NATURAL HEALTH PRODUCT PROTECTION ASSOCIATION
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Submissions of the **Natural Health Product Protection Association** on Bill C-224

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These are the submissions of the Natural Health Product Protection Association (NHPPA) to the Standing Committee on Health in support of Bill C-224.

The NHPPA would like Bill C-224 **passed *without amendments***.

Facts showing how misguided applying the therapeutic product category to Natural Health Products is.

(1) NHPs are primarily essential nutrients. Natural Health Products (NHPs) are primarily essential nutrients such as vitamin C and thiamine. ***We do not need to be protected from vital nutrients that are essential for our health***. Vital nutrients need to be pushed upon Canadians as essential for their health. Instead, they are being restricted by being classed as *therapeutic products*. This is morally wrong and misguided. *Restricting access to vital nutrients and natural remedies causes sickness and death.*

The spell over Parliament is broken. We can see that it is wrong to class vital nutrients such as vitamin C and thiamine in the same category as our most dangerous drugs such as Vioxx and thalidomide.

(2) NHPs are beyond ultra safe - it is unreasonable to regulate them as drugs. In risk analysis there is what is called the ultra-safe, or *de minimus* line. This line is at one death per million of the population per year. You do not regulate when at the ultra-safe line as the safety signal is too low to measure if you are making a difference. NHPs are ***far below the ultra-safe line***. A risk analysis done by Professor Ron Law just prior to NHPs being regulated as drugs, showed that Canadians were over seventeen times more likely to be struck by lightning than to be harmed by a NHP. Recent studies using E.U. and U.K. data mirror the Canadian data. We have posted the following for the Committee's Review at https://nhppa.org/nhppa-brief-c-224/:

Document 1 - Risk Table by Professor Ron Law including Canadian statistics;

Document 2 - Risk Table by Professor Ron Law using U.K. data;

Document 3 - Risk analysis on natural health products.

It is unnecessary to regulate NHPs. It is unreasonable to regulate NHPs as drugs. It is beyond unreasonable to put NHPs into the most dangerous class of drugs, the *therapeutic product* class. Canadians were perfectly safe with the protections in the *Food and Drugs Act* against fraud, adulteration, and unsafe manufacture. We did not need the *Natural Health Product Regulations (NHP Regulations)*. We do not need to be classified as *therapeutic products*.

(3) NHPs are classed as food in the U.S. In the U.S. NHPs are deemed by law to be safe. The U.S. Congress held hearings into whether NHPs should be regulated as drugs. They learned that NHPs were ultra-safe. They learned that NHPs include vital nutrients that should be promoted rather than restricted. They concluded that it would be asinine to class NHPs as drugs. Congress passed the *Dietary Supplement Health and Education Act, 1994*. Under this Act:

- NHPs are classed as food, not drugs;
- NHPs are deemed by law to be safe.

Canadian NHPs are not demonstrably safer than U.S. NHPs - the Canadian experiment in regulating NHPs as drugs has been a complete waste of resources. Canadian NHPs are strictly regulated as drugs in Canada. The rational by Health Canada is that Canadians need to be protected from the "risks" of NHPs. ***The Emperor (Health Canada) has no clothes.*** NHPs in the U.S. are unregulated. They are classed as food. They do not need government pre-approval. ***The elephant in the room is that strictly regulated Canadian NHPs are not demonstrably safer or demonstrably better than the unregulated U.S. NHPs. We have spent billions of taxpayer and industry funds on regulatory compliance with zero benefit.***

It is no surprise that Canadian NHPs are not demonstrably safer than U.S. NHPs. NHPs are beyond ultra-safe. With products that are ultra-safe, you should not regulate as you cannot measure whether the regulations are making a difference. The safety signal is so low as to be non-existent.

It is a fraud on the Canadian populace for Health Canada to be claiming that it needs the *therapeutic product* provisions to protect Canadians. Moving NHPs into the *therapeutic product* category is actually doubling down on a system that has proven itself to be a complete waste of resources.

It is *a "fraud"* to say we need strict regulations on NHPs when Canadians are safely accessing unregulated U.S. NHPs. Since our NHP Regulations came into force in 2004, Canadians have been importing unregulated NHPs from the U.S. There is no safety difference between Canadian and U.S. NHPs. ***The fact that for 22 years Canadians have been safely using U.S. NHPs that are not strictly regulated, makes a mockery of all claims we need strict drug regulations***. It is beyond fraud to claim we need to have essential nutrients classed as *therapeutic products*.

Canada is in a trade war imposed on it by the U.S. Bill C-224 helps Canadian business compete in this trade war.

(4) Having NHPs in the therapeutic product category of drugs is already causing harm. There is strict censorship of truthful health information from Health Canada. If a drug (chemical or NHP) is approved by Health Canada, the only information allowed to the public is the label claim. The label claim is the purpose for the drug that Health Canada approved. Other truthful health information is illegal. Health Canada actively attacks practitioners and manufacturers who share truthful health information beyond the label claim.

This censorship is causing death because of how we have structured our drug regulations. Our drug regulations are designed so that, for serious health conditions, the only drugs approved are, almost without exception, novel chemicals that had a patent when they were approved. If anyone has to go to

the hospital for a serious health condition, almost without exception, the only legal treatments will be surgery, chemical drugs, or a combination of surgery and chemical drugs. This is by design.

The NHPPA is not aware of a single NHP that has been approved to treat a serious health condition. Our regulations are designed to ensure that only chemicals with a patent can be approved for a serious health condition.

Many Canadians are only alive today because NHPs have cured them of serious health conditions. Many more Canadians were disabled by serious health conditions and only found health through NHPs. For these Canadians, the approved chemical drugs have failed them.

Because of Health Canada censorship, it is illegal for those who know NHPs treat serious health conditions, to share this truthful information with Canadians. Without truthful health information, Canadians cannot make life-saving and/or life-changing health decisions.

Under the *therapeutic product* category, the penalty for sharing truthful health information has increased to $5 million for every day of violation. Previously, the maximum fine was $5,000 per offence. No natural health company or practitioner could survive even a fraction of these crippling fines. This is leading to self-censorship. For example, for the Canadian product EMPpowerplus made by Truehope Nutritional Support, there are 32 peer-reviewed journal publications, all funded by governments around the world, including the Alberta Government. These studies are freely available to Americans on Truehope's U.S. website. Truehope has removed these government studies from their Canadian website because they could not survive the crippling fines for disobedience.

Truthful health information, including government funded peer-reviewed studies, are not available to Canadians because NHPs are now classed as *therapeutic products*.

In the area of health, censorship of truthful health information leads to death and suffering. You are responsible for stopping this.

(5) Promoting access to NHPs and promoting truthful health information is a matter of life and death. When someone's life is saved by a NHP, it is illegal for those who know (the medical practitioners and the manufacturer) to share the truth with you. Because of this, the NHPPA broadcast a health show for three weeks during which Canadians shared their health journeys. The Committee should watch these three weeks of testimonies at https://nhppa.org/speakers/.

To make the point that promoting access to NHPs and promoting truthful health information is a matter of life and death, we will share the testimony of Dr. Marion Laderoute. Dr. Laderoute is a PhD. immunologist who at the time of her testimony was working for Health Canada in Ottawa. She suffered terribly from chronic fatigue syndrome. She could not sleep at night which led to extreme fatigue. This prevented her from having any life other than working for Health Canada. For example, she described how one day she resolved to go for dinner with a friend. She passed out in the restaurant and face-planted into her food. That ended any type of life outside of her work life. At the end of the work-day at Health Canada, everyone but Marion would get into their cars and drive home. Marion would stay and try to nap enough so that she could drive home without passing out. Canada's expert in chronic fatigue syndrome had no treatment for her. Marion was candid during her testimony, and said that if she had not found a solution she was going to end her life. *This was a matter of life and death*. Fortunately Marion found a NHP which solved her problem within 24 hours. For the last 20 years she

has slept well and has thrived. She is only alive because of NHPs. You can watch her testimony at: https://nhppa.org/speakers/recovering-chronic-fatigue-naturally/.

We can no longer pretend that restricting access to NHPs with ever-stricter regulation is not costing lives. We can no longer pretend that censoring truthful health information is not costing lives. People like Marion who are suffering terribly, with no relief using the chemical drugs, do not need to end their lives. There is hope and solutions with NHPs.

(6) Regulating NHPs as drugs discriminates against women. Since the formation of the NHPPA in 2008, the overwhelming majority of our supporters have been, and are, women. Women are disproportionately engaged in our campaigns to protect our access to NHPs. This is because women rely on NHPs for their health, and for the health of their families. Moving NHPs into the *therapeutic product* category of drugs will have a disproportionate impact upon women.

(7) Regulating NHPs as drugs discriminates against economially disadvantaged Canadians. As discussed above, strictly regulating NHPs as drugs have not made NHPs any safer than U.S. NHPs which are not regulated as drugs. Strictly regulating NHPs as drugs has driven the cost of NHPs in Canada dramatically higher than NHPs in the U.S. Economically disadvantaged Canadians can no longer afford to purchase essential nutrients that are necessary to be healthy.

We should be doing all that we can to ensure that disadvantaged Canadians have the best nutrition possible. Not only should we move NHPs out of the *therapeutic product* category, but we should stop regulating essential nutrients as drugs.

(8) Regulating NHPs as drugs discriminates between ethnic groups. There are several ethnic groups in Canada with a rich history of using NHPs. For example, we have First Nations healers, we have Traditional Chinese Medicine healers, and we have Ayurvedic healers. Unless NHPs are de-regulated as drugs, these ethnic groups will not be treated equally. Because of the *United Nations Declaration of Indigenous Rights Act* S.C. 2021, c. 14, our First Nations healers will eventually be free to fully practice their traditional healing practices without being subject to the *NHP Regulations* or the *Food and Drugs Act*. Other ethnic groups will not have this same freedom, as their access to NHPs will continue to be restricted under the drug category. Moving NHPs into the strictest form of drug regulation, the *therapeutic products* category, will aggravate this inequality.

(9) Regulating NHPs as drugs gives United States companies an unfair advantage over Canadian companies. Canadian NHPs have been strictly regulated as drugs since 2004. Canada's strict regulations only apply to Canadian companies. Canadians are free to import U.S. NHPs which are not subject to the same strict regulations. This gives U.S. companies an unfair advantage over Canadian companies. U.S. companies do not have to comply with Canada's strict regulations to ship to Canadian consumers. This gives U.S. companies a price advantage. Because of Canada's strict drug regulations, it costs Canadian companies more to make NHPs. This is unfair to Canadian companies. Because Canadian NHPs are not demonstrably safer or better than U.S. NHPs, there is no justification for placing this unfair regulatory burden on Canadian businesses.

The U.S. has engaged Canada in a trade war. C-224 will help Canadians to compete.

(10) Chemical drugs are so dangerous that our health policy should be that NHPs should be tried first. At https://nhppa.org/nhppa-brief-c-224/, the first three Exhibits demonstrate the risk of chemical drugs. These Exhibits clearly indicate that chemical pharmaceutical drugs pose significant risks to Canadians. These Exhibits concerning risk relate only to the large number of deaths caused by the chemical drugs. They do not assess the risks of injuries short of death caused by the chemical drugs.

At the NHPPA online health show, Professor Alan Cassels revealed that the third leading cause of death in Canada is chemical anti-depressant drugs. Professor Cassels' testimony can be viewed at: https://nhppa.org/speakers/exposing-overdiagnosis-and-the-politics-of-prescription-drugs/.

Chemical drugs pose such a high risk of death, that prudent health policy would be to encourage the use of NHPs prior to allowing the use of chemical drugs. Moving NHPs into the *therapeutic drug* category does the opposite by putting additional regulatory barriers between Canadians and NHPs.

(11) Nicotine is a red-herring. During the last Parliament, Bill C-368 was in Committee to also move NHPs out of the *therapeutic drug* category. Amendments were made to C-368 to accommodate a perceived threat of nicotine.

This nicotine issue was a complete shock to the natural health community. There are tens of thousands of NHPs. There are only a handful of NHPs with nicotine. Most NHPs are essential nutrients necessary to survive and to thrive. If nicotine is an issue of concern to the Committee, it should be dealt with separately. The access to Canadians of essential nutrients and remedies we need to survive and to be healthy should not be high-jacked by concern over a handful of NHPs with nicotine.

In any event, C-224 is drafted to exclude NHPs used for nicotine replacement therapy. NHPs used for nicotine replacement therapy would continue to be *therapeutic products* under C-224.

The Charter of Health Freedom is the solution

We have listed reasons why NHPs should be moved back out of the *therapeutic product* category.

The current issue before the Committee is the result of Health Canada's ongoing policy of trying to restrict access to essential nutrients and natural remedies by imposing ever-stricter drug regulations upon them.

This problem cannot be solved until we change the law to protect and promote access to NHPs.

We also cannot have the best health outcomes if we try to regulate away risk, without considering benefits. For example, ambulances are very risky. They speed. They run red lights. They cause death and harm when they cause accidents. If we regulated ambulances out of existence to protect against the risk they cause, we would have worse health outcomes. This is because the benefits of ambulances outweigh their risk. So to get the best health outcomes, we have to reduce risk without losing the benefits. In other words, we have to balance both the risks and the benefits.

What is missing in the regulation of NHPs is that there is no balancing between the risks and the benefits. This is leading to harm.

All of this would be solved by adopting the *Charter of Health Freedom* as law. The Charter can be found at: https://www.charterofhealthfreedom.org/the-charter/.

The 18 year public resistance to classifying NHPs as *therapeutic products*

Bill C-224 removes NHPs from the *therapeutic product* class of drugs in the *Food and Drugs Act*, R.S.C., 1985 c. F-27 (the "Act"). A meaningful consideration of Bill C-224 cannot occur without knowing the history leading to the very recent inclusion of NHPs as *therapeutic products*.

In April 8, 2008, Bill C-51 was tabled (Document 4 at https://nhppa.org/nhppa-brief-c-224/). Bill C-51 was the first attempt to create a *therapeutic products* class. The original definition of *therapeutic product* in Bill-C51 included all drugs as *therapeutic products* (both chemical drugs and NHPs).

Bill C-51 also introduced most of the increased fines and Health Canada powers that apply to *therapeutic products* that were later included in *Vanessa's law*.

Canadians strongly opposed Bill C-51. They saw the inclusion of NHPs as *therapeutic products* as a threat to NHPs. ***A Citizen movement caused the government to completely back down.***

To understand Citizen concern about Bill C-51 read the Discussion Paper which formed the framework for Citizen opposition (Document 5 at https://nhppa.org/nhppa-brief-c-224/).

Vanessa's Law in 2014 - the *therapeutic product* class resurfaces but now does not apply to NHPs

On December 6, 2013, Bill C-17, called *Vanessa's Law* was introduced (Document 6 at https://nhppa.org/nhppa-brief-c-224/). .

The major difference between Bill C-17 and the former Bill C-51 is that Bill C-17 excluded NHPs from the new *therapeutic product* class. Bill C-17 did not affect NHPs because *therapeutic product* was worded to exclude NHPs. The definition of *therapeutic product* read:

> "*therapeutic product*" means a drug or device or any combination of drugs and devices, **but does not include** a natural health product within the meaning of the *Natural Health Products Regulations*;

This is almost *the exact wording* Bill C-224 seeks to re-introduce into the Act. The only difference is the new exclusion of NHPs used for nicotine replacement therapy.

There was not a Citizen rebellion to Vanessa's Law because it did not apply to NHPs. The NHPPA prepared a Discussion Paper on Bill C-17 which warned that it would only require a definition change to make NHPs subject to the *therapeutic product* definition. A copy of the Discussion Paper can be found as Document 7 at https://nhppa.org/nhppa-brief-c-224/.

16 years after first trying, NHPs are classed as therapeutic products without Citizens having time to react

As predicted, NHPs became *therapeutic products* with a definition change. This occurred by sneaking the definition change into the *Budget Implementation Act 2023, No. 1*, S.C. 2023, c. 26. Citizens did not have time to react to the budget bill. But now, three years later, all MPs understand that Canadians support Bill C-224.

Supporters of the Natural Health Products Protection Association *alone* have:

- sent over 493,000 e-letters to MPs, in support of removing NHPs from the *therapeutic product* category of drug. They have also sent regular letters;
- given 5,170 signatures to the registered e-petition in support of Bill C-368;
- distributed over 1.2 million postcards to stores and clinics opposing the Self Care Framework (SCF) that the move of NHPs to the *therapeutic product* class is a part of.

There can be no doubt that Canadians strongly support Bill C-224 and oppose the SCF.

The addition of NHPs to the *therapeutic product* class is one part of the implementation of the broader Self-Care-Framework

This Committee cannot realistically consider the issue of whether NHPs should be classed as *therapeutic products* without understanding that this change is just one part of a broader move to completely change how NHPs are regulated.

With NHPs becoming popular in the 1980s and 1990s, Health Canada began applying the chemical drug regulations. This drove many NHPs off of the market. Canadians rebelled to protect their access to NHPs. Their core messages were:

- do not treat NHPs as drugs, and
- Canadians wanted increased access to NHPs. Any regulations should be to increase access.

The public rebellion was so great that in November of 1997 this Committee was asked to advise the government on how to regulate NHPs. This Committee held perhaps the broadest consultations of any standing committee. The inquiry lasted a year and resulted in the report *Natural Health Products: A New Vision*. It was clear to this Committee that:

- it was inappropriate to regulate NHPs in the same way as chemical drugs (the exact thing the SCF is implementing), and
- that Canadians wanted increased access to NHPs and so any regulatory environment was not to restrict access.

A copy of this report can be found as Document 8 at https://nhppa.org/nhppa-brief-c-224/.

It took 13 years for NHPs to come into compliance with the NHP Regulations.

The NHP Regulations came into force in 2004. Their implementation was a disaster. Health Canada could not process licence applications. The need for compliance was delayed. Both Health Canada and the industry had to learn how to comply with the regulatory scheme.

It took roughly 13 years (to 2017), for the natural health community to be largely compliant. We are estimating that it cost billions of dollars to the government and to industry to reach compliance.

Just as compliance is reached, Health Canada announces the Self Care Framework to undo the compliance

In 2017, just as the industry had reached compliance with the NHP Regulations, Health Canada announces that a new regulatory framework will be imposed, the Self Care Framework (SCF). The Framework was adopted by the Minister of Health on May 12, 2016.

The purpose of the SCF is to regulate NHPs exactly like chemical over-the-counter drugs. This includes the harmonization of powers and penalties. This has been accomplished by moving NHPs into the *therapeutic product* category. Bill C-224 seeks to undo this.

The SCF completely undermines the work of this Committee and the 20 years of Health Canada and the natural health community learning how to apply the NHP Regulations. It is important for this Committee to understand that moving NHPs into the *therapeutic product* category is part of a wider policy initiative.

HESA held hearings into how NHPs should be regulated, resulting in the report *Natural Health Products - A New Vision*. The consultations by HESA for this inquiry were apparently one of the broadest ever for a Parliamentary Committee. HESA's work should not be discounted. By contrast, *the SCF was conceived by four bureaucrats with no expertise in the regulation of NHPs and without public consultation*. See the NHPPA Discussion Paper on the Origins of the Self Care Framework - Document 9 at https://nhppa.org/nhppa-brief-c-224/.

For a full discussion on the SCF, review the Discussion Paper on 2023 Health Canada Initiatives found as Document 10 at https://nhppa.org/nhppa-brief-c-224/.

The penalties are too strict and will lead to administrative tyranny

There is never perfect compliance with a law. Nor do we want perfect compliance. It is the outliers, the resisters, that cause positive change. The outliers must be able to survive a struggle with the bureaucracy. In a healthy democracy we impose penalties meant to get most people to comply with a law. Penalties are meant to be like bee stings. They hurt so that you will comply, much in the same way you won't go near the bee hive again. Penalties are not meant to destroy.

The penalties being imposed on the natural health community are meant to destroy. A $5,000,000 per day fine may be pocket change for a large pharmaceutical company, however, no natural health practitioner or company can withstand even a fraction of such a fine.

When penalties are too large there can be no reasonable resistance to Health Canada. In the past, companies have resisted Health Canada to save lives. The Court in the Truehope case acquitted Truehope because it was legally necessary to resist Health Canada or more Canadians would have died because of Health Canada's actions (oral decision 2006 ABPC 196).

Unless Bill C-224 passes, the penalties are too large for there to be reasonable resistance to Health Canada. No company or practitioner can survive the penalties, so resistance to protect access to a product is meaningless. The product will disappear because the company or practitioner will be destroyed, so why resist? There is no danger to the public by resistance. Indeed, history has taught us that resistance is necessary to save lives. Health Canada can always apply to Court for an injunction. If there is a product danger, the Court will intervene. If there is danger by intervening, a Court will not intervene.

This is about human sovereignty

What is at issue here, at its core, is human sovereignty. Do Canadians have sovereignty over their own bodies? Do Canadians have the right to have access to NHPs like their American cousins do?

The majority of Canadians engaging you in support of C-224 are women concerned about health and fitness. They want to get their essential nutrients and natural remedies from Canadian sources. They do not want to have to rely on U.S. companies. This has become even more of an issue due to the deteriorating relationship between the U.S. and Canada.

Recalls should require Court supervision

Health Canada has always had the power to apply to Court for a recall. The NHPPA is not opposed to a reasonable Court supervised recall power such as is found in section 13 of the *Charter of Health Freedom* (https://www.charterofhealthfreedom.org/the-charter/).

Permitting recalls without Court supervision puts conflicting duties upon health companies. Under the *Criminal Code*, a person cannot take a remedy off of the market if to do so would cause death or harm. That is criminal negligence and/or culpable homicide. Allowing Health Canada to order a recall when there is a risk that the recall will cause harm, creates conflicting legal duties. This is avoided by Court supervised recalls. Parliament should not be imposing conflicting legal duties.

It is also dangerous to permit bureaucrats to interfere with medical decisions. A recall interferes with the management of patients by medical practitioners. Health Canada cannot know how many people rely on a treatment when a recall is ordered. Health Canada cannot assess the risk a recall poses. There is no independent mechanism in the current recall provision (section 21.3) for doctors or patients to get access to a needed treatment.

When Health Canada wants to order a recall, Health Canada's interest in pursuing its mandate can conflict with the interests of doctors and patients. In the Truehope case, Health Canada was demanding that Truehope stop selling and recall. Truehope refused. The Court found that Truehope's refusal saved lives. Health Canada's actions led to death. More people would have died if Truehope had followed Health Canada's orders (oral decision 2006 ABPC 196).

Almost without exception, when Health Canada "asks" for a recall there is a recall. Companies only resist Health Canada requests for a recall when they are concerned the recall will cause harm and they have conflicting legal duties under the *Criminal Code*. In the rare instance where a company will not voluntarily recall, Health Canada should not have a recall power. Rather, mandatory recalls should be supervised by Courts which will balance the interests of Health Canada with the interests of doctors and patients. This is how you protect Canadians.

The issue before this Committee is not whether Health Canada should be allowed to recall essential nutrients or vital remedies. The issue is whether Health Canada should be allowed to recall any drug, including chemical drugs, without Court supervision. Experience has taught us that Health Canada should not have a recall power. This Committee should call family members of persons killed by Health Canada's actions as witnesses (for example, as occurred in the Truehope case).

Recommendation to the Committee

The NHPPA recommends the Committee pass Bill C-224 ***without amendments***.

About the Natural Health Product Protection Association

The Natural Health Product Protection Association (NHPPA) was incorporated as a federal not-for-profit in 2008. The NHPPA's incorporated goals include protecting access to NHPs, promoting the dissemination of truthful health information concerning NHPs, and protecting the right of Canadians to make health decisions of their choice.

Then NHPPA represents average Canadians. It is a citizen organization. The NHPPA is not an industry organization. We are the largest citizen organization in Canada supporting NHPs. The NHPPA has been the prime organization educating the public about the *therapeutic product* category of drug and Bill C-224. The NHPPA has been the prime organization enabling citizens to communicate with their MPs about Bill C-224. The NHPPA is the only organization we are aware of that can represent the average Canadian Citizen in Committee on Bill C-224.