NATURAL HEALTH PRODUCT PROTECTION ASSOCIATION
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Bill C-368 does not need amending - all of the amendments cause trouble

Bill C-368 simply returns Canada back to where we were prior to the 2023 Budget Bill that moved natural health products ("NHPs") into the *therapeutic product* category. Since 2008 Canadians have resisted Health Canada efforts to class NHPs as *therapeutic products*.

This isn't complicated. Canadians don't want their NHPs classed as *therapeutic products*.

There are now six proposed amendments to Bill C-368 in the Standing Committee on Health. All of the proposed amendments complicate matters and go against what Canadians want.

Amendment NDP-1 - a complete undermining of Bill C-368

This amendment makes Bill C-368 meaningless. It keeps NHPs as *therapeutic products*, granting a couple of meaningless exceptions. It would be more honest for the NDP to simply be clear that they oppose the Bill.

There is a separate NHPPA Discussion Paper on this amendment as we found it so threatening. You can access that Discussion Paper at: https://nhppa.org/billc368-amendment/

Amendment NDP-2 - not logically coherent - imposes food fines on NHPs - may impose unlimited penalties (drafting is too poor to know)

One of the biggest problems with classifying NHPs as therapeutic products is the excessive five million dollar a day fines meant for large pharmaceutical companies. Bill C-368 is trying to correct this. Amendment NDP-2 surprisingly may impose larger fines. It is difficult to be certain as the drafting is poor.

Subsection 31.1(1) of the *Food and Drugs Act* currently reads:

> 31.1 (1) Every person who contravenes any provision of this Act or the regulations, as it relates to food, is guilty of an offence and liable
>
> (a) on summary conviction, to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months or to both; or

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(b) on conviction by indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding three years or to both.

Amendment NDP-2 would amend subsection 31.1 to read:

> 31.1(1) Every person who contravenes any provision of this Act or the regulations, as it relates to food, or, despite section 31.2 and subject to section 31.4, to natural health products within the meaning of the *Natural Health Products Regulations*, is guilty of an offence and liable
>
> (a) on summary conviction, to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months or to both; or
>
> (b) on conviction by indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding three years or to both.
>
> (emphasis on wording added by Amendment NDP-2).

Section 31.2 limits the application of the therapeutic product penalties to a list of violations.

Section 31.4 allows for unlimited fines for *therapeutic products* in certain circumstances.

Amendment NDP-2 should be read with NDP-1 which would keep NHPs in the *therapeutic product* category.

The amendment appears to do two conflicting things. They are:

(1) subject NHPs to the penalties that apply to foods, and

(2) subject NHPs to *therapeutic product* penalties.

The amendment is very unclear and confusing.

I challenge anyone to point out a case where the former fines for NHPs were not enough to ensure compliance. Why is NDP Health Critic MP Peter Julian wanting higher fines on NHPs? Why is he introducing an amendment that is so unclear?

This amendment should be resisted.

Amendments BQ-1 and CPC-1 - the nicotine amendments - ban camomile tea

"Nicotine" has never been part of the 16 year struggle between Canadians and Health Canada concerning whether NHPs should be *therapeutic products*. However, to justify what

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they have done, the government is now claiming Bill C-368 will put at risk vulnerable youth who are accessing vaping and other nicotine products. No, we did not make that up!

In what appears to be good faith efforts to get around this, both the Bloc Quebecois and the Conservatives have proposed the same amendment which would create two classes of NHPs, those with nicotine and those without nicotine. NHPs without nicotine would not be *therapeutic products*. NHPs with nicotine would be *therapeutic products*.

This will create a lot of uncertainty and confusion without in any way addressing youth vaping and using other nicotine products.

We have had only minutes to look into the issue, but it appears the list of plants with nicotine is long. They include: black tea, green tea, camomile, rose hips, sage, blackberry, mate, linden, peppermint, papaya, celery, cauliflower, eggplant, tomatoes, and potatoes.

Testing for nicotine will likely also be complicated by the use of nicotine-based pesticides in some countries.

Now many of our most benign NHPs like camomile tea will be classed as dangerous *therapeutic products*. NHP manufacturers and practitioners will invariable be subject to the *therapeutic product* provisions, including the excessive fines, because of their camomile or peppermint teas.

These are awful amendments that should be resisted. They will create uncertainty and confusion with zero meaningful gain.

This will add new testing requirements to further drive up the price of NHPs. And none of this will protect a single youth from vaping.

If there is a concern about nicotine products, delete section 2(b) from *SOR/2018-133(Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act*). Section 2(b) exempts NHPs from the *Tobacco and Vaping Products Act*. Deleting section 2(b) will make NHPs that would otherwise be subject to the *Tobacco and Vaping Products Act* also subject to that Act. Parliament can add all the powers and penalties they want to in the *Tobacco and Vaping Products Act*, but leave natural health products alone.

Amendments BQ-2 and BQ-3 - the recall amendments

These amendments would affect natural health products as follows:

1. Health Canada could order recalls for safety concerns;

2. Health Canada could manage environmental risk by: ordering recalls; ordering costly assessments and studies (even if they would bankrupt the company and even if the product was not on the market); disclosing

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confidential information, and requiring label changes.

No serious Canadian is worried about the environmental risk posed by an NHP. These sections do not need to apply to NHPs.

The real issue is: should Health Canada be able to order recalls without Court supervision?

Clearly not. In my 30 years of working with the regulation of NHPs I can only think of two NHP companies that did not recall when requested. One was Truehope and the Court thanked them for not recalling. The Court found there would have been more deaths if Truehope had listened to Health Canada. The other company did not recall nattokinase on the advice of a medical doctor with expertise in risk analysis. I believe lives were saved. In both cases, Health Canada could have applied to Court for an injunction which would have the same effect as a recall.

Health Canada should not have the power to recall any drug without Court supervision, including chemical drugs. The power to recall is a ***medical decision***. A recall interferes with the medical decisions of doctors. Doctors and other health care practitioners make the best decisions for their patients based on that patient's individual need and the doctor's best judgement. Often access to these treatments are a matter of life and death. A recall interferes with this.

Health Canada inspectors who would order recalls are not doctors. They have no idea of the health impact their decision to recall would have. Their statutory obligation is to get full compliance with the law, not to protect the health of Canadians. This should not be allowed. If Health Canada believes there should be a recall, Health Canada should be required to apply to Court for a recall. The Court should be obligated to take the health consequences of any recall into account and to ensure that the health of Canadians is protected. A Court process would:

(1) make the focus of a recall protecting health rather than ensuring compliance, and

(2) permit doctors and patients who rely on a treatment to access it under Court supervision.

Under no circumstances should Health Canada be empowered to order recalls, which is a medical decision they are not qualified to make. The current power to recall should not be extended to NHPs. The current power to recall chemical drugs should be removed from the Act.

Health Canada in no way needs the power to recall NHPs. These amendments should be resisted.

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What Needs to be Done:

This is an urgent call for you to:

1. Contact all members of the Standing Committee on Health and NDP leader Jagmeet Singh to let them know that you disagree with Peter Julian's NDP-1 amendment. NHPPA has drafted an electronic letter campaign to make this process simple!

2. Contact all members of the Standing Committee on Health to insist they reject all proposed amendments and move forward with Bill C-368 in its original form.

   We suggest you do so by contacting the Standing Committee on Health members. Their contact information is available here: https://www.ourcommons.ca/Committees/en/HESA/Members

   You can:
   a. Call their offices
   b. Email each member
   c. Visit their constituency office, if you live nearby

Call for Comments:

This Discussion Paper is the opinion of the author, Shawn Buckley. As with all Discussion Papers, the NHPPA welcomes your comments. Please contact us at info@nhppa.org.