them without being given the specific text of the changes. Rather, we have to try to anticipate the changes based on vague statements in the "Consulting" document.

Real consultation would include providing the actual changes and then asking for comments.

The "Consulting" document does not overtly say that NHPs are the target of the proposed changes. However, a review of the document makes it clear that NHPs are a target. Cosmetics, NHPs and chemical drugs are mentioned. The proposed changes are not likely to significantly change how cosmetics and chemical drugs are regulated. The proposed changes would significantly change how NHPs are regulated.

The changes would also place anyone involved in the manufacture, sale and distribution of NHPs in significant jeopardy of financial destruction and jail for anything but total obedience to Health Canada. I have been involved in situations where obedience with Health Canada would lead to death or harm. Indeed, in one instance a Court found that it was necessary to defy Health Canada to avoid death. Now, persons facing Health Canada directions in similar situations will either have to cause death and/or harm by following the directions of Health Canada, or face total financial destruction. Considering the extremely low risk profile of NHPs, Health Canada is proposing to swat flies with sledge hammers.

Abolishing the NHP sub-category of drug and regulating NHPs the same as chemical drugs

How Natural Health Products are currently regulated

NHPs are health products whose ingredients are primarily vitamins, minerals, plant or animal materials. Because they are not chemical drugs, they were not regulated in any consistent way until 2004, when the *Natural Health Product Regulations* (the "NHP Regulations") came into force. The NHP Regulations came about because Canadians were demanding increased access to NHPs. Health Canada had been using the chemical drug regulations to drive NHPs from the market. Canadians concerned about their access to NHPs demanded that Health Canada stop treating them the same as chemical drugs. When the NHP Regulations came out many, myself included, were critical because NHPs were still being regulated as drugs. There had been an expectation based on their very low risk, that they would be regulated as foods in the same way the United States does under the *Dietary Supplement Health and Education Act of 1994*.

Despite NHPs being regulated as drugs instead of as food, they were given special considerations in the NHP Regulations to reflect both their very low risk profile, and the absence of intellectual property rights. For example, the level and type of evidence needed to be sold is different than that for chemical drugs.

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By way of illustration, if a chemical drug company created a new chemical to treat scurvy, it would have to run clinical trials to show the chemical is "reasonably safe", and that it is reasonably effective in treating scurvy. A NHP company that wanted to sell concentrated limes (rich with vitamin C) to treat scurvy would not have to do this. Traditional and historical references and studies on vitamin C could be used. This is all quite reasonable. Even the records from the British Navy would rather conclusively demonstrate the vitamin C in limes cures scurvy.

It is fortunate, and essential to prevent deaths from chemical drugs, that NHPs be permitted to be sold based on these different types of evidence. Using the scurvy example, when I said the chemical drug company would have to show their new chemical for scurvy is "reasonably safe", I did not mean "safe" like limes. In the drug world, Health Canada will approve chemical drugs that cause death and other serious side-effects, as long as the perceived benefit outweighs the risks. So for example, common over-the-counter pain and cold remedies with acetaminophen cause a number of deaths every year. These deaths are tolerated as the perceived benefit of reduced pain for those of us who do not die outweighs the deaths caused by the drug. In our scurvy example, if the chemical scurvy drug had a risk profile similar to acetaminophen (which I think is roughly 1 death per million people a year – so 36 deaths a year in a country like Canada) it would likely be approved providing it was reasonably effective in treating scurvy. Contrast this with the lime NHP. The NHP would cure all scurvy but would never cause a single death. Given the choice most of us would chose the NHP over the chemical drug to treat scurvy. However, if the same approval rules that applied to the chemical drug also applied to the NHP, the NHP would never be licensed, and hence available. **This would lead to deaths because the only available remedy would be the chemical drug which has a higher risk profile.** The reason why the NHP would not get through the approval process is not because clinical trials would fail to show that limes cure scurvy. Rather it is because our intellectual property right laws would make it unrealistic for the clinical trials on the NHPs to be done.

The company that developed the chemical scurvy drug would have intellectual property rights to the drug. Because of this, they, or investors can fund clinical research on the drug in order to get Health Canada approval. If successful they would have a monopoly on the drug until their patent expires. Their monopoly would enable them to charge a high price for the drug. This would enable them to recover the cost of going through the chemical drug approval process. This is why chemical drugs are so expensive until their patent expires.

The company making the lime NHP would have no intellectual property rights. They did not invent limes and cannot patent limes. They would be unlikely to raise the capital necessary to go through the chemical drug approval process, as they would have no monopoly on the product if they succeeded. Without intellectual property rights any other company could cheaply copy their NHP keeping the price too low for the cost of the chemical drug approval process to be recouped.

This intellectual property right point is crucial. It is only because natural remedies are not subjected to the chemical drug approval process that they are so widely available. If you want to have continued access to NHPs, Health Canada's proposal to regulate NHPs and chemical drugs in the same way is a major threat.

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Health Canada wants to group NHPs into the same risk categories as chemical drugs – (1) the "scientific evidence" issue, and (2) the lost risk issue

(1) The scientific evidence issue

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. Remembering the scurvy example above, this can lead to poor health outcomes. The point to remember is that we cannot assume without serious inquiry that the evidence standards that Health Canada

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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 products 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.

Health Canada is now wanting to turn the different types of evidence into a "safety" issue. Using the lime example, Health Canada would consider the lime NHP to be more risky then the chemical drug for scurvy because the chemical drug will have gone through a clinical trial showing efficacy and the NHP would not have. This is ignoring that the lime NHP would be 100% effective in treating scurvy. In the Consultation document Health Canada uses the example of cough remedies to suggest NHPs are more dangerous as they may not be as effective as chemical drugs. I fully expect that Health Canada has not tested the efficacy of NHP and chemical cough remedies to see if there are differences in efficacy. Nor do I expect that Health Canada has done an honest evaluation of the value of the different types of evidence to support their assertion. If Health Canada has not evaluated the efficacy of various cough remedies or of the different types of evidence, their example could be very misleading.

Large companies, such as pharmaceutical companies, may want a very strict and expensive drug approval process to ensure that smaller companies, and natural health companies, are forced to close. Economists call this rent seeking. Rent seeking is simply where large companies encourage the government to create an expensive regulatory environment that drive the smaller competition from the market. This creates a semi-monopoly for the large companies that survive.

(2) The lost risk issue

In 2004, when the NHP Regulations were passed, it was made clear that the main reason why it was inappropriate to regulate natural remedies the same way as chemical drugs was that natural remedies are extremely safe compared to chemical drugs. Now, Health Canada is ignoring the very different risk profiles of natural remedies and chemical drugs. Health Canada is wanting to regulate them in the same way, ignoring their own stated rationale for the current NHP Regulations.

I am not aware of a single death ever caused in Canada by a NHP. A few years back I even made an *Access to Information Act* request to Health Canada to provide evidence of any deaths caused by NHPs going back to confederation in 1867. Health Canada did not provide me with evidence of a single death caused by a NHP.

I also recall professor Ron Law from New Zealand preparing a risk analysis based on Canadian Government statistics that showed that Canadians are more likely to be bitten by a shark then harmed (not killed) by a NHP. Curiously, because so many Canadians go south in the winter, some of us are bitten by sharks. The point being, that the risk of a Canadian being bitten by a shark is extremely low, and the risk of being harmed (not killed) by a NHP is lower.

Because the risk of NHPs is so low, many question why they are regulated as drugs at all. NHPs in the United States are regulated as food, and do not need to go through a licencing process. Many have been critical of the NHP Regulations as having caused harm by forcing

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some natural remedies off of the market. For example, I have been quite public with my belief that Health Canada has caused deaths by forcing nattokinase from the market. Nattokinase is an enzyme that can thin the blood. I know of medical doctors who used nattokinase for this purpose. Contrast nattokinase with the Health Canada approved chemical drug, blood thinner Pradaxa. At the same time that the media reported that Pradaxa was causing deaths due to the absence of an antidote if the blood became too thin, Health Canada took away a safe natural alternative. Those being safely managed with nattokinase had to move to the chemical blood thinners which have a much higher risk profile. When patients are moved onto more risky drugs, harm ensues.

Any changes to our regulation of remedies, whether natural or chemical, should be premised upon a balanced risk analysis. A balanced risk analysis involves not just assessing the risk of having a product on the market. It must also assess the risk of removing products from the market. For example, in taking nattokinase from the market Health Canada only assessed risks they could identify with nattokinase. They did not assess the risk of taking it away from patients which would force the patients to take riskier substances.

Changing standards of evidence for health products, will change which products are available. Before making such changes a balanced risk analysis must be done. The Health Canada Consulting document makes it clear that Health Canada has not done a balanced risk analysis concerning the changes it is proposing.

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

As indicated earlier, 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;

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- 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;

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- 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.

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.

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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. For example, when Health Canada briefly restricted Canadians' access to EMPowerplus, I am confident that this caused deaths. At the trial I called Ron Lajuenesse who had been the President of the Alberta branch of the Canadian Mental Health Association as a witness. He 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. The company was acquitted on the defence of necessity. In effect the Court found that it was necessary for the company to continue to make EMPowerplus available to Canadians. 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 health risk of nattokinase being taken away, with 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.

The difficulty facing the company I was advising on nattokinase is that there are legal obligations in the *Criminal Code* that must be followed. In Canada, a person cannot put a remedy onto the market, allow people to become dependent on the product, and then remove the product from the market. If there is harm or death the person who took the remedy away can be charged with criminal negligence. In the case of a death, the penalty can be life imprisonment. Our criminal law requires people to take into account the risk of removing a health product from the market. In my experience, Health Canada never takes the risk of removing a NHP from the market into consideration when demanding a company recall a NHP.

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.

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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 I have outlined, 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.

Cost Recovery and Access to NHPs

Health Canada currently charges chemical drug manufactures significant fees for the drug approval process. Indeed, despite the clear conflict of interest, Health Canada depends upon the pharmaceutical companies for part of their budget. NHP companies are not currently charged for going through the licensing process. In the Consultation document Health Canada is signaling that they want a "more consistent" fee approach meaning they want to start charging NHP companies for licensing.

Health Canada has been signaling for some time that they were wanting to charge for the licensing of NHPs. The last time they proposed a fee structure, many in the natural health community became alarmed that the fees would lead to the loss of many NHPs. I remember being consulted by a solid middle sized NHP company that did not think it could financially survive the fees.

Because Health Canada is not giving a fee structure in the Consultation document, it is impossible to comment on the effect fees will have on access to NHPs. Consumers that depend upon NHPs for their lives or for serious health conditions should, however, watch this issue carefully in case any future fee structure will endanger their access. There is little downside in currently stocking up on NHPs that are essential.

Innovation and the right for fully informed adults to make their own health decisions

I became passionate about ensuring that Canadians continue to have access to natural remedies after being involved in two court cases in which Canadian companies innovated to make products that saved lives. The first involved the Strauss Heart Drops. Herbalist Jim Strauss was charged with practicing medicine without a licence for claiming his Heart Drops could treat some heart disease. We challenged the charging legislation as being unconstitutional.

To give the Court context I had five middle class professional witnesses who:

- all had heart disease;
- all had gone through at least one open heart bypass surgery;

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- all had continued to have heart disease because the reason their arteries were plugging up was not being addressed, and

- all needed another open heart bypass surgery to survive.

Where some of these witnesses varied was that:

- some of them were too weak to survive another bypass surgery and so the medical system would not allow them to have another operation, and

- some had so many complications with their first surgery that they were not willing to have another surgery.

Because the medical system was a dead end for them, they all turned to the natural health community and eventually went on the Heart Drops. All had been too sick to work. All recovered and went back to work. One of them, Doug Henderson, wrote a book about his experience.

My point about the Strauss Heart Drops is that this was an innovative Canadian product that I am convinced has saved lives and made a significant quality of life difference for many. I strongly suspect that even under our current NHP Regulations, such an innovative product would not make it onto the market if it was developed today. With the proposed changes Health Canada is signaling in the Consultation document I am concerned that innovation such as the Heart Drops would be at an end. It is difficult to measure the health consequences of innovative products that will never be developed due to our regulatory structure.

The case of EMPowerplus that I discussed earlier was another example of an innovative product that has saved lives. I believe that there is currently more independent published research on EMPowerplus then on any other multi-ingredient NHP in the world. However, when the product was first developed, the people taking it knew there was no research. Indeed, they were being tracked as part of the initial research. Many had been in and out of psychiatric wards being drugged out on various chemical cocktails. Many became well and have never been back to a psychiatric ward. They have told me, and some have told the court, that they would not be alive but for the product.

EMPowerplus likely could not enter our market if developed today. I am very concerned that if Health Canada changes the evidence for NHPs that it would certainly not make it on the market if it was a new product. This raises a very important issue about whether Canadians should have the ability to make their own health decisions. In the case of EMPowerplus, the early participants knew that the product was untested. They knew what it contained. There was no misunderstanding of the situation. They voluntarily chose to be early participants. Many got well. Some did not. Should they not have had the opportunity that they did? EMPowerplus is simply a combination of vitamins and minerals. Should adult Canadians not be able to make such decisions when they are fully informed and when all of the Health Canada approved treatments are not working for them? Who should have control over our bodies, Health Canada or us?

This is a fundamental issue of health freedom that should be taken into account when considering changes to health policy. Prior to 2004, NHP companies were free to innovate, and many innovations have saved lives and/or brought tremendous relief to people who were suffering.

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One of my major criticisms of the NHP Regulations that came into force in 2004, is that they have dramatically reduced innovation by requiring the pre-approval of Health Canada before they can be sold. There was no pre-approval process for them prior to 2004. Similar products do not require pre-approval in the U.S. Now Health Canada is signaling they want to impose even stricter evidence requirements to show efficacy before a NHP can be sold. This will further stifle innovation.

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.

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 stand-alone 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;

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- 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: 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.

In the seven years since the Charter was drafted, we have gathered enough petition signatures to be the third largest federal petition in Canadian history.

I believe now, more than ever, that the Charter is vital as the solution to the current problems facing NHPs.

Keeping the terminology correct to preserve credibility

Whenever interacting with elected officials and/or bureaucrats, credibility is lost if it is clear you do not understand the regulatory structure. Several key groups consistently make fundamental errors in the law concerning the status of NHPS.

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The primary mistake are statements that NHPs are not drugs.

Under our current regulatory environment, NHPs are considered as drugs and are regulated as a drug. They have their own regulations as a special type of drug, but they are a drug. The only other options under the *Food and Drugs Act*, are food, cosmetics, and medical devices. NHPs are not being regulated as food, cosmetics or medical devices. One of my primary criticisms of the 2004 NHP Regulations has been that NHPs were being treated as drugs, rather than as foods (as they are in the U.S.).

In the current responses by some groups to the Health Canada Consultation document, I have seen the fundamental confusion on the drug status of NHPs made. It is not helpful to tell Health Canada or MPs to ensure that Health Canada does not succeed in regulating NHPs as drugs, when they are currently being regulated as drugs. What Health Canada is proposing is to regulate NHPs differently than they are currently being regulated. In both cases Health Canada is, and intends to continue, regulating NHPs as drugs.

Making fundamental legal mistakes will hurt all of our efforts and I am encouraging all groups to correct their understanding of the law.

Call to action and support

The NHPPA has been quite consistent over the eight 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 inevitable.

The NHPPA has, however, been a victim of its own success in its efforts to force Health Canada to become more reasonable. We had been given much feedback by the industry that it was largely our efforts that encouraged a more reasonable licensing environment. Companies having faced years of back-logs, saw things become more reasonable, and indeed tolerable.

Our funding dried up and frankly, quite recently, we were discussing ceasing operations. Then, with Health Canada's Consultation document, fear returned and our expertise in analysis and in creating public action is again necessary.

We expect that Health Canada will have to give some time after the October 24, 2016 consulting deadline, before the actual changes are introduced. They must give the appearance of considering the public comment they have asked for.

If the natural health community is wanting us to be engaged in the upcoming fight and in pushing for the Charter as a solution, we are going to need significant 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 are not aware of many other organizations that have even come close to being able to provide the accurate and balanced analysis of proposed regulatory changes that the NHPPA does. Nor or we aware of any other organization that has been as successful in creating public backlash against proposed changes, such as Bill C-51, when it was necessary.

If the natural health community wants the NHPPA to be involved, this time they will have to step up to the funding plate.