



If the NHP Regulations are not really meant to protect you, then who are they for?

Whenever a government imposes strict regulations that will restrict consumer choice and raise the price of the products that remain, a justification must be given to consumers so that they will support the new regulations. Almost without exception the justification is safety. The average consumer has become so accustomed to accepting restrictions in the name of safety, that seldom is there any resistance to new regulations.

Few consumers are savvy enough to understand that instead of blindly supporting "safety" regulations, that they should be wary whenever any government says their freedom needs to be restricted for "safety" reasons. This will change in the near future, but for now the average consumer accepts safety regulations without any critical analysis. This has been largely true with the *Natural Health Product Regulations* (the "NHP Regulations").

We are told that we need the NHP Regulations to protect us from such evils as adulterated products, fraudulent claims, and unsafe products. Despite these assertions, there has never been a death caused by a natural health product in all of our history. I have asked Health Canada under an *Access to Information Act* request to provide any evidence of death caused by a natural health product since Confederation (1867). I was given no evidence. This begs the question: if there has never been a single death caused by a natural health product, is there really a safety risk?

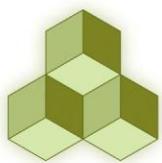
For example, we know that Canadians, mostly children, die every year from nut allergies by eating things such as peanut butter. Compared to every natural health product on the market, peanut butter is significantly more dangerous. However, peanut butter is not dangerous enough for us to support spending hundreds of millions of dollars to set up a separate directorate to protect us. As wasteful as a Health Canada Peanut Butter Directorate would be, ironically it could save the odd life. Unfortunately, my fear is that NHP Directorate is actually going to cost lives. That is we are spending hundreds of millions of dollars to "protect" us but that "protection" will actually lead to suffering and death that would not occur if we did not have the NHP Regulations.

The primary problem with the Regulations is that they require Health Canada's pre-market approval before a product can be sold. To get this approval, one must show that the product is safe and effective for the condition it is sold for. This sounds very reasonable.

Unfortunately, in our every day real lives, it is having very unreasonable consequences.

For example, I recently received a call from a lady named Geri. She was diagnosed with breast cancer in 1988. She had surgery and radiation treatment but the cancer returned in 1993. There was a several month delay before she could have surgery, and rather than doing nothing during that period, she consulted a naturopathic doctor and began taking specific natural health products. When the lumps were removed they came back as benign which puzzled the surgeon as the biopsies had shown both were malignant. Her cancer did not return until 2008. She put off surgery for a year taking supplements recommended by naturopathic doctors. During that year the tumours shrunk.

Geri was calling me because the main natural health product that she relies on is now unavailable in Canada. The U.S. manufacturer will simply no longer sell in Canada because they do not have Health Canada's approval. Geri explained to me that ever since she was diagnosed with cancer 24 years ago she has been very alert to people getting cancer around her.



She has gone to funeral after funeral of friends and family members who have died from cancer. She explained she had done better than anyone else she knows who has been diagnosed with cancer. She attributes this to the supplement that she can no longer get. For Geri, the NHP Regulations are denying her a product she has relied on to stay alive. I can tell you she does not feel "protected" by the Regulations. I wish Geri's case was isolated but I have received similar stories from people across Canada.

There are many people with serious health conditions who have tried all of the doctor recommended chemicals either without success, or for whom the side-effects were intolerable. They have found natural products that work. Health Canada is now taking those products away. This is putting them at risk for either death, or at best tremendous suffering. The risk of taking away products that people rely on to stay alive or to manage serious health conditions is completely ignored by Health Canada.

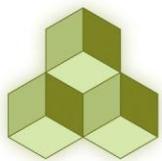
In my law practice I advise companies targeted by Health Canada. The typical scenario I am currently seeing are demands by Health Canada to stop selling natural health products because a "consumer" has complained that the products do not have Health Canada's pre-approval. The "consumer" is never identified and the demand is always for the person to stop selling the products complained of. When we get these demand letters the first thing we have to do is determine whether removing any product will cause harm. You cannot put a product out on the market, have people to come to rely on it for serious health conditions, and then remove it from the market. If anyone suffers or dies, you can be convicted of criminal negligence. The penalty for criminal negligence causing death is life imprisonment.

Health Canada never asks how many people are taking the product. Nor do they ask what benefits people are reporting. There is always simply a demand to stop selling. This means that you or I could complain to Health Canada about any unapproved product (roughly half of the products on the market are unapproved). Because of our complaint Health Canada will demand the product be removed from the market without any idea of the health effects. The product could be relied on by thousands of Canadians to treat serious health conditions and it would not matter. People may be taking the product under the direction of their health professionals, be they medical doctors or natural practitioners. In effect, our complaint would over-ride the medical decisions of anyone taking the product as well as the advice of their medical practitioners. This can only be described as reckless and dangerous.

In what I can only think of as Orwellian irony, Health Canada actually brags about forcing natural products off of the market. People have sent me communications from Health Canada in response to complaints about losing access to natural products. In these communications, Health Canada actually brags about the number of natural products that they have forced to be taken off of the market. According to Health Canada, some of these posed a potentially serious health risk. The bias in Health Canada's enforcement actions speaks volumes about their lack of support for natural products.

For example, let's assume that for a one year period Health Canada would remove every product that caused a single death regardless of whether the product was chemical or natural. After a year, not a single natural health product would be removed. Would there be any chemical drugs left? Even over the counter products like pain killers and cold medications would likely be recalled for causing death.

If the NHP Regulations endanger us instead of making us safer, then the question begging to be asked is whose benefit are the NHP Regulations for? We really can only speculate about this. That said, my speculation is that the NHP Regulations are an exercise in what economists call rent seeking.



Rent seeking is where large players in an industry encourage the bureaucracy to over-regulate an industry, usually in the name of safety. The bureaucracy benefits because it gets to grow to implement the new regulations. Although the cost of doing business increases, the large players benefit because the over-regulation drives the smaller players out of business. I am haunted by a quote in a study on industry perceptions of the NHP Regulations published at BMC Health Serv Res. 2006; 6:63 in which a large player in the natural health product industry was quoted as saying:

"the faster the weaker players get out of the business, the better, from a commercial side or predatory side...there's only going to be 3 or 4 big players that are going to survive. We intend on being one of them. So I'm saying if you're going to cause that, then do it faster. Quit slow bleeding us."

There is no question that the NHP Regulations will benefit the large companies, be they pharmaceutical companies or large natural health product companies who will have less competition once the full effect of the Regulations are in play. The Regulations also benefit Health Canada which was given funds to expand their bureaucratic empire and create a new directorate. The "benefits" for the consumer are that they get to pay higher prices and have less selection.

Some of us get to die when products we rely on are taken away. Others of us get to suffer when the only products we are able to manage serious health conditions with are taken away.

All of us get the benefit of learning that the word "safety", the stated reason for the Regulations, means something different than what we thought.

Shawn Buckley
Natural Health Products Protection Association
March 2012