

NATURAL HEALTH PRODUCTS UNDER THREAT



By Shawn Buckley, LL.B., for Vitality Magazine Dec 6, 2016

Freedom of Choice in Health Care Faces Uncertain Future

We all have defining moments when it becomes clear that what we believe is simply not true. In the area of the regulation of natural health products (NHPs), I have had two defining moments which made it clear that my beliefs were false. Prior to these two defining moments, I actually believed Health Canada wanted to protect us. I also believed that the wishes of the people meant something to the government.

My first defining moment happened during a trial (in the early 1990s) where I was defending a NHP company from Health Canada charges such as selling their product without a licence. At the time, only the chemical drug regulations existed and such a product could not be licenced. A Health Canada inspector was in the witness box. I suggested to her that the purpose of Health Canada was to protect the health of Canadians. I thought this was a no-brainer suggestion. I fully expected her to say yes. She did not. Rather, what she explained was that the purpose of Health Canada was to enforce the Food and Drugs Act and Regulations.

Not surprisingly, people in the courtroom were stunned. We all believed that the purpose of Health Canada was to protect us. This turned out to be a false belief. The purpose of Health Canada is to enforce the law as it is currently written, not to protect our health. Fortunately in that case, the court acquitted the company of all charges finding that it was legally necessary for the company to protect people rather than be in strict compliance with the law. (This was a case in which I asked the Court to rule that Health Canada had caused deaths by restricting access to a natural remedy.)

My second defining moment happened when I was lobbying in Washington, D.C. (in mid-2000) concerning proposed changes to how their dietary supplements were regulated. We had just finished meeting with a Senator. While we were packing up, the Senator's Aid asked if he could speak to us. This Aid was around fifty years old and had been an Aid to senators and congressmen for his entire working life. In short, he was a Washington insider. He explained to us that at that time there were one-and-a-half full time pharmaceutical lobbyists for every senator and congressman. He went on to explain that the influence of the pharmaceutical lobby is so great that most senators and congressmen are aware of the share prices of the pharmaceutical companies. He was in effect trying to make it clear to us that we would in no way have any influence on government policy because we could not compete with the pharmaceutical lobby.



Does Health Canada Protect Public Health?

I already knew that there was a strong pharmaceutical lobby in both the U.S. and Canada, but I simply did not appreciate how pervasive it was. In my defence, this was before the release of Dr. Shiv Chopra's book, *Corrupt to the Core*, which gave an insider view of corruption within Health Canada. Dr. Chopra's book should be required reading for anyone who thinks Health Canada can currently be trusted to protect us.

These two defining experiences made it clear to me that:

1. Health Canada is not there to protect my health. They are there to enforce the law (regardless of the flaws in the law);
2. I could not count on the law being drafted to protect my health if my approach to health conflicted with the interests of the pharmaceutical lobby.

My dealings with Health Canada over the years have strengthened my belief that this government body is not there to protect us. In every instance where I have been involved as a lawyer in a case where Health Canada has sought to remove a particular natural health product from the market, Health Canada has never taken into account the risk of removing access to the NHP from Canadians who may depend on it.

In the court case I referred to earlier, I provided evidence of deaths caused by Health Canada restricting access to a NHP. Despite warnings that restricting access to the NHP could lead to deaths, Health Canada never took into account the danger of removing the product. Health Canada was only concerned with enforcing the law, regardless of the law causing harm and death. I have never seen Health Canada do a balanced risk analysis (i.e. one that balances a risk posed by a product against the risk of removing the product) to ensure that the safest course of action is taken. Health Canada is only concerned with strict compliance with the law, even if strict compliance will lead to harm.

Because Health Canada demands strict compliance with the law, we should be very concerned about any moves to strengthen their ability to take natural remedies away.

The Threat to Natural Health Products from Health Canada

Currently Health Canada is signalling that they want to change how natural remedies are regulated. These changes may signal the endgame for any practitioner or company that is more committed to good health outcomes than the over-regulation of natural remedies.

Currently, NHPs are regulated as a special type of drug. Yet much of our knowledge of natural remedies comes from anecdotal experience. For example, the British Navy learned that the vitamin C in limes prevented scurvy, so theoretically limes or lime extract could be licensed as a NHP based on this learned experience. It would not be necessary to run expensive clinical trials to prove that limes treat scurvy. Indeed, if it was necessary to run expensive clinical trials for a lime-scurvy remedy, we would never have access to limes to treat scurvy. This is because of our intellectual property right laws.

If a chemical drug company invented a new drug that they wanted to use to treat scurvy, they could get a patent on the new drug. Their patent would prevent any other company from selling a copy of the drug until the patent expired. The patent in effect creates a monopoly. Because there is a monopoly on the drug, the company can afford to go through the expensive clinical trial process. If they are successful, they can recover the costs of the clinical trials by charging a high price for the drug. They have a monopoly so the high price has to be paid. This is why new drugs are so expensive until after the patent expires.

On the other hand, a NHP company wanting to sell a lime extract for scurvy would not have a monopoly on their product. They did not invent limes and will have no intellectual property rights to limes or lime extract. In short, they cannot patent limes or lime extract. They would not be able to raise funds to go through the clinical trial process, as they would not be able to recover the cost by charging high prices. This is because they would not have a

monopoly on the remedy. Any other company could copy the product and sell it at a lower price because there is no patent.

Canadians Need Unrestricted Access to Natural Health Products

If we want to maintain our access to natural remedies, it is essential that NHPs are not required to undergo the same type of testing as is required for chemical drugs. Unfortunately, Health Canada is currently proposing subjecting NHPs to the same evidence standards imposed on chemical drugs. Not only does this ignore the differences in intellectual property rights, it also ignores the risks of further restricting our access to natural remedies.

There has never been a death caused by a NHP in Canada. Years ago, I made an Access to Information Act request of Health Canada asking for evidence of any deaths caused by NHPs going back to confederation in 1867. Health Canada could not point to a single death caused by a NHP. When our current NHP Regulations were introduced, the Regulatory Impact Statement made it clear that it was inappropriate to regulate NHPs the same as chemical drugs because the NHPs had such a low risk profile.

Unfortunately chemical drugs do not share the same low risk profile as natural remedies. Indeed, chemical drugs are some of the leading causes of death in Canada. Even over-the-counter chemical drugs like common pain killers and cold remedies cause a number of deaths each year.

It is because chemical drugs are so dangerous that restricting our access to natural alternatives will lead to death and harm. For example, nattokinase is a naturally occurring enzyme that can thin the blood. It is freely sold in the U.S. It used to be freely sold in Canada. Then Health Canada decided to restrict access to nattokinase, saying it was risky. I searched Health Canada's Adverse Reaction Database and could not find a single harm event, let alone a death, caused by nattokinase in Canada. When I searched the same database for harm and death caused by the chemical drug blood thinners, there were many reports.



At the time that Health Canada took nattokinase off the market (October 2012), many Canadians were being safely managed on it by health care practitioners, including medical doctors.[1] But those patients then had to be transitioned onto other blood thinners, like Warfarin (rat poison) or Pradaxa, once access to nattokinase was lost. The chemical blood thinners have a much higher risk profile, including death. You cannot take natural product (that has never caused a death) away from a patient, and put that patient on drugs with a risk profile of many deaths, and not expect harm and death. My point is that there can be serious health consequences from taking away access to natural remedies.

When I am hired as a lawyer because Health Canada is demanding that a natural remedy be taken off the market, we sometimes do a risk analysis to determine if people are likely to be harmed if Health Canada's directions are adhered to. Under the Criminal Code, persons can be charged if they put a remedy on the market, people come to rely upon it, and then they are harmed if the product is taken away. In short, the Criminal Code recognizes a duty to ensure that people who rely on a remedy are not harmed by it being taken away.

When Health Canada is demanding that a natural product be removed, but the demand is not met, the penalties under the Food and Drugs Act are fines of up to \$5,000 and/or three years of jail. Most persons or companies who have put a natural remedy on the market can survive such penalties. This enables them to act responsibly if following Health Canada's direction would put Canadians at risk. If Health Canada's directions are not followed, they can apply to a Superior Court for an injunction or other orders to ensure the law is followed. However, a Court will also have the opportunity to hear about the risk of removing a product, and will try to steer the safest course.

Now Health Canada is wanting to change the status quo. They want to be able to order recalls for NHPs without involving the Court. They also want to increase the penalties to fines of \$5,000,000 a day for any violation, including for not following Health Canada recall orders. In addition, any management or employees involved in the violation could also be personally subjected to the \$5,000,000 a day fines.

I cannot think of a single company that could withstand such fines. In effect, the ability to resist Health Canada demands for any reason will be at an end.

Anyone who is concerned about giving a government regulatory body absolute power over what remedies are available should be concerned about the proposed changes. When new regulations and/or amendments to the Food and Drugs Act are introduced, we are all going to have to be ready for action.

This is the most threatening proposal since the infamous Bill C-51.

I am inviting all readers to do three things to prepare:

1. For a thorough understanding of the proposed changes, visit <http://nhppa.org/?p=11604> and read my Discussion Paper;
2. Visit www.charterofhealthfreedom.org to familiarize yourself with the Charter of Health Freedom which is a solution to the over-regulation of natural products;
3. Financially support groups that will be resisting these changes. Advocacy for your health rights does not happen in a financial vacuum. Support for groups such as the NHPPA gives them the resources to work on your behalf.

We are entering a time when, unless we stand up and be counted, we will forever lose the right to decide for ourselves how we will treat ourselves or our loved ones when we/they are sick. Will you be counted?

References

[1] <http://www.straight.com/article-822951/vancouver/feds-swoop-pharmacy>