DISCUSSION PAPER ON 2023 HEALTH CANADA INITIATIVES

(1) Cost Recovery; (2) New Regulatory Burdens, and (3) New Health Canada Powers

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Discussion Paper on 2023 Health Canada Initiatives:

(1) Cost Recovery;
(2) new regulatory burdens, and
(3) new Health Canada powers

ALERT - Small and many Medium sized natural health product companies will not survive these changes. Health Care Practitioners will lose their products. Consumers will lose their products.

Health Canada is moving to:

(1) charge natural health product businesses significant new fees;

(2) impose new regulatory burdens on natural health product businesses, and

(3) give itself dramatic powers over the natural health product community.

Summary

- We are going to lose natural health products and the practitioners that rely on them. Unless Canadians step up to stop this, this is the end of non-pharmaceutical health care.
- The fees being imposed will drive small and many medium Natural Health Product ("NHP") businesses and practitioners out of business.
- The new fees will fund new permanent inspection/regulatory programs that will dramatically increase the regulatory burden on NHP businesses and practitioners.
- The new regulatory burden being imposed will drive small and many medium NHP businesses and practitioners out of business.
- We will lose natural health products, natural health companies and eventually natural health practitioners.
- Prices to consumers will increase which removes products for people who can no longer afford them.
- Censorship of truthful health information will increase which is a way of taking products away. If a person cannot be told a product can help them, the product is effectively taken away.
- Taking away natural health products and censoring truthful information about them will have negative health consequences.
- The powers and penalties we fought against in Bill C-51 in 2008 will be imposed on those in the natural health community. Fines will increase from a maximum of $5,000 an offence to

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$5,000,000 per day of an offence. Directors, officers and employees are also personally responsible for these $5,000,000 a day fines.

- Health Canada will get almost God-like powers. They can order you to take any "corrective action". Failure to comply can result in $5,000,000 a day fines.
- This is only the beginning. Further Self-care Framework changes to be implemented soon include:
    - restricting NHPs/Self-care products to conditions for which a person would not seek the advice of a health care practitioner licenced by a province. This will greatly reduce the conditions for which NHPs can be approved. It will eliminate professional products;
    - removing the ability to use traditional use evidence to support efficacy claims;
    - requiring the same levels of evidence for efficacy and safety as is required for chemical over-the-counter drugs;
    - most likely removing the compounding exemption.

This is the end of the Natural Health Community. We strongly recommend stocking up on all natural health products that you rely upon for your life and health while you still can.

Scope of this Discussion Paper

This Discussion Paper is the opinion of the author, Mr. Shawn Buckley. Although Mr. Buckley is the President of the Natural Health Product Protection Association, his opinion is not necessarily that of the NHPPA or of anyone connected with the NHPPA. As with all Discussion Papers published by the NHPPA we invite comment and further information.

Structure and necessity of understanding the history of the regulation of natural health products ("NHPs")

This Discussion Paper has six parts:

Part 1 - Restricting NHPs is dangerous and contrary to the public interest;

Part 2 - Increased Health Canada powers;

Part 3 - Cost Recovery;

Part 4 - History of Natural Health Product Regulation;

Part 5 - Other Self-care Framework changes, and

Part 6 - What needs to be done.

Reading Parts 1 and 4 is essential to understand that these changes are not intended to support health. Parts 2, 3 and 5 have no context without Parts 1 and 4.

Context - these changes are part of the Self-care Framework which is being implemented according to the Health Canada plan introduced in 2017. You must understand what comes next.

Health Canada's current actions to:

(1) charge natural health product businesses significant new fees;

(2) impose new regulatory burdens on natural health product businesses, and

(3) give itself dramatic powers over the natural health product community,

are just three parts of the Self-care Framework being imposed by Health Canada. What is also coming under the Self-care Framework is:

- Claims will be restricted to minor conditions – conditions for which a person would not seek the advice of a health care practitioner licenced by a province such as a naturopathic doctor, a traditional Chinese medicine doctor, an Ayurvedic doctor, a nutritionist, a herbalist, etc. Anyone who thinks professional natural products will be around in 2 years is naive;

- Traditional use evidence will no longer be allowed to support all claims. Traditional use evidence will only be allowed to support claims for the most minor of conditions, claims for topical, periodontal or dental claims. For greater clarity, the main advantage of the NHP Regulations, the ability to use traditional use evidence for claims, is for the most part being taken away. This is a disaster for the natural health community;

- The final phase of the self-care framework is to impose the same standards of evidence for chemical drugs on natural health products. This will be the death knell for any realistic truthful claims for natural products. It will be the death knell for innovation;

- Whereas now it is functionally illegal to treat serious health conditions with natural products, it will become functionally illegal to treat anything but the most minor of conditions with natural products;

- The Good Manufacturing Practices for the chemical drug companies will be imposed on the natural health companies. This will further increase the costs on the NHP community;

- The compounding exemption for individual patients "may" be lost. Health Canada will not confirm or deny;

- Censorship of truthful health information will increase through: the restriction of claims; increased fines and administrative penalties for telling the truth;

- Access to natural products will be reduced;

- Prices will increase;/

- Small and medium manufacturers will go out of business reducing competition and access to innovative products;

- There is no scientific or political justification for these changes. They are being imposed by four bureaucrats, some of whom were involved in trade negotiations. The recommendations of the Standing Committee on Health are being discarded. For more read our Discussion Paper on the Origins of the Self Care Framework found at: https://nhppa.org/?page_id=15963.

The Self-care Framework is a "non-negotiable" plan being imposed from above

The changes outlined in the Summary above, and explained in detail below are only two parts of the imposition of Health Canada's Self-care Framework introduced in 2017. Some important points to consider about the Self-care Framework are:

- it was presented to the NHP Community as "**non-negotiable**". Health Canada toured Canada to introduce it in 2017. It was made clear that the plan could not be changed it was "non-negotiable";

- the NHP Community was told that the "non-negotiable" plan was drafted by a "committee" of "senior management". An Access to Information Request revealed that four people, none of whom appear to have expertise in NHPs or the regulation of NHPs created the "non-negotiable" plan.

For a full understanding of how this "non-negotiable" plan was drafted by four persons without meaningful consultation and on limited evidence see the NHPPA Discussion Paper on the Origins of the Self Care Framework found at: https://nhppa.org/?page_id=15963.

Part 1 - Restricting NHPs is dangerous and contrary to the public interest

Health decisions always involve a balanced cost-benefit analysis. Decisions contrary to health focus on risk to create fear

A proper health decision involves balancing the benefits of a health product against the risks. It would not be a proper health decision to remove a product that had great benefit and minimal risk. It would not be a proper health decision to remove a group of products that have great benefit and minimal risk. That is what is happening here.

When the Self-care Framework is fully implemented:

- we will lose many manufacturers, distributors, and stores;

- we will lose a large number of natural health products;

- we will lose a large number of health care practitioners who rely on NHPs (naturopathic doctors, homeopathic doctors, traditional Chinese Medicine doctors, nutritionists);

- censorship of truthful health information will dramatically increase preventing us from benefiting from the products that remain;

- innovation will grind to a halt.

Decisions contrary to health focus on risk to create fear. We are being subjected to shameless propaganda and gaslighting to support international trade decisions that have nothing to do with health

Proper health decisions require a balancing of benefits and risk. As set out below, the removal of NHPs will cause death and suffering. The Government documents justifying the Self-care Framework (by Health Canada and the Auditor General) never speak of the benefits of NHPs. They present only risks. This identifies them as having an agenda that has nothing to do with health.

When the Government tells you to be "afraid" because of a risk, you must compare the risk with other risks to get perspective

Governments use fear to justify restrictions on our freedoms. Access to natural health products is a freedom that is being taken away. True to form, we are being told we are at "risk" and need stricter Health Canada oversight to protect us.

Whenever the Government tells you to be afraid because of a risk **you must** compare the risk with other activities to get a proper perspective. For example, you likely are not very concerned about being struck by lightning and would not give up any freedom to be protected from lightning. And yet you are 14 times more likely to be struck by lightning than to be killed by a natural health product.

Some years ago I submitted an *Access to Information Act* request to Health Canada to get all information on deaths caused by any NHP. Health Canada responded by informing me that since 1965 when they started the Adverse Reaction Database, they could not point to a single death caused by a natural health product. Since that request I am aware of "reports" of a few deaths cause by NHPs, but I have not looked into them and must confess to being sceptical.

Assuming there have been a handful of deaths caused by NHPs since 1965, it would mean that the entire NHP industry is dramatically safer than a single over-the-counter pain medication, acetaminophen (brand name Tylenol). My understanding is that acetaminophen causes roughly one death per million people a year. So if Canada has 38 million people we can expect 38 deaths a year caused by acetaminophen. Assuming there have been a handful of deaths caused by NHPs, here is the comparison:

- since 1965, all of the natural health products have caused a handful of deaths;

- each year acetaminophen causes 38 deaths.

Other risk comparisons

Attached as Appendix 1 is a table prepared in 2004 by Professor Ron Law to show how the risk of natural health products compared to other risks. Professor Law is a risk analysis expert who prepared this based primarily on Canadian Government statistics. I have seen more recent risk comparisons which convey the same message. I am choosing to use this 2004 table as:

- natural health products were unregulated until 2004. So if stronger regulation makes us safer, then 2004 should be when NHPs were the most dangerous, and

- there were as many or more NHPs on the market, all completely unregulated.

Remember risk is relative. For you to judge if you need to be concerned about a risk, you need to understand how that risk compares to other risks you face. The Professor Law table shows us:

- you are **14 times more likely to be struck by lightning** than to die from a natural health product;

- you are **428 times more likely to die from bicycling** than to die from a natural health product;

- you are **714 times more likely to die in a school bus accident** than to die from a natural health product;

- you are **1,071 times more likely to be murdered** than to die from a natural health product.

Important point! - You must understand what the Health Canada and Auditor General messaging means

The Auditor General did a report that Health Canada is relying on for the current initiatives discussed in this Paper.

Health Canada and the Auditor General are both stating that there needs to be stricter regulation and cost recovery to protect you from the risk of natural health products.

Do you think it is remotely possible that Health Canada and the Auditor General do not know that:

- you are **14 times more likely to be struck by lightning** than to die from a natural health product;

- you are **428 times more likely to die from bicycling** than to die from a natural health product;

- you are **714 times more likely to die in a school bus accident** than to die from a natural health product;

- you are **1,071 times more likely to be murdered** than to die from a natural health product?

Health Canada and the Auditor General do know that you are more likely to be struck by lightning than to die from a NHP. They know there is no meaningful risk from NHPs that require any government action.

What the Health Canada and Auditor General messaging means is that both agencies are willing to mislead you to achieve an agenda not connected to health.

The loss of natural health products and of natural health practitioners will cause death and suffering

The Self-care Framework being imposed will:

- dramatically reduce the number of natural health products;
- reduce the number of natural health practitioners;
- increase prices - which is the same as removing products for those who can no longer afford them;
- stifle innovation, and
- bring about a significant increase in the censorship of truthful health information which is the same as removing a product. If you cannot be told how a NHP can help you, the product is lost to you.

Many Canadians are only alive because of natural health products. Many more solve or manage serious health conditions with them. We cannot pretend that taking away treatments people rely upon for their lives and/or well-being will not lead to death or suffering.

I like to use Truehope as an example, as almost everything I say is documented in Court files with evidence taken under oath. Truehope developed EMPowerplus to treat serious mental health conditions such as bi-polar disorder. As multi-ingredient NHPs go, there is probably more research on EMPowerplus than any other product in the world. All of this research is publicly funded, usually by universities. A former director of the Natural Health Products Directorate told one of the principals of Truehope that Health Canada knows the product works but that they would never get approval to sell it to treat a serious mental health condition. I am not surprised that some at Health Canada know the product works. I recall one Health Canada expert changing her position during Court proceedings after doing more research. However, at the beginning there was no research. There was only an idea and some desperate people who were finding relief.

When EMPowerplus was new, the people who decided to try it knew there was limited information. In effect, there was just anecdotal evidence (personal stories) of people claiming to have been helped. Symptoms and the progress of participants were being tracked to create further evidence, but all knew this was a novel product based on a then novel idea (that nutrition can assist with mental health). I have interviewed many of these people. Some of them I have called as witnesses in Court. Their story is the same. They had severe mental illness. They were in and out of psychiatric wards. They were not likely to survive long due to their suicide risk. They all got well. They became normal. They never went back into a psychiatric ward. Their lives were saved. I am not exaggerating

this "their lives were saved" point. A Court found that it was legally necessary for Truehope to continue to make EMPowerplus available despite Health Canada demands that they stop selling. At the trial, the former President of the Alberta Branch of the Mental Health Association testified about attending funerals when some ran out of EMPowerplus.

This is a single example of where restricting access to a single NHP for a short period of time led to a number of deaths. There are many more examples. See for example my discussion on Strauss below were the witnesses prepared for Court were only alive because of the product.

It is reckless in the extreme to be bringing about changes that will remove health products Canadians rely on.

Part 2 - Increased Health Canada Powers

Increasing Health Canada's powers over the Natural Health Community is a solution without any problem

We are being told by Health Canada and the Auditor General that we are at risk from natural health products. That we need to be protected by dramatic costs and new regulatory burdens for us to stay safe.

As discussed above, risk is relative and you are 14 times more likely to be struck by lightning than to die from a natural health product.

Also as discussed above, there will be death and suffering when the Self-care Framework succeeds in removing natural products from Canadians.

The reality is that there is no "risk" from natural health products requiring any solution, let alone the ones Health Canada and the Auditor General are promoting.

We are being presented with a solution without a problem.

Health Canada has adequate powers to manage any "risk" presented by NHPs

Health Canada currently has the following powers under the *Food and Drugs Act* concerning natural health products:

- Health Canada Inspectors can attend at any business premises/property for unannounced inspections to determine whether there is compliance with the Act and Regulations;
- if during an inspection concern over a product arises the product can be seized;
- if during an inspection concern over equipment or premises arises the equipment or premises can be seized;
- criminal charges under the Act can be laid for non-compliance. Convictions can result in fines of up to $5,000 and/or three years of imprisonment. It should be noted that the

liability of three years of imprisonment is more than the amount of imprisonment that a person in the chemical drug industry faces. For those products (called therapeutic products) violations of the Act and/or Regulations carries a maximum of only two years of imprisonment;

- Health Canada can apply to a Court for an injunction against selling or doing anything that would be a violation. In this case, the Court would also have the opportunity to consider the risk of removing a product from the market if such a risk existed;
- Health Canada can apply to a Court for a search warrant to seize product and/or business facilities;
- Health Canada can revoke the product's licence, and any site licences, rendering the continued manufacture and sale illegal;
- Health Canada can issue public advisories.

Persons involved in the manufacturing and sale of natural health products are also subject to the provisions of the *Criminal Code*. If a person was harmed or died due to actual malfeasance, such as the spiking of a natural product with a chemical, the perpetrators could be facing homicide charges (with life imprisonment), let alone manslaughter or criminal negligence charges (for which there can also be life imprisonment when there is death).

A solution without a problem? – There is no need to subject the natural health community to chemical drug penalties and powers

In my law practice I defend and am consulted by natural health companies and practitioners facing Health Canada demands and charges. As President of the NHPPA I am briefed by others facing Health Canada demands and charges. I am not aware of a single instance where the current powers Health Canada has concerning natural health products were not sufficient for their role of enforcing the Food and Drugs Act and Regulations.

I challenge Health Canada to point out a single instance where their powers were inadequate for their enforcement mandate.

The "scary" example of risk presented by the Auditor General Report is a misleading paper tiger

The Auditor General prepared a report called *Report 2—Natural Health Products—Health Canada*. In the Report the Auditor General refers to a case where a NHP was spiked with a chemical pharmaceutical. The Auditor General highlighted the case even giving it the following exhibit number and heading:

> *Exhibit 2.3 Health Canada was not able to have a natural health product containing pharmaceutical ingredients removed from the market*

The Auditor General's Report then recommends Health Canada respond to this problem. The Report then reproduces Health Canada's response as follows:

The department's response. Agreed. In addition to the immediate steps Health Canada already takes to protect the health and safety of Canadians when a serious risk to health is identified, the department will:

- *take steps to propose new tools to strengthen its ability to deter and address non.compliance, which include moving forward with a proposal to extend to natural health products the use of powers under the Protecting Canadians from Unaafe Drugs Act (Vanessa's Law).*

So that it is clear, the Auditor General's Report and Health Canada's response reproduced **are misleading and fraudulent**. **"If" a NHP is spiked with a pharmaceutical drug, the NHP is already a therapeutic product, and all the therapeutic product powers in Vanessa's Law already apply.** A product to which the therapeutic product powers already apply cannot be used as an example as to why the therapeutic product powers should apply.

History of the "new" powers - first introduced in 2008 in the infamous Bill C-51 - later introduced for chemical drugs only in Vanessa's law now law as Health Canada snuck them into the Budget Bill (Bill C-47)

On April 8, 2008, Health Minister Tony Clement introduced Bill C-51 which sought to impose the exact powers being discussed in this Paper on all drugs, including natural health products. The Natural Health Community rebelled and Health Canada backed off. The public backlash was so severe that the author was told at a meeting at the Prime Minister's Office that the mail to the Minister of Health was being delivered in wheelbarrows. Health Canada took notice. They had to be patient.

On December 6, 2013, the powers that were in Bill C-51 returned with the introduction of Bill C-17 also known as Vanessa's Law. Bill C-17 brought in the Bill C-51 powers but they did not apply to NHPs. They only applied to chemical drugs. This was done by creating a new category of drugs within the *Food and Drugs Act* called therapeutic products. The NHPPA released a Discussion paper on Bill C-17 on December 13, 2013.

Health Canada and the Government know that there would be great public resistance if they were honest and put forth a specific bill to apply the Vanessa's Law Powers to natural health products. Such a bill would end up before the Standing Committee on Health and there would be time to resist it. To avoid this honest and open process Health Canada and the Government snuck the changes to make Vanessa's Law apply to natural products into the Budget Bill (section 500 to 504 of Bill C-47). Budget bills pass quickly and do not go to the Standing Committee on Health. We are sad to announce that without the public knowing this was happening, Bill C-47 became law on June 22. Now natural health companies are at the total mercy of Health Canada When the new investigative arm to enforce censorship of truthful claims is set up, natural health practitioners and companies cannot resist without being completely destroyed. Nor can they resist the other changes outlined in this Discussion Paper.

This does not detract from the need for Citizens to rebel on this issue. The only change is that rather than calling on Members of Parliament to take sections 500 to 504 out of Bill C-47, we

call on them to repeal sections 500 to 504.

Bill C-47 makes the therapeutic product powers in the Act apply for the first time to natural health products

Bill C-47 makes the therapeutic product powers in the Act apply to NHPs by changing the definition of "therapeutic product" in the *Food and Drugs Act* (section 500).

For a short period of time three therapeutic product sections of the Act do not apply. They are:

- s. 21.31 the power to require assessments;
- s. 21.32 the power to require tests or studies, and
- s. 21.8 the requirement of health care institutions to report adverse drug reactions.

We know that these exemptions are temporary because subsections 501(2), 502(2) and section 504 set out that the exemptions are repealed on a day to be fixed by order of the Governor in Council. The Governor in Council is the Federal Cabinet. In other words, Bill C-47 makes it

law that the exemptions end when the Government decides they end. No further steps or notice need to be given. The Order ending the exemptions will be published in the *Canada Gazette*.

Fines going from $5,000 per offence to $5,000,000 per day

Bill C-47 became law on June 22. Prior to this the maximum fine for offences connected to a natural health product were $5,000 an offence. An "offence" could last over a period of time, such as over several months or years.

The new fines are a maximum of $5,000,000 for each day that an offence continues.

An offence can include not following a Health Canada Order (a new power being imposed).

Officers and Directors are personally liable for the $5,000,000 a day fines - the corporate veil is pierced

Bill C-47 became law on June 22. Prior to this officers and directors of a NHP business were not personally liable for offences committed by the company.

Now officers and directors will be liable for both imprisonment and the maximum $5,000,000 a day fines if they direct, authorize, assent to, acquiesces, or participates in the commission of an offence. Any knowledge without protest can attract liability.

Orders to conduct assessments or to conduct tests

Now that Bill C-47 has passed, Health Canada can order the holder of an NPN or DIN-HM to conduct assessments, tests or studies regardless of the cost or the merit of the order. It does not matter if the product is on the market or not.

Failure to adhere to such orders can be punished by the maximum $5,000,000 a day fines for both the company and the officers and directors.

These powers may make sense for pharmaceutical companies whose products are extremely risky and for whom $5,000,000 a day fines are pocket change. They are over-kill for any NHP business.

Recalls without Court Supervision are dangerous

Health Canada will now be able to order the recall of NHPs without Court supervision.

In the area of chemical drugs which carry a very high risk profile, it may be more defensible to permit Health Canada to order a recall without Court supervision. I say "it may be more defensible", as in the area of products which persons may rely upon for their lives or for serious health conditions, it is always dangerous to allow a regulator the only say. Mistakes can cost lives and there is no downside to having a Court supervise the process to ensure people are not harmed.

Concerning NHPs, although there has probably never been a death caused by an NHP, I am confident that there have been deaths caused by Health Canada removing NHPs from the market. I have already spoken about the Truehope example, where the President of the Alberta branch of the Canadian Mental Health Association testified of deaths caused by this restriction. There was other evidence I relied on to invite the Court to find Health Canada had caused deaths.

If Health Canada could have ordered a recall backed by penalties that would have been certain to destroy the company, its directors and employees, I am confident that there would have been many more deaths. As it was, it came out during the trial that many deaths were prevented only because law-abiding Canadians became smugglers to protect their lives or the lives of their loved ones.

To further illustrate the danger of giving Health Canada the power to recall NHPs without Court supervision, I would like to share the example of a company I was assisting when Health Canada took nattokinase off of the market. At the time Health Canada directed every company that had submitted a licence application for nattokinase to perform a full recall. On behalf of the company I hired a medical doctor to perform an analysis of the risk of following Health Canada's direction. The doctor determined that because Canadians were relying on nattokinase for serious medical conditions, often under the direction of medical doctors, that it would be irresponsible to perform an immediate recall. People relying on nattokinase needed time to find alternative sources or to transition to other treatments. What the company did, was to stop selling any further nattokinase, but to let stores sell their existing stock. The company also advised stores and customers that individuals could legally access nattokinase by purchasing from U.S. companies for personal importation. My understanding is that this was the only company that did not do a recall as demanded by Health Canada. I found their actions laudable

as they took steps to mitigate the risk of nattokinase being taken away, and there was zero financial gain for themselves. The irony in our law is that Health Canada can tell Canadian retailers and manufacturers they cannot sell a product like nattokinase, but Canadians can legally purchase from other countries.

And now nattokinase is permitted to be sold in Canada again with Health Canada's blessing.

Considering there has likely never been a death caused by NHPs and that companies have a responsibility to take the risk of removing a product from the market into account, the powers Health Canada is signalling they want are excessive. As outlined above, Health Canada currently has significant powers to protect Canadians from any supposed risk concerning an NHP. Matters like recalls should be supervised by the Courts so that the risk of removing a product from the market can be properly managed.

The penalties and powers have been increased so much that any resistance to Health Canada is impossible, regardless of the health consequences

Bill C-47 became law on June 22. Prior to June 22, the penalties in the Act concerning NHPs reflected their low risk. Because of this, companies were able to act responsibly, as in the nattokinase and EMPowerplus examples, to ensure that no one was harmed, or that harm was minimized. NHP companies that defied Health Canada in order to minimize risk could still be punished but not destroyed. Now no company can withstand defying Health Canada to comply with their Criminal Code obligations and to comply with their ethical obligations as human beings. I do not know of any NHP company that can survive five million dollar a day fines for any non-compliance.

When you add the fact that every director, officer or employee involved can also be charged and face five million dollar a day fines, non-compliance is unrealistic.

No NHP business will be able to resist Health Canada demands and orders, regardless of how harmful or needless they may be. Health Canada is being given a sledgehammer to swat a fly.

Part 3 - Cost Recovery

Cost Recovery – (1) SITE LICENCES - New Fees

1 – Government Notice and confirmation the fees will be imposed

Part of the Self-Care Framework is to impose the fees paid by the chemical drug companies on the NHP Community.

On May 13, 2023 Health Canada published a *Notice of Intent to consult on Health Canada's proposed fees for natural health products*. This Notice can be found at:

Canada Gazette, Part I, Volume 157, Number 19: GOVERNMENT NOTICES

There is also an invitation to comment. However, the Notice makes it clear that fees will be imposed, regardless of comments. This is found as follows:

> The fee proposal is subject to a 75-day consultation period. The feedback received will be used to refine the proposal as the Department seeks to implement fees that reflect the NHP program in a fair and transparent way. The fee proposal will then be finalized, and a fee order will be published in the Canada Gazette, Part II. Fees are planned to come into force on April 1, 2025.
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> Please visit the fee proposal consultation page for details on how to participate in the consultation. The fee proposal will be posted for 75 calendar days, ending July 26, 2023.
>
> (emphasis added).

To explain the fees proposal to the NHP Community, Health Canada has published a document called: *Proposed fees for natural health products: Fees and fee policy*. This document can be found at:

> https://www.canada.ca/en/health-canada/programs/consultation-proposed-fees-naturalhealth-products/fees-fee-policy.html.

2 – Site Licencing Fees *Proposed fees for natural health products: Fees and policy* (the "Fee Proposal") - Three Points:

(A) each "activity" counts as a separate fee to create a cumulative fee;

(B) the fees are for each building;

(C) fees for distribution and wholesaling are yet to come.

The *Proposed fees for natural health products: Fees and policy* (the "Fee Policy") sets out the following annual site licence fees:

Annual Fee	Yearly Amount
Application fee for site licence or an amendment of a site licence	$4,784
Fee to manufacture drugs in sterile dosage form	$40,071
Fee to manufacture drugs in nonsterile dosage form	$23,071
Fee to import drugs	$20,035

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Fee to package drugs	$7,650
Fee to label drugs	$6,921

2A - The fees are cumulative - you must pay a fee for each of the activities

It is important to understand that each fee is cumulative. In addition to the yearly Application fee, a fee for each separate activity listed must be paid annually. This is clear in the Fee Proposal which includes:

> Table 1 details each activity category for which fees are being proposed, along with corresponding performance standards (existing or proposed standards, whichever applies).

The Drug Fees Regulation are also cumulative (see sections: 29, and 33-39).

Examples of the cumulative fees:

(i) - a business that: (1) manufactures sterile NHPs, (2) manufactures non-sterile NHPs, (3) imports (4) packages, and (5) labels, all in a single building

This business would pay the following annual fees:

Annual Fee	Yearly Amount
Fee to manufacture drugs in sterile dosage form	$40,071
Fee to manufacture drugs in nonsterile dosage form	$23,071
Fee to import drugs	$20,035
Fee to package drugs	$7,650
Fee to label drugs	$6,921
Total	**$97,748**

If any changes requiring an amendment to the site licence was required there would also be the $4,784 Application fee.

(ii) - a business that: (1) manufactures non-sterile NHPs, (2) imports, (3) packages, and (4) labels, all in a single building

This business would pay the following annual fees:

Annual Fee	Yearly Amount
Fee to manufacture drugs in nonsterile dosage form	$23,071
Fee to import drugs	$20,035
Fee to package drugs	$7,650
Fee to label drugs	$6,921
Total	**$57,677**

If any changes requiring an amendment to the site licence was required there would also be the $4,784 Application fee.

2B – The fees are per building – the cumulative fees must be paid for each building

Site licence fees apply on a per-building basis. For each building the fee for each activity must be paid for that building. See for example the *Fees in Respect of Drugs and Medical Devices Order* (SOR/2019-124) sections 29, and 33-39.

Using the examples above, if each activity took place in two building the fees would be double as follows:

(i) – a business that: (1) manufactures sterile NHPs, (2) manufactures non-sterile NHPs, (3) imports (4) packages, and (5) labels, all in TWO buildings

For each of the two buildings this business would pay $97,748 for an annual total of $195,496.

(ii) – a business that: (1) manufactures non-sterile NHPs, (2) imports, (3) packages, and (4) labels, all in TWO buildings

For each of the two buildings this business would pay $57,677 for an annual total of $115,354.

2C – The fees for distribution and wholesaling are being delayed – but expect them later

These "proposed" fees are almost identical to the fees charged to chemical drug companies under the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)* (the "Drug Fees Regulation") which can be found at:

https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/index.html.

The Fee Proposal and the Drug Fees Regulation are almost identical. They cover the same activities. The amounts are almost identical. The minor amount differences are likely due to different inflation adjustments.

The stated goal of the Self-care Framework is to harmonize the regulation of chemical over-thecounter drugs and NHPs. It is important to note that Drug Fees Regulation have the following annual fees for distribution and wholesaling:

- Distribution - $16,527;
- Wholesaling - $9,644.

As with the other fees, **these fees are (1) cumulative, and (2) per building.**

We can expect these fees to be added later. Currently NHP distributors and wholesalers are not required to have a site licence. Once the regulation of NHPs and chemical drugs are harmonized under the Self-care Framework site licences for distribution and wholesaling will be required. At that point these fees will be charged.

Cost Recovery – (2) PRODUCT LICENCING – New Licensing Fees – Annual right to sell fee for each product licence – fees will increase

2 – Fees for Product Licensing

The *Proposed fees for natural health products: Fees and policy* (the "Fee Policy") sets out the following product licence application fees:

Fee	Amount
Class I application or amendment	$1,124
Class II application or amendment	$2,761
Class III application or amendment	$7,209
Class III novel application	$58,332
Class III novel safety and efficacy amendment	$23,333
Class III novel quality amendment	$8,750

These fees are for each single product and are charged for every amendment application.

For an understanding of the different Classes, refer to the *Natural Health Products Management of Applications Policy*.

2. Annual right to sell fee for each NPN or DIN-HN

The *Proposed fees for natural health products: Fees and policy* (the "Fee Policy") sets out an annual fee of $542 for each NPN or DIN-HN.

Cost Recovery – (3) – ADMINISTRATIVE BURDEN – increased administrative burden increases costs – need to disclose business information.

3A - Increased Administrative Burden

In addition to the new fees, NHP businesses will have an increased administrative burden to:

- qualify for the small business reductions (see below);
- complete yearly site licence documentation to pay the yearly site licence fees;
- complete yearly right to sell documentation for the yearly right to sell fees;
- comply with the much more rigorous regulatory oversight including inspections;
- comply with stricter GMPs.

3B – There is a Small Business deduction for qualifying businesses willing to disclose business information

In their policy document *Proposed fees for natural health products: Fees and fee policy*, Health Canada signals that the small business deductions in the *Fees in Respect of Drugs and Medical Devices Order (SOR/2019-124)* would also apply to NHP businesses. The small business deduction applies to businesses with either fewer than 100 employees or with gross revenue under $5 million (s. 1(1)). A "business" includes all the "affiliates" of the business as set out in s. 1(3) to 1(6).

The small business deduction includeincludees:

- the first product licence application for free (s. 17);
- 50% reduction of all subsequent product licence application fees (s. 25), and
- 25% reduction for site licence and annual right to sell fees (ss. 49 and 53).

An application must be made to qualify for a small business deduction. Typically a business needs to provide:

(A) a list of the persons with which the person was affiliated in the person's last completed fiscal year,

(B) the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,

(C) the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and

(D) the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year[.]

(see for example s. 16).

However, once an application for a small business deduction is made, Health Canada can require any "additional information" that "is necessary to demonstrate that the person met the definition of small business" (s. 5). This permits a fairly invasive investigation into the structure and business of an applicant.

The need to apply for a small business deduction also imposes a new administrative burden.

Cost Recovery – (4) – NEW INSPECTIONS – a brave new world of Health Canada oversight

Health Canada's *Proposed fees for natural health products: Annex B, Costing data and tables* document outlines the new inspections and regulatory oversight that are coming with the new fees as follows:

Prospective costs

Health Canada is committed to undertaking new activities to improve the NHP program. Our goal is to:

- establish a risk-based approach to:
- quality oversight before we issue or renew a licence
- inspections to promote and verify compliance of the NHP industry with good manufacturing practices (GMP)
- improve labelling of NHPs
- obtain information about which products are available on the market
- require licence holders to display a Canadian label, including an NPN or DIN-HM, in advertisements targeted to people in Canada

- implement a comprehensive, proactive risk-based monitoring strategy to ensure that advertising of NHPs is consistent with the product licence
- implement a permanent risk-based inspection program
- develop new tools to strengthen our ability to deter and address non-compliance, including a proposal to extend to NHPs the use of powers under the Protecting Canadians from Unsafe Drugs Act

To meet the proposed obligations, including establishing a robust fee regime, we need more resources, such as:

- staff for a new inspection program
- more staff to handle new review components within the existing NHP framework and to ensure performance standards are sustainably met
- more management and management support staff to support new reviewers
- invoicing capabilities
- more information technology (IT) resources
- increased operating budgets to support these additional resources

(grammatical and punctuation issues in original).

This document can be found at:

https://www.canada.ca/en/health-canada/programs/consultation-proposed-fees-natural-health-products/annex-b-costing-data-tables.html

It is clear that the administrative burden on NHP businesses will dramatically increase.

Cost Recovery – (5) - FINAL FEES UNKNOWN

Surely we are going higher

The fees discussed in this Paper are initial fees - there is uncertainty as to the final fees. When getting an industry to agree to new fees, you don't start with the ending fees. You start lower.

There are three obvious reasons to believe the costs are going higher after cost recovery is imposed than those currently being offered. These reasons are:

(1) the stated goal of the Self-care Framework to have identical fees for NHP businesses and chemical drug companies;

(2) the discrepancies between the fees set out in the *Proposed fees for natural health products: Fees and fee policy*, and the *Proposed fees for natural health products: Annex B, Costing data and tables* document;

(3) the application fees for both products and site licence applications are based on the current number of applications (total Health Canada costs/number of

applications = application fee). As the number of applications decrease, the application fee will increase, and

(4) Health Canada has made clear some expected costs are not yet added.

Note also: all fees are adjusted for inflation on a yearly basis.

1. The stated goal of the Self-care Framework is to have identical fees for NHP businesses and chemical drug companies

Health Canada is clear that the end goal is total harmonization between NHPs and chemical over-the-counter drugs. So we will end up with the same costs as the chemical drug companies face.

The proposed site licencing fees for NHP businesses are roughly 25% lower than those paid by the chemical drug companies. So either Health Canada has already factored the Small Business Deduction which will apply to practically every NHP business into the proposed fees already, or we can expect a 25% increase going forward.

The proposed product licencing fees are lower than the chemical drug fees. However, a different part of the Self-care Framework is to streamline the application process for over-the-counter chemical drugs (see Canada Gazette, Part I, Volume 156, Number 51: *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Agile Licensing)*). So to arrive at identical licencing standards (including the same standards of evidence), NHP requirements will become harder and chemical drug regulations will become lighter. The eventual licencing costs will be different than the current proposal.

2. The discrepancies between the fees set out in the *Proposed fees for natural health products: Fees and fee policy*, and the *Proposed fees for natural health products: Annex B, Costing data and tables* document

There are the following discrepancies between the fees set out in the *Proposed fees for natural health products: Fees and fee policy*, and the *Proposed fees for natural health products: Annex B, Costing data and tables* document:

Activity	Proposed Fee	HC Costing Data Amount
Class I application or amendment	$1,124	$1,366

Class II application or amendment	$2,761	$3,355
Class III application or amendment	$7,209	$8,759
Class III novel application	$58,332	$70,880

3. The application fees for both products and site licence applications are based on the current number of applications (total Health Canada costs/number of applications = application fee). As the number of applications decrease, the application fee will increase

Product licence fees

The *Proposed fees for natural health products: Annex B, Costing data and tables* document shows that the proposed licence application fees are calculated by dividing the total costs to Health Canada by the number of current applications. The formula is:

total costs/number of applications = application fee.

Because there is no fee for applying for an NPN there are a number of duplicate applications and applications for products that will never make it to the market. These applications will drop or cease altogether due to the new fees.

The cost-recovery fees will drive a number of NHP businesses and practitioners out of business. This will also drop the number of product licence applications.

With fewer applications, the application fee for products will rise.

Yearly right to sell fee for each NPN DIN-HM

The *Proposed fees for natural health products: Annex B, Costing data and tables* document shows that the annual right to sell fees are calculated by dividing the total costs to Health Canada by the number of current applications. The formula is:

total costs/number of applications = application fee.

The cost-recovery fees will drive a number of NHP businesses and practitioners out of business. This will also drop the number of product licence applications.

With fewer applications, the application fee for products will rise.

Site licence fees

The same applies to site licences. The *Proposed fees for natural health products: Annex B, Costing data and tables* document shows that the proposed site licence application fees are

calculated by dividing the total costs to Health Canada by the number of current applications. The formula is:

> total costs/number of applications = application fee.

The cost-recovery fees will drive a number of NHP businesses and practitioners out of business. This will also drop the number of site licence applications. As this happens, the site licence application fee will rise to adjust for the drop in applications.

4. Health Canada has made clear some expected costs are not yet added

The *Proposed fees for natural health products: Annex B, Costing data and tables* informs us that some new costs are still coming. It includes:

> We have not factored into the current fee structure the costs associated with conducting risk management plan (RMP) reviews. We will, however, be tracking our costs and revising the fee structure in the future as appropriate.

Prices to Consumer will increase

The *Proposed fees for natural health products: Annex B, Costing data and tables* document reveals that Health Canada seeks to recover the following annual costs from the Natural Health Community:

Expense	Amount
Table 5: Estimated total costs for EVAL fees (Class I, II & III application or amendment and Class III novel application - combined total of existing and prospective costs to be recovered)	$42,645,642
Table 6: Estimated total costs for SL fees (applications and amendments)	$5,499,703
Table 7: Estimated total costs for SL fees (annual fee)	$15,817,986
Table 8: Estimated total costs related to licence renewal and the GMP inspection program	$15,817,986
Table 9: Estimates total costs for RTS fees	$36,835,885
Total	**$116,617,202**

These costs are the amounts of fees expected to be collected from NHP businesses on an annual basis. These costs **do not include the additional costs that will be incurred by NHP businesses to comply with the more strict administrative/regulatory regime being implemented on them**.

The fees collected by Health Canada along with the increased fees of doing business to comply with the more strict administrative/regulatory regime will eventually be passed onto the consumer. Increased prices will prevent poor people from accessing natural products.

Products will disappear

Many small and medium sized NHP businesses will become non-viable and disappear. Their products will be lost.

Of the NHP businesses that survive, many will restructure to reduce costs, such as dropping a couple of marginal imported products to avoid the yearly site licence import fee. Products will be lost to this restructuring.

This is of course the beginning of the loss of products and the end of the Natural Health Product Community as we know it

There are currently four parts of the Self-care Framework being implemented: (1) cost recovery, (2) giving Health Canada dramatic powers over the Natural Health Community, (3) reducing the regulatory burden for chemical over-the-counter drugs, (4) and changing labelling.

These four current initiatives simply confirm that the non-negotiable Self-care Framework is being implemented. Still to follow are measures such as:

- restricting claims to minor conditions for which a person would not seek the advice of a health care practitioner;
- imposing the same standards of evidence as is required for chemical drugs;
- no longer allowing traditional use evidence to support treatment claims;
- imposing the chemical drug GMP standards on NHPs, and
- likely taking away the compounding exemption.

The full implementation of the Self-care Framework will be the end of the Natural Health Community as we know it.

Part 4 - History of Natural Health Product Regulation

Forgetting what we have learned - Health Canada is trying to re-do a failed approach

1 - The expertise and political capital to get to the Natural Health Product Regulations

Our current drug approval process was structured for novel chemical drugs that have intellectual property rights and which have a high-risk profile. It is inherently risky to introduce novel chemicals into the human body in amounts meant to create a noticeable physical reaction. It is appropriate to start with the presumption that novel chemicals introduced in levels meant to create a physical reaction are inherently dangerous. This assumption is not, however, appropriate for natural substances in our food supply, such as natural health products.

The 1990s - In the 1990s, there were no regulations for NHPs. The only regulations were for chemical drugs. NHPs by and large could not comply with the drug regulations. For example, a NHP has never gone through the new drug approval process for a serious condition. Despite the drug regulations not being appropriate for NHPs, in the 1990s Health Canada began insisting that NHPs comply with the drug regulations. When targeted products could not comply, Health Canada drove them off of the market.

This targeting of natural products so alarmed Canadians that a citizen rebellion ensued. Canadians also supported a lawsuit started in 1997 to stop the regulation of natural products under the chemical drug regulations. Three sets of regulations and the definition of "drug" in the Food and Drugs Act were challenged as being unconstitutional (Ontario Divisional Court File 499/97). On the eve of the lawsuit, the Government backed down. On October 4, 1997, the Minister of Health, Allan Rock issued a news release that included:

> Health Minister Allan Rock today called a halt to new regulations coming into effect January 1, 1998 for natural health remedies in favour of a full public review of the legal regime governing such products.
>
> ---
>
> Making the announcement in Toronto with several members of the government caucus, the Minister said he will ask the Standing Committee on Health to conduct a public review and make recommendations on the most effective way to strike the right balance between freedom of choice and ensuring the safety of consumers.
>
> "As a government, we must respect and allow room for Canadians' freedom of choice when it comes to natural health products. Canadians should have the broadest range of options available to them."
>
> ---
>
> The Minister stressed that the hearings will be more than a casual assessment - they will be a thorough review…

The Committee also considered submissions from over 1000 more experts and concerned citizens through briefs and letters. Following this broad consultation of experts and concerned

citizens, the Committee issued a report with 53 specific recommendations for the regulation of natural products called "Natural Health Products: A New Vision"

On March 26, 1999, Health Minister Allan Rock issued a press release announcing that the Government was accepting all 53 recommendations of the Committee. The Office of Natural Health Products was formed. A transition team was used to assist in determining how to follow the 53 recommendations and issued a report, "*A Fresh Start: Final Report of the ONHP Transition Team*", on March 31, 2000.

The end result of the extensive work by the Standing Committee on Health, the Transition Team, and the Office of Natural Health Products, was the Natural Health Product Regulations. These Regulations came into force on January 1, 2004.

2 - Enormous resources have gone into complying with the Natural Health Product Regulations

The implementation of the new Regulations was difficult for both Health Canada and the natural health industry. Interim regulations had to be passed to recognize that Health Canada could not comply with the licensing backlog. Health Canada and the industry had to learn how to make the new regulatory regime work. This involved extensive consultations back and forth, including the formation of expert panels to deal with issues such as the standards of evidence. You can read more about a partial history of this process provided by Health Canada.

It is unknown how much has been spent by the Government and by industry to regulate and to comply with the Natural Health Product Regulations. The number is likely in the billions of dollars.

After a difficult transition into the new Regulations, consumers and industry have accepted the new regulatory regime.

3 - There was Complete Agreement on Key Points

After the broad and inclusive process to arrive at the Natural Health Product Regulations, there was broad agreement by the Standing Committee on Health, the Government, the natural health industry, and consumers on the following fundamental issues:

(1) it was not proper to regulate natural products under the same regulations as chemical drugs; and

(2) it was not proper to impose the chemical drug standards of evidence onto natural health products.

For example, the Standing Committee on Health Report *Natural Health Products: A New Vision* includes:

> The members of the Committee acknowledge that the current definitions of a food and of a drug in the Food and Drugs Act do not adequately accommodate NHPs. This is reflective of the Committee's guiding principle on the different nature of NHPs.

Therefore, the Committee recommends that:

Health Canada, in conjunction with a new separate NHP Expert Advisory Committee, set out an appropriate definition of NHPs and amend the Food and Drugs Act accordingly;

While the Committee agrees that consumers will be the final judges as to the effectiveness of a product, it does feel that the government has a role to play. If a person wishes to make a health claim about a product, we feel that reasonable evidence is required. This does not mean, however, that the evidence needed should be equivalent to that required for pharmaceutical products....

Thus, the Committee feels that the validity of a claim must be assessed. Because of the high safety of many of these products, pharmaceuticals standards are generally too rigorous. The Committee believes that the type of evidence needed should depend on the type of claim being made. For more serious claims, more rigorous evidence will be needed. While double-blind clinical trials should be required for certain serious claims, other claims should require different evidence. Thus, unlike pharmaceuticals, the evidence that is required for certain NHP claims should be more flexible. They should include generally accepted and traditional references, professional consensus, clinical evidence including but not limited to double-blind trials and other types of clinical or scientific evidence...

Therefore, the Committee recommends that...

The evidence not be limited to double blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence[.]

Because the Government accepted all the recommendations of the Committee, the standards of evidence for showing safety and efficacy are deliberately different than the standards of evidence for chemical drugs. For example, traditional medicines can be used based on evidence of their traditional use (see Health Canada's guidance document, Pathway for Licensing Natural Health Products used as Traditional Medicines). Non-traditional NHPs can be licensed using various forms of evidence depending on the claim being sought (see health Canada's guidance document Pathway for Licensing Natural Health Products Making Modern Health Claims).

The current approach to the regulation of NHPs was arrived at only after considerable consultation by the Committee and extensive input of experts (both within and outside of Health

Canada). This process has taken roughly 24 years. Arguably we have the best regulatory regime of NHPs in the world due solely to the expertise and time that has been invested. We are now throwing this away on the advice of a handful of non-experts.

Part 5 - The next Self-care Framework changes that will finalize the end of the Natural Health Community (both products and practitioners)

The timetable got bumped back with covid, but the Self-care Framework steps are being taken in the order Health Canada said they would

The non-negotiable Self-care Framework is proceeding in the exact order Health Canada has said it would. Health Canada is no longer publishing the timeline. But when they were, we set it out in our Discussions Papers dated October 16, 2017 and May 11, 2019. As set out in those Papers the order was:

(1) bring in labelling changes to NHPs. This step has been done;

(2) bring in Self-care Framework regulations for chemical non-prescription drugs, making it easier for them to be licenced and regulated. This step is currently underway;

(3) harmonizing the regulation of natural health products with the chemical non-prescription drugs including:

- Limiting claims;
- Losing the right to use traditional use evidence to support all but the most minor of claims;
- Losing the right to use natural health products for conditions for which one would seek the advice of a health care practitioner licenced by a province (such as Naturopaths, TC/M practitioners, Ayurvedic practitioners, Herbalists, Nutritionists, etc.);
- Imposing the chemical drug standards of evidence on natural products;
- Imposing chemical drug GMPs on the natural health community;
- Imposing the chemical drug penalties on the natural health community, such as increasing fines from $5,000 an offence to $5,000,000 per day of an offence;
- Imposing new Health Canada powers such as the ability to order "corrective action" (whatever that means);
- Imposing administrative penalties to pay for increased inspections;
- Imposing cost recovery (licence application fees, yearly product licencing fees, and yearly site licencing fees);
- Perhaps taking away the compounding exemption.

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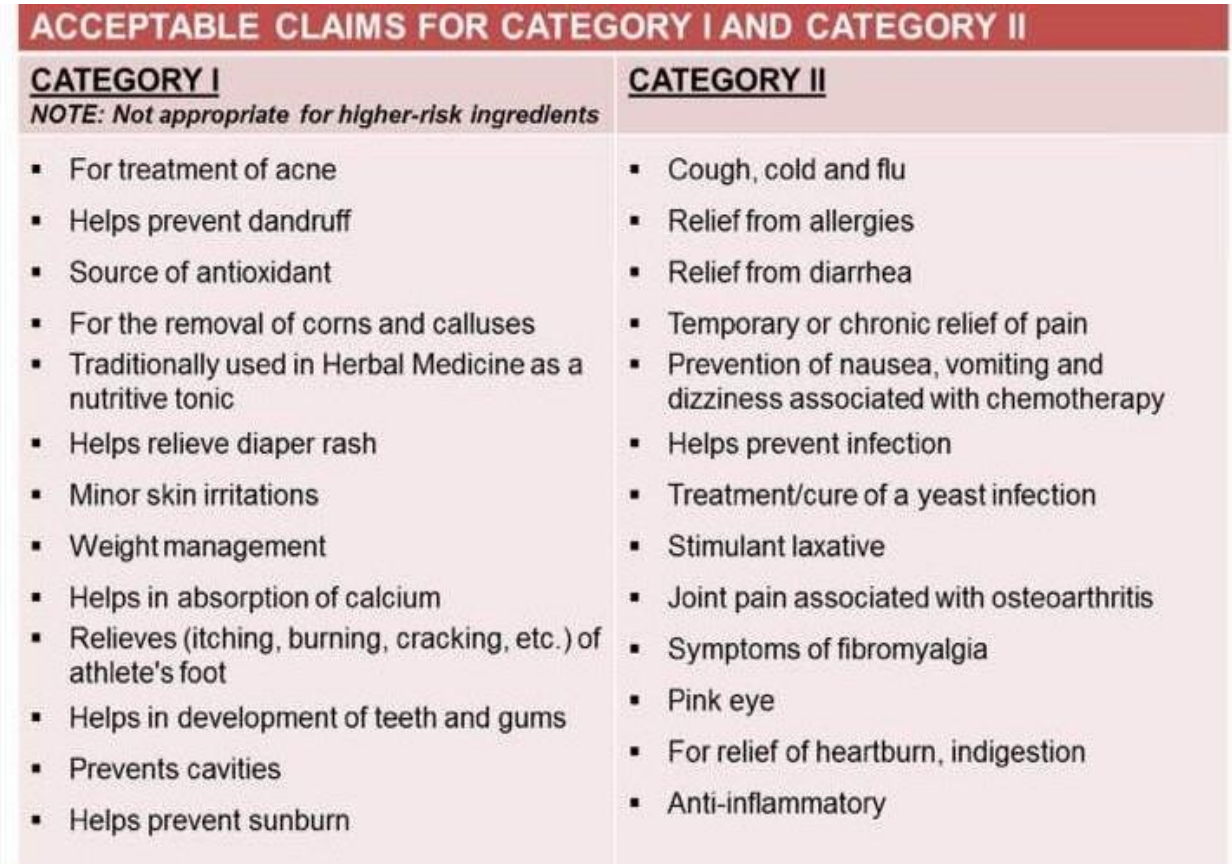
Several items listed in the third step on harmonization are underway and discussed earlier in this Discussion Paper. You need to be aware of the next steps.

The "Secret Slides"

Health Canada has been secretive about the details of the Self-care Framework. When they toured Canada in 2017 to give the NHP Community the details of the Self-care Framework we took photos of the slides they presented to explain the details. Because they are photos of slides, please forgive the poor quality.

The types of claims allowed under the new proposal

Under the new proposal there will be two categories of self-care products for which claims can be made. For both categories the claims will be limited to soft structure function claims. To illustrate this, I reproduce a photo of a Health Canada slide taken during one of their presentations in 2017. The list of "acceptable claims" clearly telegraphs that only soft structure function claims will be allowed.



ACCEPTABLE CLAIMS FOR CATEGORY I AND CATEGORY II

CATEGORY I *NOTE: Not appropriate for higher-risk ingredients*	CATEGORY II
▪ For treatment of acne	▪ Cough, cold and flu
▪ Helps prevent dandruff	▪ Relief from allergies
▪ Source of antioxidant	▪ Relief from diarrhea
▪ For the removal of corns and calluses	▪ Temporary or chronic relief of pain
▪ Traditionally used in Herbal Medicine as a nutritive tonic	▪ Prevention of nausea, vomiting and dizziness associated with chemotherapy
▪ Helps relieve diaper rash	▪ Helps prevent infection
▪ Minor skin irritations	▪ Treatment/cure of a yeast infection
▪ Weight management	▪ Stimulant laxative
▪ Helps in absorption of calcium	▪ Joint pain associated with osteoarthritis
▪ Relieves (itching, burning, cracking, etc.) of athlete's foot	▪ Symptoms of fibromyalgia
▪ Helps in development of teeth and gums	▪ Pink eye
▪ Prevents cavities	▪ For relief of heartburn, indigestion
▪ Helps prevent sunburn	▪ Anti-inflammatory

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Truthful information about natural products treating serious and/or chronic health conditions will not be allowed

Many NHPs are tremendously effective in treating serious health conditions. I have already spoken about Truehope, whose vitamin and mineral supplement treats serious mental health conditions such as bi-polar disorder. For those who simply could not be managed on the chemical psychiatric drugs, EMPowerplus was not simply a safer option, it was the only option.

I became passionate about defending our right to natural products when I defended the herbalist Jim Strauss. Jim was claiming to be able to cure heart disease with the Strauss Heart Drops. There was no clinical evidence to rely on but on the day of trial I had five middle class professional witnesses who:

- all had heart disease;
- all had experienced at least one open heart by-pass surgery;
- all continued to have heart disease as the reason their arteries were plugging up was not being addressed, and
- all needed another by-pass surgery to survive.

A couple of the witnesses were not strong enough to survive another by-pass surgery and so surgery was not an option for them. The other witnesses had experienced terrible complications from their first surgery and were not willing to go through another surgery. For all, the mainstream medical system was now a dead end. All were expected to die quickly. All had not been able to work for years. All then used the Strauss Heart Drops, got well and went back to work. At the time of the trial, I had the names, addresses and phone numbers of thousands who were alive because of the Heart Drops. For these, the Heart Drops were not simply a safer treatment option, they were the only option.

I have shared in earlier writing that my father can dance again because of Bell Shark Cartilage. His arthritis had progressed to the point where it was too painful to dance. The shark cartilage brought such relief that he was able to dance again. I know of another man who was disabled due to his arthritis and became well because of the shark cartilage. He became disabled while taking all of the chemical drugs his doctor prescribed. For him, shark cartilage was not “an” option, it was the only option for him. And yet it is illegal for the makers of Bell Shark Cartilage to tell you it can treat arthritis.

Because of the safety and effectiveness of many natural remedies, we cannot pretend that there is not a negative health consequence to censoring truthful information about them, and by creating a regulatory environment which will preclude most claims concerning the treatment of serious conditions.

The new Health Canada proposals will further institutionalize the censorship of truthful health information.

Risk for natural health practitioners and medical practitioners using NHPs

The proposed grouping of natural products into a "self-care product" umbrella with cosmetics and over-the-counter chemical drugs, combined with the significant limitations on claims, signals an intention to limit the use of NHP to structure function uses. Indeed, one of Health Canada's slides makes it clear that there can be no claim for a condition that would require health professional intervention, including follow up.

For greater clarity, natural products will not qualify as self-care products if meant for any health condition that will require the intervention of a health professional. If they do not qualify under the self-care product regulations, the only drug regulations they could be licenced under are the prescription drug regulations, which natural products generally cannot comply with. This would take us back to before the *Natural Health Product Regulations* when virtually all natural products were illegal. Only now it will be professional products manufactured to treat conditions requiring a doctor (be it medical, naturopathic, homeopathic or traditional like TCM practitioners) that will be illegal. Again, the devil will be in the details, but currently this is a significant concern based on the limited information Health Canada has disclosed.

Uncertainty over the current compounding exemption

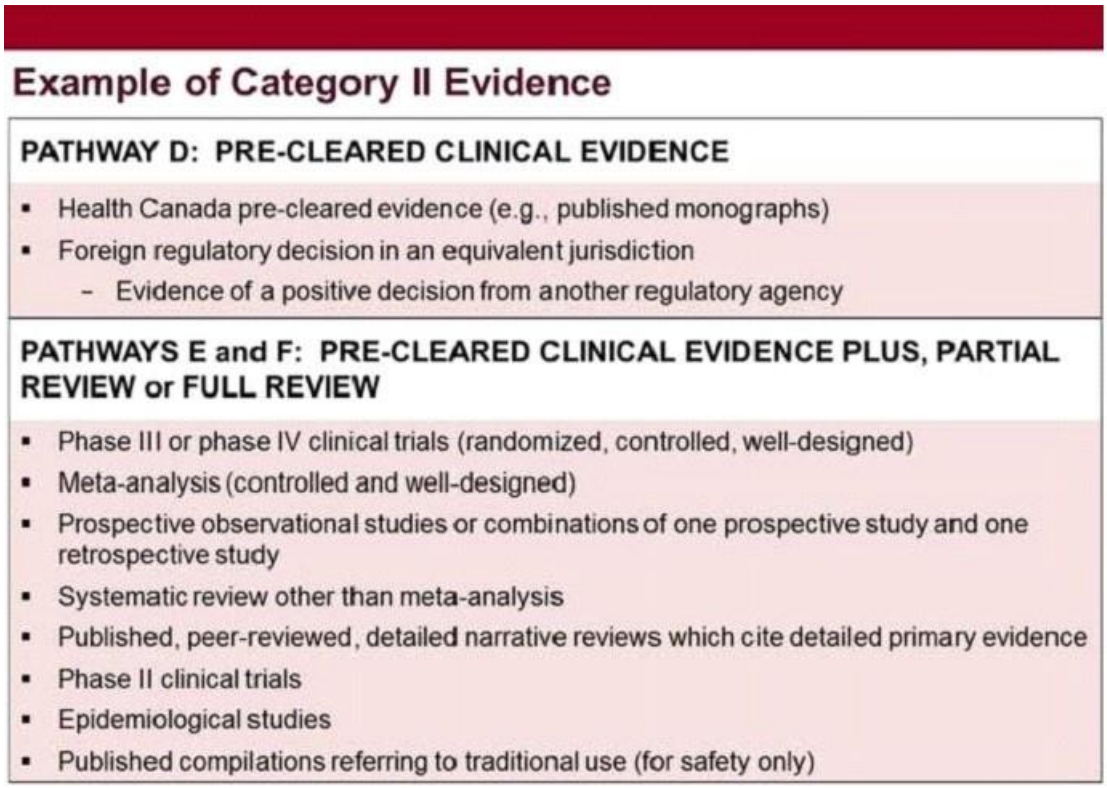
Under our current regulations, health care practitioners are free to prepare natural remedies for their patients on an individual basis. For example, if I visited a traditional Chinese doctor, that doctor could compound a remedy for me individually under the compounding exemption. It is not clear if this exemption will continue under the new proposals. In an email exchange I had with the Health Canada point person on the Self-Care Framework, Health Canada would not confirm or deny that the compounding exemption will survive.

Specifics on the Evidence Changes

Loss of Traditional Use Evidence for Category II Claims

The current Natural Health Product Regulations includes homeopathic and traditional medicines as Natural Health Products. Because of this, traditional medicines can be licensed by using evidence of their traditional use to show both efficacy and safety. This will change under the proposed changes. Health Canada has made it clear that traditional use evidence will now only be allowed to show safety, but not efficacy for Category II products. This will likely severely restrict the licencing of traditional medicines such as First Nations, Traditional Chinese, Ayurvedic, or Traditional Herbal.

Below is a copy of Health Canada's slide concerning the evidence that will be required for the limited Category II structure-function claims listed in the table above called "Acceptable Claims for Category I and Category II".



The current Natural Health Product Regulations do not specifically set out the evidence that is required for product licencing. The details are found in Health Canada's policy documents. Most likely this will be the case with the proposed changes, the details of which are not released. However, based on the above slide, it appears that the types of evidence Health Canada will be requiring for self-care products is more limited than the types of evidence allowed for natural health products. If this is the case, we can expect fewer natural health products to survive under the new regulations.

Indeed, in a different slide Health Canada writes:

- Claim must be supported by clinical evidence, with similar claims requiring an established level of evidence.

If this is correct, and a large pharmaceutical company runs a series of expensive double blind clinical trials to support a claim, such as a cold or flu claim, then every product wanting to make a similar claim may have to provide similar evidence. We do not have the details so this may not be correct. It is clear, however, that evidence requirements will be tightened to the detriment of natural products.

The Category I Uses for Which Traditional Use Evidence Can Be Used Appears To Have Been Reduced

As set out above, the types of claims allowed for self-care products will be for only the most minor of conditions. In Health Canada's 2017 cross-Canada tour they set this out in the following slide:

ACCEPTABLE CLAIMS FOR CATEGORY I AND CATEGORY II

CATEGORY I *NOTE: Not appropriate for higher-risk ingredients*	CATEGORY II
▪ For treatment of acne	▪ Cough, cold and flu
▪ Helps prevent dandruff	▪ Relief from allergies
▪ Source of antioxidant	▪ Relief from diarrhea
▪ For the removal of corns and calluses	▪ Temporary or chronic relief of pain
▪ Traditionally used in Herbal Medicine as a nutritive tonic	▪ Prevention of nausea, vomiting and dizziness associated with chemotherapy
▪ Helps relieve diaper rash	▪ Helps prevent infection
▪ Minor skin irritations	▪ Treatment/cure of a yeast infection
▪ Weight management	▪ Stimulant laxative
▪ Helps in absorption of calcium	▪ Joint pain associated with osteoarthritis
▪ Relieves (itching, burning, cracking, etc.) of athlete's foot	▪ Symptoms of fibromyalgia
▪ Helps in development of teeth and gums	▪ Pink eye
▪ Prevents cavities	▪ For relief of heartburn, indigestion
▪ Helps prevent sunburn	▪ Anti-inflammatory

On February 21, 2019, Health Canada did a presentation at the CHFA West show which included the following slide on classifying a product as a Category I or II.

This recent slide makes it clear that Category I products will be limited to products that are **topical, periodontal or dental**. In other words, **the only products for which traditional use evidence can be used to support efficacy claims are topical, periodontal or dental products.**

For all practical purposes, the use of traditional use evidence is over. This is a significant change.

Which Monographs Will Survive the Loss of Traditional Use Evidence?

We were the first publicly predicting that an extensive monograph system would develop under the NHP Regulations.

We now query which monographs will survive the transition to the Self-care Framework. Traditional use evidence will only be allowed to support claims for topical, periodontal or dental products. Many current NHP monographs are based on traditional use evidence. These are clearly at risk once the Self-care Framework is implemented.

Losing Innovative Products

Before the Natural Health Product Regulations came into force in 2004, products for serious conditions such as Truehope's EMPowerplus or the Strauss Heart Drops were developed and

marketed. Many lives were saved. One of my major criticisms of the Natural Health Product Regulations was that they would stifle innovation. Because there are no intellectual property rights for natural health products, innovation would be stifled because clinical research would be needed and the cost could not be recovered.

Some will say this is positive, that we do not want products on the market for serious conditions for which there is no research. **The problem with this is that Canada has a proven track record of developing natural products that save lives**. There is a health cost to stopping this innovation. A more balanced risk approach would involve mandating full disclosure of the lack of evidence so that consumers and health practitioners are fully informed.

The new proposals will further stifle innovation. They will further restrict claims allowed for products preventing them from being sold for what they are for. They will require the same type of evidence for innovation as is required for chemical drugs, taking away the discretion permitted under the current regulations for different types of evidence.

Increased Ability to Cancel Product Licences

Under the current regulations, once a licence has been issued, Health Canada can cancel a licence at any time if it is necessary to prevent injury. Absent the risk of injury a licence can only be cancelled for violating the law or if it is discovered the licence application was fraudulent. In both of these cases, the license holder must be notified before the cancellation and is given the opportunity to rectify any problem.

Under the new proposal Health Canada will be able to refuse or cancel a licence under "reasonable grounds". It is completely unclear what "reasonable grounds" are. I suspect Health Canada will be given more discretion to remove products.

It should be noted that when Health Canada removes natural products from the market for perceived contraventions, a risk analysis of removing the product from the market is never done. Health Canada has made it clear in Court that its role is not to protect the health of Canadians. Rather its role is to enforce the law (the Food and Drugs Act and Regulations).

Part 6 - What needs to be done!

Members of Parliament only act when there is great pressure on them. The NHPPA will be spearheading a campaign to create such pressure. We need you to get plugged in so that we alert you to actions. We need you to:

(1) visit www.nhppa.org to see what action plans get posted;

(2) subscribe to NHPPA alerts so you know when we need you to take action.

Our specific goals are to:

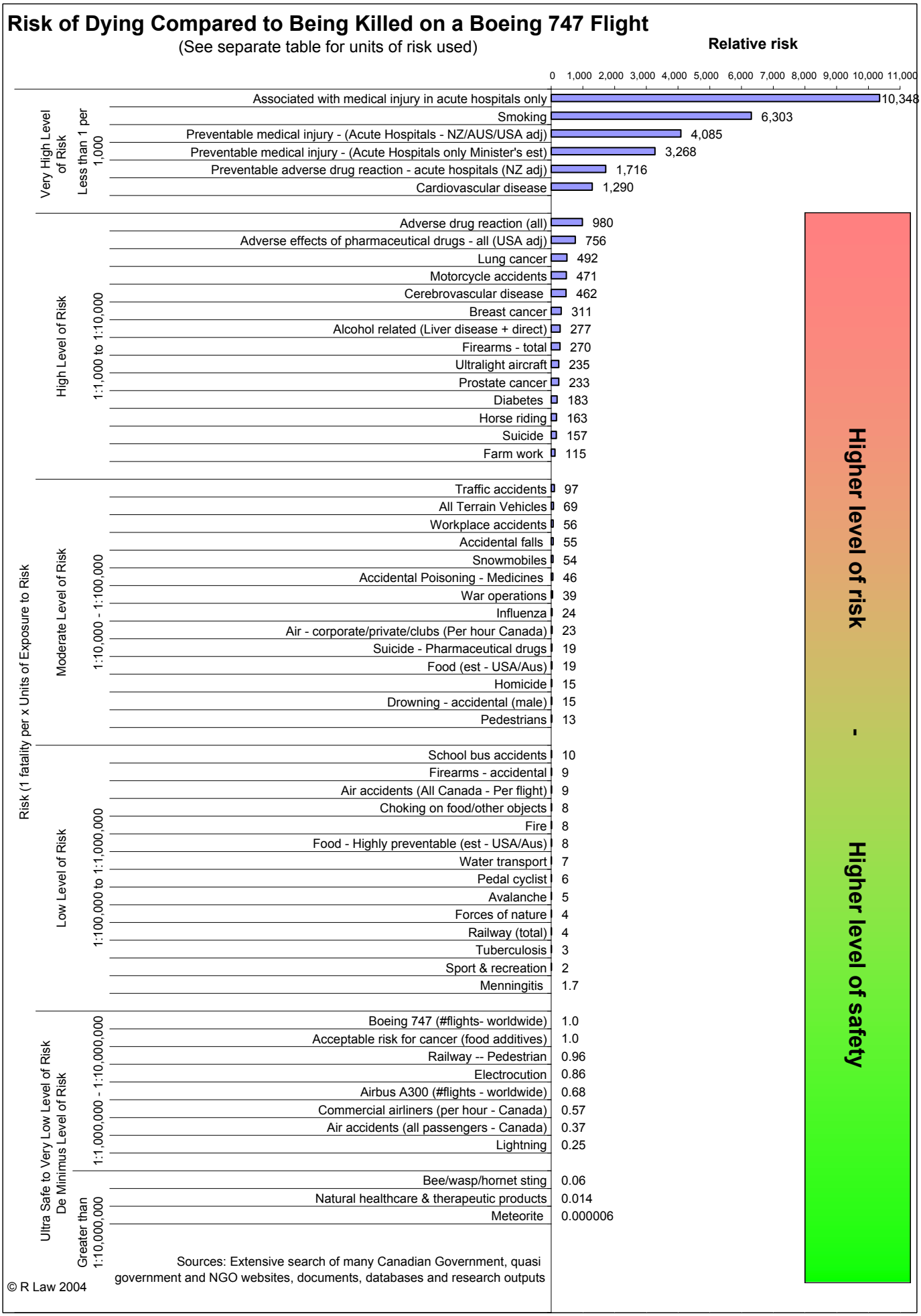
(1) repeal section 500 to 504 of Bill C-47;

(2) get cost recovery for natural health product businesses stopped. The specific cost recovery notice is found here: Canada Gazette, Part I, Volume 157, Number 19: GOVERNMENT NOTICES;

(3) get the *Charter of Health Freedom* enacted, and

(4) de-regulate natural health products. Since 2004 Health Canada has been making the requirements for natural health product businesses stricter and stricter leading to fewer and less effective products. It is time to stop regulating natural products as dangerous drugs. It is time to regulate them in the manner that the Standing Committee on Health recommended in their report: Natural Health Products: A New Vision.

APPENDIX 1


Risk of Dying Compared to Being Killed on a Boeing 747 Flight
(See separate table for units of risk used)
Relative risk
0 1,000 2,000 3,000 4,000 5,000 6,000 7,000 8,000 9,000 10,000 11,000
Risk (1 fatality per x Units of Exposure to Risk
Very High Level of Risk
Less than 1 per 1,000
Associated with medical injury in acute hospitals only 10,348
Smoking 6,303
Preventable medical injury - (Acute Hospitals - NZ/AUS/USA adj) 4,085
Preventable medical injury - (Acute Hospitals only Minister's est) 3,268
Preventable adverse drug reaction - acute hospitals (NZ adj) 1,716
Cardiovascular disease 1,290
High Level of Risk
1:1,000 to 1:10,000
Adverse drug reaction (all) 980
Adverse effects of pharmaceutical drugs - all (USA adj) 756
Lung cancer 492
Motorcycle accidents 471
Cerebrovascular disease 462
Breast cancer 311
Alcohol related (Liver disease + direct) 277
Firearms - total 270
Ultralight aircraft 235
Prostate cancer 233
Diabetes 183
Horse riding 163
Suicide 157
Farm work 115
Moderate Level of Risk
1:10,000 - 1:100,000
Traffic accidents 97
All Terrain Vehicles 69
Workplace accidents 56
Accidental falls 55
Snowmobiles 54
Accidental Poisoning - Medicines 46
War operations 39
Influenza 24
Air - corporate/private/clubs (Per hour Canada) 23
Suicide - Pharmaceutical drugs 19
Food (est - USA/Aus) 19
Homicide 15
Drowning - accidental (male) 15
Pedestrians 13
Low Level of Risk
1:100,000 to 1:1,000,000
School bus accidents 10
Firearms - accidental 9
Air accidents (All Canada - Per flight) 9
Choking on food/other objects 8
Fire 8
Food - Highly preventable (est - USA/Aus) 8
Water transport 7
Pedal cyclist 6
Avalanche 5
Forces of nature 4
Railway (total) 4
Tuberculosis 3
Sport & recreation 2
Menningitis 1.7
Ultra Safe to Very Low Level of Risk
De Minimus Level of Risk
1:1,000,000 - 1:10,000,000
Boeing 747 (#flights- worldwide) 1.0
Acceptable risk for cancer (food additives) 1.0
Railway -- Pedestrian 0.96
Electrocution 0.86
Airbus A300 (#flights - worldwide) 0.68
Commercial airliners (per hour - Canada) 0.57
Air accidents (all passengers - Canada) 0.37
Lightning 0.25
Greater than 1:10,000,000
Bee/wasp/hornet sting 0.06
Natural healthcare & therapeutic products 0.014
Meteorite 0.000006
Higher level of risk
-
Higher level of safety
Sources: Extensive search of many Canadian Government, quasi government and NGO websites, documents, databases and research outputs
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