Shawn Buckley LL.B. Replies Directly to MPs Regarding The Charter of Health Freedom

By Shawn Buckley | April 2014

During the summer of 2013, citizens of Canada sent a copy of the Charter of Health Freedom to **every Federal MP** for consideration and comment. Many of their replies were forwarded to the Natural Health Products Protection Association (NHPPA) for comment.

As president of the NHPPA, Shawn Buckley analyzed the letters on behalf of Canadians who support the legislative change as proposed in the Charter of Health Freedom. A change that challenges the questionable approach taken by the Natural Health Product Regulations.

Mr. Buckley looked for common themes, assumptions and automatic data forwarded from Health Canada, to offer citizens insight into the political and legal complexities of the letters.

He has made the following observations to assist both citizens and MPs in continuing an important conversation.

Where scans of these letters exist, received by constituents from their MPs, they are available to be viewed at www.nhppa.org.

Context for MP Comments

It was interesting in an Orwellian sort of way, to analyze the MP responses to the *Charter of Health Freedom* (the "Charter"). What jumped out at me immediately, was that none of the responses mentioned or spoke of the Charter. One would think that when the Charter is dropped off, along with a summary of the Charter and a letter demanding action, that some mention of the MP's thoughts on the Charter would be made.

It may be that none of the political parties are willing to accept the primary premise of the Charter that people have the right to make their own health choices. There can be no health freedom if the State makes treatment options illegal. If the Charter was passed, the state would not be allowed to remove a natural health product unless there was compelling evidence that the treatment poses a

significant health risk, and that interfering with the treatment will not create a more significant health risk than is posed by the treatment itself.

The idea that the state should not remove a treatment if the removal would cause more harm than allowing access and mitigating risks in other ways (such as label warnings or requiring medical supervision) directly conflicts with our current regulatory paradigm for natural products.

Under our current regulations, natural health products by default are illegal. There is a default assumption that they are both unsafe and ineffective. To become legal, and hence available, their safety and efficacy must be proven. This sounds good on paper, but it has led to the loss of a large number of products. For example:

- as much as MPs and Health Canada tout the number of licenses granted, there is still a roughly 40% failure rate. Those that fail are illegal and eventually will be taken away;

- the 40% failure rate does not take into account large numbers of products which are no longer available because the manufacturers discontinued them believing that they would not get through the approval process or they could not afford the approval process;

- the 40% failure rate also does not account for tens of thousands of foreign products that are no longer available in Canada because the foreign manufacturers are not wanting to go through the approval process;

- the cost of having to go through the approval process and comply with the regulations has added cost to providing natural products. This cost is passed onto consumers pricing them out of reach for the poor;

- the loss of tens of thousands of foreign product competition, as the loss of all competition, leads to higher prices making natural remedies unaffordable for the poor.

The legal presumption that natural products are unsafe prevents us from managing them based on actual risk. Nothing is risk free. That said, I am not aware of a single death in Canadian history that can be attributed to a natural health product. I have searched the Adverse Reaction Database. I have made an Access to Information Request of Health Canada for such information. At the same time, risk analysis experts tell us that taking chemical drugs carries a high risk. Indeed, prescription drugs taken as prescribed are one of the leading causes of death. If our object was consumer safety, then a balanced risk analysis would have to be done before a treatment is taken away.

This would involve an analysis of:

- the risk posed by the product;
- the risk of removing the product,
- how to best manage a risk posed by the product if removing the product was more risky than leaving it on the market.

Our current legal presumption of risk precludes such a balanced risk analysis. Any product that fails the licensing process, or which does not go through the licensing process is presumed dangerous and must be taken away despite a complete absence of any evidence of harm. Any risk of removing the product is not relevant—all illegal products must go.

In addition to the actual danger caused by our regulations, there is also the freedom issue. Our current regulatory system assumes that the state knows best and that the individual can only be allowed to use treatments that the state approves. Under the Charter, individuals have the right to any treatment, unless the treatment poses a significant health risk and removing the treatment will not cause more harm than leaving it available.

For some helpful context to these safety and freedom issues consider:

- in the U.S. natural health products are **presumed by law to be safe** (the opposite of Canada) and are not to be removed unless there is evidence of harm;

- until 2004, practically all natural products were not approved or subject to the current regulations (so we were like the U.S.);

- there are still a large number of unapproved products in Canada which are being used without any problems;

- it is completely legal for Canadians to by unapproved products from the U.S. and other countries and to use them. We are losing access in our health food stores because it is illegal for the Canadian stores to sell them not because they are considered unsafe for us to use them.

Responses by MPs

Reciting the Government Line

When the NHP Regulations were first published on June 18, 2003, the Regulatory Impact Statement said:

These Regulations are intended to provide Canadians with ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

A theme in the Conservative MP responses is reciting some version of this such as Bruce Stanton who included in his responses:

> The Natural Health Product Regulations (NHPRs) help assure that Canadians have access to a range of natural health products (NHPs) that are safe, effective, and of high quality while respecting freedom of choice and philosophical and cultural diversity.

We know from Access to Information Requests that no risk analysis was done either before or after the Regulations to show what risk natural health products actually pose. Similarly we learned that no risk analysis was done to show the risk of removing natural remedies Canadians were relying on from the market.

Despite there being no risk analysis, the Government and Conservative MP line is that the regulations are there to assure we have access. Questions about the Regulations giving us access in response to the Government line include:

1. Natural Products in the U.S. are presumed by law to be safe and cannot be taken off the market without evidence of harm. There is no licensing requirement. Our Regulations create a legal presumption of harm. Products must be removed that are not proven to Health Canada's satisfaction to be safe and effective. How does this improve my access to natural health products?

2. According to Health Canada roughly 40% of products fail the licensing process and then cannot be sold anymore. How does this improve my access to natural products?

3. In the U.S. products do not need to be licensed and are cheaper than in Canada. Since the Regulations came into force the cost of complying has been passed onto consumers. Also, tens of thousands of U.S. products that kept prices down with competition are no longer available. How are the rising prices helping my access to natural products?

The "Safety" Issue

The Government line set out above also tells us the Regulations are for our safety. This is also a theme in the Conservative and Liberal MP letters. Questions for any MP who suggests the Regulations are there to keep us safe are:

1. Can you point to a single death in Canadian history caused by a natural health product? There are not any. How can you say the regulations are needed to keep us safe?

2. Can you show me a single risk analysis done by the Government either before the Regulations became law in 2004 or after to show the risk of natural health products as defined in the Regulations [there are not any]. How can you say the Regulations are needed to keep me safe when there are no risk analyses done to support this. How come the only risk analyses done, such as by the Fraser Institute show our Regulations will cause more harm than no regulations?

3. Can you show me a single risk analysis done to show the risk of removing natural products from Canadians who are relying on them to manage health conditions. Without knowing the risk of removing products, how can you presume it is safe to do so?

4. Do you not think that before a treatment someone is relying on to manage a serious health condition is taken away there should be a balanced risk analysis that balances the risk or removing the product with the risk of leaving it on the market?

5. Do you believe that educated adult Canadians should be free to use a natural treatment that has not been approved of by Health Canada? Do you think that Canadians should have sovereignty over their own bodies?

6. Canadians are free to purchase products that are unapproved in Canada from countries such as the U.S. How can this be about safety when I can use products but I cannot purchase the locally or get advice on using them locally?

The Liberal Twist to the Safety Issue

Three Liberal MPs (Alex Lysyhn for Bob Rae; Carolyn Bennet and Heddy Fry) had almost verbatim responses. After going into the history of the regulations and touting the safety angle all three say:

> Ensuring that products available to Canadians are evaluated for safety and efficacy is a key responsibility of any government.

Questions that could be asked in addition to the questions dealing with safety above are:

1. You say that ensuring natural health products are evaluated for safety and efficacy is a key responsibility of any government. The U.S. government does not do this for natural products and their citizens are safe. Indeed, our regulations allow me to order natural products from the U.S. for my personal use without any safety concern. Are you saying I

should not be allowed to do this or that the U.S. government is being reckless?

2. You say that ensuring natural health products are evaluated for safety and efficacy is a key responsibility of any government and yet many health food stores still carry a large number of unlicenced products and we do not hear of problems. Until 2004 there were hardly any licenced products and I did not feel unsafe going into a health food store, quite the opposite. Nor do I feel unsafe ordering products from the U.S. which does not evaluate natural products for safety or efficacy. What evidence are you relying on to say this should be a government responsibility?

The Adverse Reaction Issue

Bruce Stanton wrote:

> Over the past two years Health Canada has received 500 serious adverse reaction reports and have recalled over 40 products doe to serious health risk. Safety concerns may include product contamination or adulteration, those related to specific ingredients, unsubstantiated health claims, and interactions with other products.

This is really a variation of the "safety theme". By scaring us with reports of adverse reactions, the regulations are justified. This completely ignores there has never been a death caused by a natural health product. By taking them away you force people to use chemical drugs which do cause deaths. In addition to the safety questions set out above. You may want to ask an MP who speaks of adverse reactions:

1. You speak of adverse reactions as a justification for the Regulations. We know that Health Canada cannot point to a single death in all of Canadian History caused by a natural health product. What do you think of this. Why don't you ensure that in the next 12 months every drug that causes a single death, regardless of whether it is chemical or natural be recalled. I know you do not want any Canadian dying due to dangerous products. Of course this will mean that almost every prescription drug, over the counter cold remedy and over the counter pain killer will be gone. No natural product will be removed. What do you think this would tell us about the relevance of these so called recalls you use to justify regulations restricting my access to natural products?

Legal Errors and Non-Relevant Topics

Lauri Hawn wrote that:

> The vast majority of the natural health products industry develops safe goods of high quality. In 2010 our government passed consumer product safety legislation designed to target the minority who produce products that could be harmful...

Lauri Hawn is referring to the *Consumer Products Safety Act* which has no application to natural health products. Lauri Hawn concedes this later in the letter. It appears that this is simply filler to ignore the issue. When MPs speak of the *Consumer Products Safety Act* in response to natural health product inquiries simply ask:

1. Why are you speaking about an Act that does not apply to natural health products. Can you address my concerns by speaking about things that do apply?

Peggy Nash wrote:

> In June 2012 the Conservative government announced changes to NHP regulation. The new regulations are meant to speed up the approval process for NHPs entering the market.

There were no new regulations in June 2012 concerning natural health products. There are policy guidelines aimed at meeting time targets for processing licence applications. This is not relevant to how many products are failing in the process.

The look at how many licenses we are approving line

Another theme in the Conservative letters is to tell us that so far in 2013 more products have been approved than in the first two years of the Regulations. This is apparently to reassure us that we are not losing products.

This assertion is correct. There has been a dramatic improvement in the number of licenses approved. In my law practice I am advising clients to re-submit licence applications for products that have previously failed the process because the climate has changed. The percentage of licence refusals is dropping. This is positive news but does not change the fact that the licencing requirement has led to a significant loss of products and an increase in price as set out above.

The following questions from the access section also apply here:

1. Natural Products in the U.S. are presumed by law to be safe and cannot be taken off the market without evidence of harm. There is no licensing requirement. Our Regulations create a legal presumption of harm. Products must be removed that are not proven to Health Canada's satisfaction to be safe and effective. How does this improve my access to natural health products?

2. According to Health Canada roughly 40% of products fail the licensing process and then cannot be sold anymore. How does this improve my access to natural products?

3. In the U.S. products do not need to be licensed and are cheaper than in Canada. Since the Regulations came into force the cost of complying has been passed onto consumers. Also, tens of thousands of U.S. products that kept prices down with competition are no longer available. How are the rising prices helping my access to natural products?

The meaningless comparison with chemical drugs

Another theme is to point out that there are more licences for natural products than for chemical drugs. For example, Gordon O'Connor wrote:

> Since 2006 the NHPD has issued almost 42,000 product licences representing over 61,000 NHPs. This is compared to 15,251 active DINs on the market.

A "DIN" is a Drug Identification Number which is issued when a chemical drug is approved.

This theme is spouted to somehow reassure us that we are not losing access. It does not address any of the access issues set out above. It is comparing apples to oranges. Logically how does the number of DINs issued in any way affect our access to natural products? In addition to raising the access questions set out above, you may want to call them on it by asking:

1. You make a comparison between the number of product licenses for natural products and the number for chemical drugs. Why did you do this? How does this in any way address whether we are losing access to natural products?

Shawn Buckley for the NHPPA | April 2014