CANADIAN HEALTH FOOD ASSOCIATION COMPETES WITH MONTY PYTHON'S FLYING CIRCUS

Rebuttal to President of CHFA Helen Long's E-mail to CHFA Members Regarding NHPPA's Discussion Paper

Prepared by Shawn Buckley, LL.B., President of the Natural Health Products Protection Association on May 22, 2018

Canadian Health Food Association competes with Monty Python's Flying Circus

This is an opinion piece of Shawn Buckley, President of the Natural Health Products Protection Association ("NHPPA"). This is meant for all Canadian Health Food Association ("CHFA") members.

On May 10, 2018, the NHPPA released a Discussion Paper concerning the upcoming repeal of the *Natural Health Products Regulations*. This Discussion Paper is a must read for all CHFA members and is available for download here: http://tinyurl.com/nhppadiscussionpaper

On May 16, 2018, the CHFA sent an email to its members which begins with:

> CHFA has been made aware of a recently released discussion paper about the ongoing self-care products framework which was distributed broadly by email last week.

I am assuming that the CHFA was afraid to identify the Discussion Paper as coming from the NHPPA because the CHFA does not want its members to read the Paper.

The CHFA email continues:

> I would like to take this opportunity to update you on this file and CHFA's regulatory activities, as well as provide the most up-to-date and **accurate** information regarding government relations in our sector.
>
> First and foremost, no changes to the existing regulations have been implemented. CHFA remains actively engaged in Health Canada's consultation process, and continues to represent the industry to ensure that natural health products remain on the market, that claims can be made, and that Canadians will still have access to affordable, safe and effective products.
>
> The discussion paper distributed refers to the original 2016 proposal, which is no longer representative of its current direction after months of consultations, many meetings and discussions, and your participation in advocacy efforts. We remain vigilant to ensure that this ongoing process is not used as a delay tactic by Health Canada but a genuine attempt at incorporating the concerns you have raised to your Members of Parliament as they evaluate policy direction.
>
> (emphasis in original).

By putting "accurate" in bold and by stating the "discussion paper distributed refers to the original 2016 proposal, which is no longer representative of its current direction", the CFHA is attempting to discredit the Discussion Paper by implying it is inaccurate.

Let's talk about "accuracy" starting with the repeal of the Natural Health Products Regulations

On November 25, 2016, Health Canada released a consultation paper which clearly signalled that the plan is to harmonize the regulation of natural health products, over the counter drugs, and cosmetics under a single set of regulations for a new category of "self-care products". This can only mean the *Natural Health Product Regulations* will be either

repealed, or re-written so that they are the same as the regulations governing chemical over the counter drugs.

On April 18, 2017, Health Canada published "Self-Care Products and Health Canada". This document includes:

> Health Canada is proposing to put in place one sensible system that treats self-care products with low risks the same way and does not create new burdens for industry. The proposed approach would also give Health Canada the authority to recall any product that may pose a danger to Canadians – while continuing to treat them differently than prescription drugs, which can pose more serious safety concerns.

This makes it clear that natural products are going to be regulated under the same regulations as chemical drugs.

In the spring of 2017 Health Canada held consultations in which they explained their plan to regulate natural health products under the same regulations as chemical drugs. Summaries of these consultations can be found here: https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products.html. NHPPA members attended some of these consultations and took photographs of all of the slides. Some of the slides are contained in the Discussion Paper. At these consultations Health Canada made it clear their plan is to regulate natural health products under the same regulations as chemical drugs. This must involve the repeal or re-writing of the *Natural Health Products Regulations*.

A few months ago, on February 21, 2018, Health Canada published a time-line for the implementation of the changes. The time line includes:

- **Phase II – Early 2019:** Introduce, for consultation, targeted amendments to the Food and Drug Regulations to introduce a risk-based approach to regulatory oversight for non-prescription drugs.
  These include:
  - expedited pathways for lower-risk products

  These changes are intended to align the oversight for non-prescription drugs with other self-care products of comparable level of risk.

- **Phase III – 2020:** Introduce, for consultation, regulatory amendments to address:
  - evidence standards for similar health claims
  - extending risk-based regulatory oversight
  - seeking additional powers for Health Canada, such as the ability to require a recall or label change for all self-care products

This very recent Health Canada document makes it clear that Health Canada is moving ahead with its plan to repeal the *Natural Health Product Regulations*. Health Canada is timing this unpopular change for after the next federal election so that it does not become an election issue.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that Health Canada is not planning on regulating natural products under the same regulations as chemical over the counter drugs, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If Health Canada is going to repeal the *Natural Health Product Regulations* please explain for the CHFA Members how, after 14 years of working to comply with the Regulations, it is now in their interests for the Regulations to be repealed?

Let's talk about "accuracy" concerning new penalties that would crush any CHFA Member

Health Canada's November 25, 2016 Paper includes:

> There are **inconsistencies and gaps in post-market powers**. Although self-care products are generally considered to be of lower risk, safety concerns can still arise when companies do not follow the regulations. The law provides Health Canada with powers to take action on products that are already on the market. At this time, Health Canada does not have the authority to order a recall or a label change for natural health products or cosmetics. Instead, Health Canada must work with a company to encourage it to remove a product from the market or change its label. In contrast, for non-prescription drugs, Health Canada has the power to demand a recall or a label change exists. Further, for those who break the laws for natural health products and cosmetics, the maximum fine is $5,000 compared with fines in excess of $5 million for non-prescription drugs.
>
> To protect the health and safety of Canadians, it is paramount for the Department to have the right set of tools to swiftly address a safety concern.

There is nothing in the public consultations or subsequent Health Canada documents to suggest the Health Canada is deviating from its stated intention of subjecting natural health companies to the same penalty structure as applies to chemical drugs.

Currently, natural health manufactures, distributors, vendors (such as health food stores) and practitioners are subject to fines of up to $5000 for each offence. If you committed an offence continually for a month, that entire month could be a single offence meaning you could be fined up to $5,000 for the month of activity. The change to the chemical drug penalties will subject anyone charged to fines of up to $5,000,000 a day of an offence. So if an offence occurred over a month, each day is a separate offence subject to a fine of up to $5,000,000 a day (so for a 30 day month that is fines of up to $150,000,000).

In addition, under the chemical drug penalties, every director, officer, manager and employee that is involved in any violation can be personally liable for $5,000,000 a day fines in addition to fines imposed on the company.

These high fines may make sense for large pharmaceutical companies and for chemical drugs which have a very high risk profile despite being over the counter. As explained in the Discussion Paper, such high fines for natural products can, paradoxically, lead to poor health outcomes.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that Health Canada is not planning on raising the fines CHFA Members are subject to from $5,000 per offence to $5,000,000 for every day of an offence, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If CHFA Members are going to be subjected to $5,000,000 a day fines instead of fines of $5,000 per offence, please explain for the CHFA Members how this is to their benefit?

3. If you have any credible information that Health Canada is not planning on subjecting directors, officers, managers and employees to $5,000,000 a day fines for violations of a company, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

4. If directors, officers, managers and employees are going to become personally liable for fines of up to $5,000,000 a day for offences committed by the company, please explain for the CHFA Members how this is to their benefit?

Let's talk about "accuracy" concerning ensuring that natural products will never be used for serious health conditions

Nothing in the *Natural Health Product Regulations* prevents Health Canada from approving claims for serious health conditions under those Regulations. Indeed, many in the natural health community expected there to be claims for serious health conditions. Health Canada had other ideas. They have managed the Regulations as if the only claims allowed were structure function claims.

If the *Natural Health Product Regulations* are repealed, and natural products are regulated as self-care products, it is clear from Health Canada's documents that the self-care product regulations will not allow serious health claims. Indeed, the intention is to further restrict claims. If this is the case, then the only avenue to get approval for serious health conditions will be the new drug approval process. Because natural products do not have intellectual property rights, it is unrealistic to expect any to get through this process to get approval to treat a serious health condition. In effect the change will institutionalize that the only drugs which will be legal to treat serious health conditions are chemical drugs with intellectual property rights at the time they went through the new drug approval process. In the Discussion Paper examples are given to show how preventing natural products from being used for serious conditions can lead to poor health outcomes. Please correct me if I am wrong, but is it not the CHFA's position that many natural products are effective at treating serious health conditions? Is it not the CHFA's position that Canadians should have the right to access natural products for serious health conditions?

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that the Regulations for self-care products will allow claims for serious health conditions, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If the Regulations for self-care products will not allow for claims for serious health conditions, please explain for the CHFA Members how this is to their benefit?

3. If you have any credible information that the Regulations for self-care will not restrict health claims more than the *Natural Health Products Regulations*, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

4. If you do not have any credible information that the Regulations for self-care will not restrict health claims more than the *Natural Health Products Regulations*, please explain for the CHFA Members how having further restrictions on claims is to their benefit?

Let's talk about "accuracy" concerning the potential loss of the compounding exemption

Health Canada has not specifically addressed what will happen to the compounding exemption found in the *Natural Health Products Regulations*. The compounding exemption permits health care practitioners such as herbalists or Traditional Chinese Medicine doctors to compound for a patient without being considered a "manufacturer". Under the current chemical drug regulations, the only persons who can compound are pharmacists and doctors authorized to use prescription drugs. A concern of the NHPPA's is that this compounding exemption will be lost if natural products are regulated with the same regulations as chemical drugs.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that the compounding exemption will remain when natural health products are regulated as self-care products, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If the compounding exemption will be removed with the new regulations, please explain for the CHFA Members how this is to their benefit?

Let's talk about "accuracy" concerning the loss of traditional use evidence for efficacy claims and subjecting natural products to the same standards of evidence as chemical drugs

In their public consultations, Health Canada made it clear that traditional use evidence would no longer be accepted to support an efficacy claim. Indeed, the driving justification for regulating natural products with the same regulations as chemical drugs is so that claims for both chemical and natural drugs are supported by the same standards of evidence.

In Health Canada's subsequent published information on the proposed changes there is nothing to say that traditional use evidence will be allowed to support treatment claims. I acknowledge that Health Canada has received significant feedback on this point and that backing down on this is possible. Considering that the main purpose of the harmonization is to bring in the same standards of evidence, I am very concerned. Indeed, in Health Canada's last publication, the time line published on February 21, 2018, Health Canada writes:

Phase III – 2020: Introduce, for consultation, regulatory amendments to address:

- evidence standards for similar health claims

One of the strengths of the *Natural Health Product Regulations* is that they allow for the types of evidence the Standing Committee on Health, and the expert panels set up to advise Health Canada such as the Office of Natural Health ProductsTransition Team made clear were appropriate. Harmonizing the standards of evidence with a completely different category of drug could lead to poor health outcomes and further restrict allowable claims.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that traditional use evidence will still be allowed for efficacy claims, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If you do not have any credible information that traditional use evidence will still be allowed for efficacy claims, please explain for the CHFA Members how this loss is to their benefit?

3. If you have any credible information that natural products will not be subject to chemical drug standards of evidence, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

4. If you do not have any credible information that natural products will not be subject to chemical drug standards of evidence, please explain for the CHFA Members how being subjected to chemical drugs standards of evidence will be to their benefit?

Let's talk about "accuracy" concerning administrative penalties

Health Canada is clear that it is bringing in a new administrative penalty regime. Typically such regimes use the monetary penalties to pay for more inspectors so that there are regular inspections and regular small fines to pay for the inspections. The intention of this is clear. Regulated parties such as CHFA Members will be subject to increased inspections and penalties. Penalties can also be imposed on advertising, giving Health Canada a new tool to censor truthful health information.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that an administrative penalty regime will not be imposed on CHFA Members, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If an administrative penalty regime will be imposed, please explain for the CHFA Members how this is to their benefit?

Let's talk about "accuracy" concerning cost recovery

Health Canada speaks in the consultation paper of bringing in cost recovery for things such as licence applications and yearly licencing fees. The actual amount of the final fees once the changes come in are unknown. What is certain is that this will be yet another cost,

imposed yearly on CHFA Members that they do not currently face. I am personally concerned that cost recovery alone could lead to a drastic loss of NHPs.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that cost recovery will not be imposed upon CHFA Members, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If cost recovery will be imposed on CHFA Members, please explain for the CHFA Members how this is to their benefit?

Let's talk about "accuracy" concerning recalls without Court supervision

Currently, Health Canada must involve the Courts to get a recall order for natural health products. One of the changes will be to subject natural products to the same recall power Health Canada has for chemical pharmaceutical drugs. As explained in the Discussion Paper, there is a significant safety issue in allowing Health Canada employees without medical training, to recall drugs (be they chemical or natural). For example, a recall of a chemical drug places patients and their doctors in the situation where medical decisions and treatment are being overridden by a bureaucrat without medical training. If a Court is involved, the Court will always take into account the risk of removing the product and structure any order in such a way to minimize risk. This is explained in the Discussion Paper.

I have the following "accuracy" challenges for the CHFA:

1. If you have any credible information that natural products will not be subject to recall orders without Court supervision, release it now so that CHFA Members have the most accurate information and can govern themselves accordingly.

2. If natural products will be subject to recall orders without Court supervision, please explain for the CHFA Members how this is to their benefit or to the benefit of Canadians generally?

Let's talk about "accuracy" concerning how there will be almost no time to respond to the new regulations once they are published

Health Canada has not released any draft regulations for comment. Even if draft regulations were released, the Government would not be bound to stick with a draft. In short, regardless of what is being said by Health Canada during consultations, the Government is not bound by such representations.

The difficulty we face is that the entire regulatory environment can be changed very quickly. The replacement of the *Natural Health Products Regulations* with self-care regulations can be done in a month. All the Government has to do is to publish the proposed changes in the *Canada Gazette I*, wait for a comment period, and then republish the final version in the *Gazette II*. There is no vote in Parliament involved, and so pressure on MPs is futile. So is pressure on government MPs, as they can credibly say that they had no vote.

This is not a situation such as the one we faced in 2008 with Bill C-51, where there had to be three readings of the Bill in both the House of Commons and the Senate. That process gave persons opposed to the Bill time to mobilize.

Concerning the imposition of the increased fines and Health Canada powers on CHFA Members, the blame for this situation lies squarely on the CHFA. Following the public pressure that occurred over Bill C-51, it became clear to the Government that they could not impose the $5,000,000 a day fines, and the other new powers on natural health products without significant resistance. To trick the natural health community, Health Canada came up with Bill C-17 which put the powers and penalties into the *Food and Drugs Act*. The trick was that the penalties and powers only applied to a new category of "therapeutic products". Therapeutic products do not include "natural health products" as defined in the *Natural Health Products Regulations*. The NHPPA correctly warned at the time that this was a Trojan Horse Bill. The natural health community would allow the Bill to pass because on its face the new powers and penalties did not apply to natural products. Then later, the definition of natural health product in the Regulations could be changed or abolished and, *voila*, CHFA Members would find themselves subject to the chemical drug penalties and powers and have no time to react. For the record the CHFA actually **supported** Bill C-17 when the proper approach to protect CHFA Members was to demand that the definition of natural health product be put into the *Food and Drugs Act* (see the Discussion Paper for more details).

I have the following "accuracy" challenge for the CHFA:

1. Please explain how the CHFA's support for Bill C-17, which exposes CHFA Members to chemical drug penalties and powers by a simple regulatory change, was in the interest of CHFA Members?

Conclusion

The proposed changes are the largest threat to the natural health community in decades. The chances of stopping the changes **after** the next federal election will be slim to none. Unpopular changes occur after elections as it is assumed that the anger will fade by the next election. It is essential to get educated and to create pressure now. The NHPPA is in the education phase of its plan to stop the changes.

It is in this context that the CHFA sent out their email with the specific intention of telling CHFA Members to ignore the Discussion Paper and to do nothing. This is such a dangerous stance that at first I thought the email was a joke someone was playing on me. It is still difficult to believe.

In my opinion the proposed changes are so detrimental to all CHFA Members that the CHFA's attack on the NHPPA Discussion Paper must be a piece of comedy rather than a reasoned analysis. It is difficult to say whether the CHFA or Monty Python's Flying Circus will win this year's comedy award, but the CHFA is off to a strong start.

Original E-mail from Helen Long to CHFA Members

From: Helen Long **On Behalf Of** Helen Long
Sent: Wednesday, May 16, 2018 2:30 PM
Subject: News That Impacts You: CHFA's Regulatory Work on the Self-Care Products Framework

Dear CHFA Member,

CHFA has been made aware of a recently released discussion paper about the ongoing self-care products framework which was distributed broadly by email last week.

I would like to take this opportunity to update you on this file and CHFA's regulatory activities, as well as provide the most up-to-date and **accurate** information regarding government relations in our sector.

First and foremost, no changes to the existing regulations have been implemented. CHFA remains actively engaged in Health Canada's consultation process, and continues to represent the industry to ensure that natural health products remain on the market, that claims can be made, and that Canadians will still have access to affordable, safe and effective products.

The discussion paper distributed refers to the original 2016 proposal, which is no longer representative of its current direction after months of consultations, many meetings and discussions, and your participation in advocacy efforts. We remain vigilant to ensure that this ongoing process is not used as a delay tactic by Health Canada but a genuine attempt at incorporating the concerns you have raised to your Members of Parliament as they evaluate policy direction.

Secondly, contrary to opinions expressed in the discussion paper, CHFA believes that the next step in the **consultation process**, which focuses on Plain Language Labelling and is expected to launch this fall, is very controversial, and that action from the industry is needed now. If your business manufactures natural health products, we strongly encourage you to complete Health Canada's **Cost-Benefit Analysis Survey**. The data that the Natural and Non-prescription Health Products Directorate (NNHPD) receives will be used to determine the proposal's path forward. Your input is vital in understanding how product labelling changes will affect your business. Further details on the purpose of this survey can be found **here**. Submissions are due **May 30, 2018**.

In the coming weeks, CHFA will attend a session hosted by NNHPD to discuss Plain Language Labelling and the impact it has had on the non-prescription drugs sector. As we prepare to represent our own industry through upcoming, similar labelling consultations, this may be an insightful discussion for us to gain information from.

Later in June, CHFA will meet with Hon. Ginette Petitpas Taylor, Minister of Health, to present our position, discuss members' perspectives on the proposed phased approach for the framework, and share our recommendations on how to ensure the NHP industry remains intact, vibrant and growing, during and after implementation of any new regulations.

CHFA will also attend a technical session and a multi-stakeholder meeting with the Health Products and Food Branch, which will be our opportunities to provide guidance for the development of policy proposals and consultation documents.

We remain active on this file and are striving to ensure a successful outcome for our members. We are also committed to keeping you informed through regular updates on our **website** and email communications, such as the *Regulatory Report*. Please share this information with colleagues or staff in your workplace who may not be getting it directly.

Thank you for your continued membership and support,
Helen

P.S. In order to access a number of items in this email, you will have to log in to the **Member Centre** of our website. If you have forgotten your login information, **click here** to reset your password using your company email address. If you'd like to subscribe to the Regulatory Report or add additional staff members to our email distribution list, you can do so through CHFA's **Member Centre** or by emailing us at **info@chfa.ca**.

Helen Long
President
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