

Dear _____,

Regarding Bill C51 and Health Canada's (HC) regulation of Natural Health Products (NHPs), please take the time to consider the following before addressing my questions below.

The statement that Natural Health Products are not regulated as drugs, which many MPs and Ministers are making, is false. Under the Food and Drugs Act, there are currently only two choices: Foods or Drugs. In 1997, HC proposed the Establishment Licensing Act to stop regulating NHPs as foods, and move them all into the drug category. In one of the largest protests of all time, Canadians made it resoundingly clear they did not want this. The issue went to the Standing Committee on Health, and it was firmly established that the approval model used for pharmaceuticals could not be fairly applied to NHPs. Accordingly, the Committee's first of 53 accepted recommendations to Parliament was that the Food and Drugs Act be amended to provide NHP's with a distinct third category, separate from either "foods" or "drugs." HC then held country wide consultations on the issue, and publicly announced that *by far* the number one desire of Canadians was to have increased access to a wider range of NHPs. Yet, against the public's wishes, and Parliament's directive, HC classified NHP's as drugs anyway.

This was significant because it allowed Health Canada to regulate NHPs based on the premise that they are "*dangerous until proven safe*," instead of employing a "*GRAS*" standard, i.e. "*Generally Regarded As Safe*." This allowed for inappropriately stringent, drug-like controls and standards to be set. However, being that NHPs have *never* caused a death in Canada, they have demonstrated that they are comparatively safer than both drugs *and* foods, as allergic reactions to foods such as peanuts and shellfish kill people yearly. Of course, it is *possible* to harm yourself with a natural product, but that doesn't mean it's likely. In fact, with zero Canadian deaths ever from an NHP, it is *extremely unlikely*. Hence, relatively speaking, the premise that they are dangerous is invalid.

This premise is employed along with a faulty definition in the F&D Act, which defines a substance as a "drug" according to what it is used for, rather than what it is, and its inherent risk or safety. This allows the government to control what people use to support health or treat disease, because it is a foregone conclusion that all drugs are dangerous, and require control. So garlic, parsley, cayenne, rosemary, etc., all commonly used in cooking, become "drugs" as soon as they are encapsulated and used for health concerns. This is perverse reasoning and constitutes a second faulty basis for the NHP regulations.

The drug-style Natural Health Product Regulations came into effect in 2004, and since then have dramatically reduced Canadians' access to NHPs. They eliminated products immediately because virtually every Canadian company was forced to reduce the number of products on its price list, since paying to license every product made keeping slow sellers financially unfeasible. In addition, since 2004, over 20,000 products (mostly U.S. imports) have been withdrawn from Canada. This is because in the drug style regulations each product must be licensed, and is also forced to make a claim. This claim must then be supported when the product license is applied for. This is a labour intensive, expensive process and the overwhelming majority of U.S. importers simply stopped doing business in Canada, since they couldn't justify the expense or the hassle. Many of these companies had been selling their products here for 10 to 20 years, and some since the 1970's, (refer to attached list.)

Other U.S. companies submitted product license applications but gave up in frustration with shipments being stopped at the border. HC has been described as "wilfully uncooperative," in this process. Nutraceutical Inc. from Utah, makers of the Solaray brand, pulled out of Canada this year after HC denied their site license renewal. They had submitted over 500 product license applications, and had jumped through every regulatory hoop HC presented for four years. HC always claims they are simply "ensuring access to safe effective NHPs that people can use with confidence", but Solaray has some of the best, most extensively tested products in North America! Why were they hassled so? Also, why did HC wait for four years until the company had invested so much money to finally deny entry?

HC is currently failing over half the NHP license applications it processes, and these are the “easy” applications with only single ingredients! What is going to happen when they start processing the bulk of multi-ingredient products? It appears that Health Canada has no intention of increasing access to NHPs, despite the fact that their own consultations showed it is the number one desire of Canadians.

In this light, Health Minister Clement’s comments, referring to Bill C51, are laughable when he says: “... under a modernized Food and Drugs Act, the numbers and variety of natural health products will continue to grow, the natural health product industry will be enhanced, and Canadians can be confident that they will be able to access innovative, safe and effective products.” Given the above, it would appear that the exact opposite is true.

In fact, the degree of regulatory concern over NHP’s is so out of proportion to their low levels of risk that it appears obvious that what is at stake is *not* public safety, it is market control over wellness and disease. It would appear that on many fronts Health Canada is *purposefully* blocking access to NHPs, and that this was the original intent of the regulations. Why else did HC ignore the huge public outcry, and refuse to follow the parliamentary directive to create a third category? HC says they did this because amending the F&D Act would have been too involved a process, and would have taken too long. Why now is it suddenly *not* too big an undertaking to rewrite and redefine the Act in Bill C51?

Following a predictable trajectory, the Bill proposes that NHPs and pharmaceuticals be lumped together under the umbrella term “Therapeutic Product”, further erasing the distinctions between them. The injustice of this is illuminated when you consider the radically different safety profiles of the two groups: zero deaths in 60+ years, versus a conservative estimate of over 500,000 deaths in the same period for pharmaceuticals. One prescription drug alone, (Vioxx), killed over 50,000 North Americans! It is obvious that having NHPs and pharmaceuticals under the same classification, be that “Drug” or “Therapeutic Product” is totally unfitting.

Few, if any, Canadians would disagree that NHPs should be: (1) produced according to Good Manufacturing Practice standards, (2) tested for purity and potency, or (3) should have to prove their claims *if* they voluntarily make one. But these are all independent concerns, and to address them all fairly and appropriately, NHPs need a separate category.

So is it Canadian citizens who are misunderstanding Bill C51, or is it our elected representatives? Judging by their comments, it would seem that many of them have not even read the Bill. Therefore, my questions that I would like a written response to are as follows:

1. Have *you* read Bill C51 – Yes or No? If so, do you acknowledge that in giving Health Canada the power to seize private property without court supervision, without any legal accountability, and without offering the owner any legal recourse, Bill C51 is unconstitutional, violates the Canadian Charter of Rights and Freedoms, and that the powers it provides could easily be abused by HC?
2. Where do you stand on this issue? Should Bill C51 be amended to provide NHPs with a third category completely separate from pharmaceuticals, and a more suitable set of regulations that *actually* increase and protect Canadians access to them, or are you fine with the current situation?

Your answers will determine *my* vote in the next election, as well as others’ in my circle of influence.

Respectfully yours, _____ Date _____
Signature

This letter represents the views of: _____
Name (printed)

Address _____

Constituency: _____ Ph. # _____

Since 2004 Health Canada's Natural Health Products Regulations have forced over 20,000 products off the Canadian Market

Below is a list of U.S. companies whose products used to be sold in Canada prior to the 2004 implementation of the Natural Health Product regulations. Following a seven year process, in which the number one request of Canadians, by far, was that they wanted increased access to more natural health products, and in which NHP's were supposed to have been given their own category, separate from either Foods or Drugs, Health Canada came out with the Natural Health Product Regulations. Not only did these regulations classify natural products as drugs without providing the new category, they were supposed to protect Canadians' access to NHP's. As is reflected in the list below, they have had the opposite effect. There are literally multiple thousands of products (20,000 plus), that Canadian stores can no longer get or sell.

Note that this list does not reflect the products that were lost when Canadian companies shortened their pricelist due to the cost of complying with the regulations.

- 1. Solaray, Kal**, and all other products produced by **Nutraceutical Inc.** – **Over 5000 products** offered in their US pricelist. Some of the best products anywhere in North America. Sold in Canada for more than ten years when discontinued. Did everything Health Canada asked of them for 4 years before having their site license denied by Health Canada. Gave up in frustration as they couldn't spend any more money on legal fees.
- 2. HerbPharm** – producer of **hundreds of herbal tinctures** - sold in Canada for more than ten years when discontinued after the NHPD regs came into effect
- 3. Gaia Herbals** – producers of **hundreds of herbal tinctures** – sold in Canada for more than 10 years when discontinued after the NHPD regs came into effect.
- 4. Allergy Research Products** – **over 650** extremely high quality natural products of all sorts – sold in Canada for more than ten years when discontinued. Will no longer ship to Canada.
- 5. Country Life** – **Hundreds** of high quality natural products in tablets and capsules – sold for more than 10 years in Canada when discontinued because of the regulations
- 6. Source Naturals** – **2300 products** in two lines representing a full range of nutraceuticals. Will not ship to Canada period because of all the shipments held at the border.
- 7. Vitamin Research Products** - **400 plus innovative, well researched products** that are flagged and regularly denied entry at the border
- 8. Jarrow products** – **600 plus** well researched, high quality products. Submitted product license applications, but gave up in frustration with shipments being blocked at the border.
- 9. Herbasway** – producers of green tea products – no longer available due to the regulations
- 10. Yogi Teas** – these are just herbal teas – most are no longer available due to the regulations
- 11. Sweet Wheat** – high quality wheat grass products – no longer available due to the regulations.
- 12. Bernard Jensen Products** – available in Canada since the 1970's –no longer sold due to the regulations.
- 13. Organic Essentials** – **organic tampons** – disallowed because their applicator was considered a medical device by Health Canada.
- 14. Zand Herbals** – **hundreds** of herbal products sold in Canada since the 1980's – pulled out of Canada after the regs went into effect
- 15. Life Extension Products** – **hundreds** of extremely well researched NHP's no longer allowed into Canada for commercial sale
- 16. Dr. Christophers Original Formulas** -**200 plus** herbal formulas sold in Canada since the 1970's. No longer available because of the regulations

17. Vaxa – no longer allowed across the border due to the regulations.

18. Robert Grey Cleansing products - Sold in Canada since the 1980's – have pulled out of Canada due to the regulations

19. Natrol – over 1000 products. Sold in Canada until the regulations went into effect.

20. Houston Nutraceuticals – Enzymes used to improve digestion in kids. Available until the regulations came into effect. Then all commercial shipments refused entry

This is just a **partial list** of the products Canadian stores can no longer get, that they used to sell, prior to the regulations.

****There are dozens of long standing Canadian Distributors of NHP's that are experiencing great economic hardship, because Health Canada is **stopping their shipments at the Canada – U.S. Border**, for any variety of reasons, These are mostly products for which product license applications have already been submitted.

In addition, when the regulations came into effect, almost every Canadian NHP supplier shortened their pricelist (sometimes dramatically), because of the cost involved in submitting the applications for licensing each product. This is a drug-style approval system that was never supposed to be applied to NHP's, as per the Expert Advisory Committee, the Standing Committee on Health, and Parliament. They mandated that Health Canada should produce regulations that reflected the inherent safety and low risk levels of these products.

As you can see, they have done the opposite.

After losing this many safe products that Canadian consumers were used to, and are asking for, you can see why neither consumers, retailers, nor manufacturers have any faith that: “Bill C51 isn't supposed to apply to natural health products”