DISCUSSION PAPER CONCERNING THE "EVIDENCE" PROVIDED BY HEALTH CANADA

To Support the Proposed Self-Care Framework To Group Natural Health Products and Non-Prescription Chemical Drugs Under a Single Set of Regulations

Prepared by Shawn Buckley, LL.B., President of the Natural Health Products Protection Association on January 28, 2019.

Context:

Health Canada has published a time-line for:

1. regulating Natural Health Products ("NHPs") the same way as chemical drugs;
2. imposing the chemical standards of evidence for safety and efficacy on NHPs;
3. imposing the penalties and powers brought in by Vanessa's Law for chemical drugs on NHPs (despite Parliament's express intention that they not apply to NHPs); and
4. likely removing the compounding exemption for practitioners.[1]

Through requests under the *Access to Information Act* Health Canada has provided the materials relied upon to impose these changes upon the NHP community.

Summary:

- Health Canada has published a time-line to regulate NHPs under the same regulations as chemical non-prescription drugs, under a framework for "Self-Care Products";
- the current *Natural Health Product Regulations* are the result of a long and focused political process involving wide consultations. This process resulted in the conclusion that it would be inappropriate to do what Health Canada is proposing, namely, to regulate NHPs under the same regulations as chemical drugs;
- the documents released by Health Canada pursuant to *Access to Information Act* requests demonstrate a surprising lack of evidence (scientific or otherwise) to justify the changes to the regulation of NHPs;
- Parliament was clear when passing Vanessa's Law, that the powers and penalties for chemical drugs were not to apply to NHPs. Parliament's intention will be undermined with the imposition of the powers and penalties on NHPs by the proposed regulatory change.

Opinion Paper

This Discussion Paper was prepared by Mr. Shawn Buckley, counsel at Buckley & Company Law Office, and President of the Natural Health Products Protection Association. The opinions are those of Mr. Buckley. As with all NHPPA Discussion Papers, feedback is appreciated so that both Mr. Buckley and the NHPPA can refine their opinion as more is learned. This Paper deals with the lack of evidence supporting the Self Care Framework. For an in-depth analysis of the Self Care Framework and proposed changes see our *Discussion Paper on the Repeal of the Natural Health Products Regulations*.

[1] At the time of writing this it is the author's understanding that Health Canada will not confirm that the compounding exemption will remain. Considering the importance of the exemption to practitioners such as herbalists and traditional Chinese doctors, one would expect Health Canada to provide more clarity.

History

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 law suit 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 law suit, 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.[2] 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:

a. it was not proper to regulate natural products under the same regulations as chemical drugs; and

b. 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:

[2] For example, on January 26, 2010, the Natural Health Products Program Advisory Committee issued a *Report on Standards of Evidence for Non-Traditional Natural Health Products*.

> 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 then 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 22 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.

The Health Canada Proposal is to go back in time and regulate NHPs under the same set of regulations as chemical drugs

In September 2016, Health Canada announced a plan to harmonize the regulation of NHPs and non-prescription chemical drugs under one set of regulations for "Self-Care Products". In other words, the plan is to un-do the expertise and work that went into our current regulatory process, and to:

1. regulate NHPs the same way as chemical drugs;
2. to impose the chemical standards of evidence for safety and efficacy on NHPs; and
3. to impose the penalties and powers brought in by Vanessa's Law for chemical drugs on NHPs (despite Parliament's express intention that they not apply to NHPs).

The new system will do the exact opposite the Standing Committee on Health, the Government, the NHP industry and consumers agreed on

The purpose of this paper is not to outline the proposed changes. Those changes are analyzed in the *Discussion Paper on the Repeal of the Natural Health Product Regulations*.

The purpose of this paper is to reveal the names of the people responsible for the change and to show the documents they have relied upon to bring about this change. Our current regulatory scheme is based upon significant expertise, political will, effort and cost to the natural health industry. Before significant changes are made, an examination of individuals and evidence to support the change should be examined.

The First Access to Information Requests of Deane Parkes

Deane Parkes has been active in the natural health community for 45 years. He has been a retailer, a supplier and a manufacturer of natural health products. He has been heavily involved in the natural health community and has extensive knowledge in the regulation of natural health products ("NHPs").

When Health Canada recently announced its intention to regulate natural health products under the same regulations as chemical non-prescription drugs, Mr. Parkes attended one of Health Canada's information sessions on the new changes. At the session Health Canada made it clear that the proposed changes were "non-negotiable". When Health Canada was asked why the proposed changes were non-negotiable the audience was told that:

> a "committee" of "senior management" at Health Canada laid down these principles and told the Natural and Non-Prescription Health Products Directorate (the "NNHPD") to figure out how to make it happen.

The message to Canadians was clear. Despite all the efforts to arrive at our current regulatory regime for NHPs, non-negotiable changes were going to be made. They were non-negotiable because they came from a "committee" of "senior management". Mr. Parkes wanted to know who was on this committee.

To do so he made a request under our *Access to Information Act*.

His request was for:

> Please advise me the names, department/company, and position titles regarding "committee" of "senior management" in statement below. Statements from recent Health Canada meetings to public and industry:
>
> 1. Self care products making similar claims would require similar evidence
>
> 2. Self care products will be regulated according to risk to consumers
>
> 3. Health Canada should have appropriate powers to address safety and non-compliance.
>
> When asked why these principles are non-negotiable, NNHPD replied that a "committee" of "senior management" at Health Canada laid down these principles and told NNHPD to figure out how to make it happen. Provide the names of individuals at the director level and above for the following time period: April 2016 to date of the request (September 18, 2017).

The response to the *Access to Information Act* request was two pages which indicated that on May 12, 2016, four Health Canada employees met with the Health Minister Jane Philpott for 45 minutes. At the end of the meeting the Minister confirmed her support for the self-care framework.

The four Health Canada employees were:

1. Simon Kennedy;
2. Paul Glover;
3. Anil Arora; and
4. Pierre Sabourin.

Attached as Appendix 1 are the *Access to Information Act* response documents.

Simon Kennedy - is the Deputy Minister of Health Canada. He was appointed in 2015. Prior to that he was the Deputy Minister of International Trade. While Deputy Minister of International Trade the Canada-European Union Comprehensive Economic and Trade Agreement was negotiated. Attached as Appendix 2 is his biography published by Health Canada. It appears that Mr. Kennedy is not an expert in NHPs or the regulation of NHPs. Mr. Kennedy was with Health Canada for 17 months prior to the May 12, 2016 meeting with the Minister.

Paul Glover - was the Associate Deputy Minister of Health Canada at the time of the May 12, 2016 meeting. He is currently head of the Canadian Food Inspection Agency. Mr. Glover has been in several roles within Health Canada. Attached as Appendix 3 is his biography published by the Canadian Food Inspection Agency. He has a master in business administration (MBA). It is unknown to the author whether Mr. Glover is an expert in NHPs or the regulation of NHPs, although it appears unlikely.

Anil Arora - has been the Chief Statistician of Canada since September 2016. He has worked for the United Nations and the Organization for Economic Cooperation and Development. He has worked in several Federal Government Ministries. He briefly joined Health Canada in 2014 as the Assistant Deputy Minister of Health Products and Food Branch. A copy of his government biography is attached as Appendix 4. It appears that Mr. Arora is not an expert in NHPs or the regulation of NHPs. Mr. Arora briefly joined Health Canada well after the detailed process outlined above to arrive at our current regulatory regime for NHPs. He left shortly after the May 12, 2016 meeting with the Minister where the new framework was approved.

Pierre Sabourin - is currently the Assistant Deputy Minister of Health Canada's Health Products and Food Branch. He joined Health Canada in this position in March 2016, within two months of the May 12, 2016 meeting with the Health Minister that has led to the proposed changes. Prior to joining Health Canada, Mr. Sabourin was at the Canada Mortgage and Housing Corporation, the Canada Border Services Agency and Foreign Affairs and International Trade. A copy of his LinkedIn Profile is attached as Appendix 5. It would appear that Mr. Sabourin has no expertise in NHPs.

It seems clear that the "committee" of "senior management" that laid down the "non-negotiable" changes that are coming are not experts in NHPs or how they should be regulated. Except for Mr. Glover, the other three had limited experience at Health Canada, their careers being focused in other Ministries unrelated to NHPs or the regulation of NHPs.

This raises several questions, such as:

1. Why would the Minister of Health agree to significant changes that directly contradict the current regulatory scheme which was arrived at only following the significant involvement of the Standing Committee of Health, experts both within and outside of Health Canada, the natural health industry, and citizens?
2. Why would four people without expertise in NHPs be allowed to set a "non-negotiable" approach to the regulation of NHPs?
3. Why are these changes non-negotiable?

The Second Access to Information Request to get all documents that led to the Self-Care Framework being imposed by the "committee" of "senior management"

Mr. Parkes made a second *Access to Information Act* request. His second request was worded as follows:

> I am looking for ALL correspondence pertaining to the creation of the new Self Care Framework. Please send all emails, texts, letters, inter office memos, phone lists of all information leading up to the creation of the new Self Care Framework. All names and occupations of any individuals who were part of creating the new Self Care regulations.

There was some back-and-forth with Health Canada to clarify the request. For a history of this back-and-forth prepared by Mr. Parkes visit: *Deane Parkes ATI Request History*

In response to the request Mr. Parkes received 246 pages. A copy of Health Canada's response can be found here: *Health Canada Response to Mr. Parkes ATI 246 Pages*.

The highlighting and writing were done by Mr. Parkes on the originals.

When going through 246 pages supplied by Health Canada, two things were focused on:

1. who participated in the formation of this policy and who was excluded, and
2. what evidence was present to support the main changes that will be brought in by the imposition of the self-care framework, namely:

    (I) the phasing out or replacement of the *Natural Health Product Regulations* so that NHPs and chemical non-prescription drugs will be regulated under one set of regulations;

    (II) with the phasing out of the Natural Health Product Regulations, the penalties and powers brought in by Bill C-17, S.C. 2014, c-24 (Vanessa's Law) that apply to chemical drugs will apply to NHPs. This is despite Parliament's clear intention that they should not apply to NHPs (the preamble to Vanessa's Law includes: "And whereas new measures are required to further protect Canadians from the risks related to drugs and medical devices, other than natural health products");

    (III) restricting the health conditions for which NHPs can be used;

    (IV) increasing censorship of truthful information;

    (V) imposing cost recovery on the NHP industry;

    (VI) imposing the standards of evidence for chemical drugs on NHPs;

    (VII) claiming that there is a significant risk of "failed efficacy". Under Health Canada's "failed efficacy" meme, NHPs are presumed to be ineffective. Because of this Health Canada claims there is a risk that people will delay treating themselves with chemical drugs which are considered by the "committee" of "senior management" to be "proper treatments";

    (VIII) accepting double-blind clinical trials as necessary (see the NHPPA *Discussion Paper* on the proposed changes for a discussion on issues with this assumption);

(IX) potentially eliminating the compounding exemption enjoyed by practitioners such as traditional Chinese doctors and naturopathic doctors;

(X) the loss of traditional use evidence to support many efficacy claims;

(XI) the imposition of administrative penalties on NHPs.

For a detailed discussion of these changes see the NHPPA *Discussion Paper on the Repeal of the Natural Health Product Regulations*.

Who Participated in the formulation of the Self-Care approach?

The natural health community was largely not-involved in the formulation of the approach because of Health Canada's consultation document. In 2014, Health Canada published a document called *A Framework for Consumer Health Products* calling for feed-back on the new proposal.

The consultation document made it clear that the new framework would not apply to NHPs.

Specifically, it included:

> **B. Non-application**
>
> The proposed regulations will not apply to:
> ...Natural Health Products.

Because the consultation document made it clear that the proposed changes in regulation would not apply to NHPs, the natural health industry largely ignored the consultation process. The consultation documents make it clear that the *Natural Health Product Regulations* represents the most modern approach to regulating low risk products. Rather than signaling that the *Natural Health Product Regulations* will be repealed, the consultation document implies that new regulations for non-chemical drugs will use the *Natural Health Product Regulations* as a template for the new regulations.

According to the Health Canada website, there were only 31 respondents to the consultation document.

The ATI Documents - who was involved. As shown in the ATI documents, the following companies and organizations were involved:

- Vita Health Products Inc. The first 31 pages of the ATI are emails from a Health Canada email to the same Health Canada email. The Health Canada authors are not known. Nor are their qualifications known. The emails are comments on other documents. The only Person/company mentioned in the emails is: Vita Health Products Inc. According to the Vita Health Products Inc. website they are a contract manufacturer of chemical over the counter drugs and NHPs;

- Consumer Health Products Canada. According to this organization's website, they are an advocate for their members. They list twenty members including major pharmaceutical companies such as Bayer, Pfizer and Sanofi. They also list Vita Health Products Inc. as a member which indicates that the Vita submission has some overlap with this submission;

- the National Association of Pharmacy Regulatory Authorities (the "NAPRA"). The NAPRA is an association of pharmacy regulatory bodies;

- the Canadian Consumer Specialty Products Association (the "CCSPA"). The CCSPA is a trade association for the makers of consumer, industrial and institutional specialty products. The first two members listed on their website are 3M Canada and AKZO Nobel Chemicals. This is not an organization for chemical drugs or NHPs. Their submissions had to do with "disinfectants";

- the Canadian Health Food Association (the "CHFA"). The CHFA is a trade association representing some NHP companies. The CHFA's actual submissions are at pages 175-178. Because Health Canada's consultation paper said the new framework would not apply to NHPs, the CHFA's submissions are limited to: permitting samples for NHPs, stopping personal importation of NHPs from outside of Canada, and delaying cost recovery;

- the Canadian Association of Chemical Distributors (the "CACD"). The CACD is a trade association for the distribution sector of the Canadian chemical industry;

- Canadian Cosmetic Toiletry & Fragrance Association. This Association is now called Cosmetics Alliance Canada. It is a trade association for the cosmetics and personal care industry;

- the Ordre des pharmaciens du Quebec which is a regulatory body for pharmacists in Quebec;

- Food & Consumer Products of Canada (the "FCPC"). The FCPC is a trade association for the consumer packaged goods industry. Members include companies like 3M, Bayer, Campbell's and Duracell;

- Herbalife. Herbalife is a NHP company. Herbalife's submissions are one page (page 65). They focus on sampling and cost recovery;

- Amway. Amway is a distributer of personal care products and NHPs. Amway's submissions are found at pages 66-67. The focus is on sun screen;

- Loreal Canada. Loreal is a cosmetics company;

- Zep Inc. Zep sells cleaning supplies;

- an unknown company (the name is redacted) supporting the Canadian Cosmetic Toiletry & Fragrance Association submissions;

- S.C. Johnson and Son. This company sells products like laundry detergent and air fresheners;

- Shaklee Canada Inc. Shaklee sells NHPs, household cleaning products, skin care products and water filtration equipment. Shaklee's submissions are found at pages 105-106. Their focus is on sun screen, GMP requirements, and the ability of their independent distributors to give out samples;

- Traditional Medicinals. This company sells herbal teas. Their submission is at page 107. The submission is on being able to give out samples;

- Canadian Natural Products Association (the 'CNPA"). The CNPA is an association of 15 companies such as contract manufacturers. The CNPA's two-page submission is at pages 179-180;

- Allied Beauty Association. This is an association of cosmetic industry manufacturers, distributors, retailers and practitioners;

- Canadian Pharmacists Association.

The documents disclosed by Health Canada as the basis of the non-negotiable Self-Care Framework do not address the proposed changes to the regulation of NHPs

As set out above, the consultation document made it clear that the proposed changes would not apply to NHPs. As a result, there was minimal involvement by anyone involved in the NHP industry/community. The few submissions from NHP companies were largely limited to the issue of giving out samples. Contributors were not asked to address the significant changes set out above.

The documents disclosed to support the "non-negotiable" changes to the regulation of NHPs do not support or address the changes that are proposed.

The sweeping changes to the regulation of NHPs, which will undo the current regulations arrived at after broad consultations and years of work, are literally coming out of thin air without any evidence (scientific or otherwise) to support the changes. Decades of consultations, expertise and cooperation between Health Canada and the natural health community is being undermined by the direction of four individuals without expertise in the regulation of NHPs. To add insult to injury, the proposed changes are "non-negotiable". Those in the natural health industry that have worked hard to ensure the proper regulation of natural products have cause to feel betrayed by the bureaucracy.

It is completely unclear why the Minister of Health supports the Self-Care Framework

It is unclear why the Government no longer supports the 53 recommendations of the Standing Committee on Health that had been expressly adopted and supported until now. It almost appears as if the Government and Health Canada are suffering from amnesia. For example, under the self-care framework, the standards of evidence for natural products and chemical drugs will be harmonized. The meme to justify this is to prevent consumers from being confused.

For example, it is argued that consumers may see a chemical drug for cold symptoms next to a NHP for the same cold symptoms and believe that they have been subjected to the same standards of evidence.

Assuming this is not a fabricated problem to support the self-care framework, any such confusion would be fully addressed by Committee recommendations 22 and 23 which read:

> 22. The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims.
>
> 23. The label indicates clearly the type of evidence used to support the claim.

The Committee recommendations were directed specifically at the issue of how to regulate NHPs to ensure safety and efficacy issues are properly addressed. The self-care framework consultations did not ask for submissions on how to regulate natural products. Rather, the consultation documents prevented submissions on that issue by stating that the new proposals would not apply to NHPs.

We are being subjected to "non-negotiable" changes to the regulation of NHPs without any meaningful consultation and without evidence to support the changes. This is clearly a case of the emperor having no clothes. We are being given "non-negotiable" changes without science or other evidence to support them.

Call to action and support

The NHPPA has been quite consistent over the nine years since the Bill C-51 scare that Health Canada was not satisfied with the status quo and changes such as those currently being proposed were to be expected. We are now facing what we predicted would occur. We need you to work with us in the upcoming fight and in pushing for the Charter as a solution. We need your funding. We are inviting people to contact us at info@nhppa.org for setting up financial support. Alternately visit the donation page of our website at www.nhppa.org. We need your email address so that we can alert you to needed action. Please visit our website at www.nhppa.org and provide us with your email address by subscribing.

Resource documents referred to in this Discussion Paper in order of appearance:

Page 4

"***Natural Health Products: A New Vision***" Report of the Standing Committee on Health, Joseph Volpe, MP, Chair, November 1998. Retrieved from Parliament of Canada website, House of Commons HEAL Committee Report. Link: https://www.ourcommons.ca/DocumentViewer/en/36-1/HEAL/report-2/

"*A Fresh Start: Final Report of the ONHP Transition Team*", Presented to The Honourable Allan Rock, PC, MP Minister of Health, Government of Canada, Presented by: The Transition Team, Office of Natural Health Products, March 31, 2000, Link: nhppa.org/wp-content/uploads/2018/04/A-Fresh-Start-Final-Report-of-the-ONHP-Transition- Team.pdf
Archived

Natural Health Product Regulations (SOR/2003-196), Government of Canada, Justice Laws Website, Enabling Act: Food and Drugs Act. Link: https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/index.html These Regulations came into force on January 1, 2004.

Footnote 2: ***Report of the Natural Health Products Program Advisory Committee to the Natural Health Products Program Meeting #3 – January 26, 2010, Agenda item #4: Presentation of Report #1 on Standards of Evidence for Non-Traditional Natural Health Products to the Director General, Natural Health Products Directorate***. Found on Government of Canada, Health Canada website. Link: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/activities/advisory-bodies/program-committee/standards-evidence-non-traditional-program-advisory-committee-2010.html

Partial history in the development process of the current Natural Health Product Regulations 1997-2010, provided by Health Canada can be found on an archived page of the Government of Canada website. Link: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation/history.html

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"*Natural Health Products: A New Vision*" Report of the Standing Committee on Health, Joseph Volpe, MP, Chair, November 1998. Retrieved from Parliament of Canada website, House of Commons HEAL Committee Report. Link: https://www.ourcommons.ca/DocumentViewer/en/36-1/HEAL/report-2/

Pathway for Licensing Natural Health Products used as Traditional Medicines
Found on Government of Canada, Health Canada website. Link: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/pathway-licensing-traditional-medicines.html

Page 5 (continued)

Pathway for Licensing Natural Health Products Making Modern Health Claims Found on Government of Canada, Health Canada website. Link: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/pathway-licensing-making-modern-health-claims.html

Page 2, 6 & 10

NHPPA website post on "**New Discussion Paper Released by Shawn Buckley: The Repeal of the Natural Health Product Regulations**", including link to Discussion Paper, background information and call to action for stakeholders: http://nhppa.org/?page_id=13149

Direct link to ***Discussion Paper on the Repeal of the Natural Health Product Regulations***: http://nhppa.org/wp-content/uploads/2018/05/Discussion-Paper-on-the-Repeal-of-the-Natural-Health-Products-Regulations.pdf

Page 10

A Framework for Consumer Health Products Found on Government of Canada, Health Canada website. Downloaded and Archived Link: http://nhppa.org/wp-content/uploads/2019/02/Archived-Webpage-03-16-2018-A-Framework-for-Consumer-Health-Products-Canada.ca_.pdf?fbclid=IwAR0uzyKD-l3jwNfFJE_97cQeROyVH5hoq9gsM_nkzsBCY_9jZGrhNVUIS7c

Appendix 1

info@nhppa.org | www.nhppa.org | www.charterofhealthfreedom.org | 1.519.648.2050

I+I Health Canada Sante Canada

Access to Information and Privacy Division 7th Floor, Suite 700, Holland Cross - Tower B 1600 Scott Street,(Mail Stop:3107A) Ottawa, Ontario KIA OK9

NOV072017
UM

Our file: A-2017-000828 *I*

Deane Parkes
Actnatural
Corporation
1440 Creekside Suite
#403 Vancouver, BC V6J
5B6

Dear Mr: Parkes:

This is in response to your request made under the *Access to Information Act* (the *Act)"for*
the following information:

Amended text (October 2, 2017): Please advise me the names, department/company, and position titles regarding "committee" of"senior management" in statement below. Statements from recent Health Canada meetings to public and industry:

1. Self care products makingsimilar claims would require similar evidence
2. Self care products will be regulated according to risk to consumers
3. Health Canada should have appropriate powers to address safety and non compliance.

When asked why these principles are non negotiable, NNHPD replied that a "committee" of "senior management" at Health Canada laid down these principles and told NNHPD to figure out how to make it happen.

Provide the names of individuals at the director level and above for the following time period: April 2016 to date of the request (September 18, 2017).

Amended text (September 19, 2017): Please advise me the names, department/company, and position titles regarding "committee" of "senior management" in statement below. Statements from recent Health Canada meetings to public and industry:

1. Self care products making similar claims would require similar evidence
2. Self care products will be regulated according to risk to consumers
3. Health Canada should have appropriate powers to address safety and non compliance.

When asked why these principles are non negotiable, NNHPD replied that a "committee" of "senior management" at Health Canada laid down these principles and told NNHPD to figure out how to make it happen.

Original text: Please advise me the names, occupations and where person was born regarding "committee" of "senior management" in statement below. Statements from recent Health Canada meetings to public and industry:

1. Self care products making similar claims would require similar evidence
2. Self care products will be regulated according to risk to consumers

Canada

DEPARTMENTAL BRIEFING WITH MINISTER JANE PHILPOTT

Thursday, May 12, 2016
Confederation Building, Room 162
Time: 9:00 AM - 12:00 PM

Private Time **9:00 AM -10:00 AM**

Discussions:

1. First Nation Youth Mental Health Roundtable **10:00 AM -10:30 AM**

30 minutes

LEAD: Simon Kennedy (HC) Paul Glover (HC) Sony Perron (HC) Keith Conn (HC)

2. Self-Care Framework **10:30 AM -11:15 AM**

45 minutes

.LEAD: Simon Kennedy (HC) Paul Glover (HC) Anil Arora (HC) Pierre Sabourin (HC)

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Ministerial Meeting with Minister

Philpott Meeting Record of

Decisions

May 12, 2016

Participants: Simon Kennedy, Paul Glover, Michelle Kovacevic, Sony Perron, Keith Conn, Anil Arora, Pierre Sabourin, Jeannine Ritchot

1) First Nation Youth Mental Health Roundtable

The Minister was fully supportive of moving forward with the first nations youth mental health roundtable, specifically requesting that there be as much unstructured time as possible. As the proposed time slot conflicts with Cabinet, another time later in the day or the following day will be explored. It was noted that officials are working with ITK to set up an equal opportunity for Inuit youth as well.

Action items:

I) HC to work with the Minister's office to identify a time slot which is agreeable to both the Minister and the AFN.
2) The Minister's office to discuss the proposed roundtable with the Centre.

2) Self-Care Framework

[redacted]

The Minister also confirmed her full support for the proposed way forward on the Self-Care Framework.

Action items:

1) [redacted]

Appendix 2

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I+I

Government of Canada | Gouvernement du Canada

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Deputy Minister of Health Canada - Simon Kennedy

Simon Kennedy was named Deputy Minister of Health effective January 21, 2015.

Previously, he served as the Deputy Minister of International Trade and Canada's G-20 Sherpa. He oversaw the Trade Portfolio through one of the most productive periods in the history of Canadian trade negotiations. During his tenure, negotiations were successfully concluded on the Canada-European Union Comprehensive Economic and Trade Agreement. Negotiations were also concluded on the Canada-South Korea Free Trade Agreement, Canada's first free trade agreement in Asia, and the treaty brought into force.

Prior to his assignment at International Trade, Mr. Kennedy served as the Senior Associate Deputy Minister at Industry Canada from September 2010 to November 2012. One of his key responsibilities was to administer Canada's foreign investment review regime. For almost a year during this period, Mr. Kennedy was also the Prime Minister's representative on the Canada-U.S. Beyond the Border Working Group. In this role, he led the negotiation with the White House of the Canada-U.S. Action Plan for Perimeter Security and Economic Competitiveness, announced by the Prime Minister and President Obama in December 2011.

Mr. Kennedy began his career with the public service in 1990, serving in a variety of progressively senior roles at Transport Canada, the Canadian Coast Guard, and Agriculture and Agri-Food Canada. He also held several senior positions at the Privy Council Office, the department supporting the Prime Minister, in the 1990s and 2000s. These most recently included two deputy-level appointments: Deputy Secretary to the Cabinet for Operations (2008-2010) and Deputy Secretary to the Cabinet for Plans and Consultation (2007-2008).

Mr. Kennedy holds a Bachelor of Public Relations from Mount Saint Vincent University and a Master of Science in Communications Management from Syracuse University. He is a graduate of INSEAD's Advanced Management

Programme. Mr. Kennedy also holds an ICD.D designation from the Institute of Corporate Directors.

Date modified:
2015-01-20

Appendix 3

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Canada

Can adian Food Inspection Agency

Home -. About the CFIA (Canadian Food Inspection Agency) .. Organizational Information -+ President

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President

The President is the chief executive officer of the Canadian Food Inspection Agency (CFIA) and, as such, supervises its direction and its staff. The Presidenthas the rank, and all the powers, of a deputy head of a federal government department.

As President of the f .El6..(f c:1.r::! <:l_i_c:1n_ .E2.9.9...l.r.!§P 9! i.2!!...6.9 r:ifY.), Paul Glover is responsible for carrying out the Agency's mission, which is to safeguard food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

About the Gr. A.(G. D_gi n.f.Q.9.q_lf.l. P J.9._1:1,Ag n Y.l President

The Prime Minister of Canada appointed **M.,.{M.i. i t) Pau l Glover** to the position of President of the Canadian Food Inspection Agency effective October 31 51 2016. Paul also serves as the Deputy Champion for Brock University.

Paul served as the Associate Deputy Minister of Health Canada from July 2013 onwards.

Prior to his appointment as Associate Deputy Minister of Health Canada, Mr. (Mister) Glover was Assistant Deputy Minister of the Health Products and Food Branch (HPFB). HPFB (Health..Products D5LE9.99.1:3.rnncb) takes an integrated approach to managing the health-related risks and benefits of health products and food through the regulatory system. Paul also served as the AP..M (A §!§.\.?.r:iL Q§1.?.\!J/. M ini ster) Champion for the Community of Federal Regulators.

PaulGl ove r , President

Paul was the Assistant Deputy Minister of the Healthy Environments and Consumer Safety Branch at Health Canada from September 2008

to January 2011. Previous to that, he was in the Privy Council Office's Operations Branch, where he worked on a wide range of social policy issues. He began his career at Health Canada in 1986, in the informatics area. Paul then moved on to health systems management and assumed progressively more responsible jobs, eventually leading, as Director General, a number of business units, including First Nations and Inuit Health Programs, the Non- Insured Health Benefits Program, and the Safe Environments Program.

Over the years Paul has served on numerous governing bodies, including the Board of Directors of the Queensway Carleton Hospital, the Mental Health Commission of Canada, Canada Health lnfoway, the Advisory Board for the Canadian Institutes of Health Research, and the Queen's University Board of Directors for the Centre for Water and the Environment. He has been a member of the National Academies of Science in the U.S.A..(United.States . o f America) and the International Joint Commission.

Paul earned his Master in Business Administration from Queen's University.

- Executive Vice-President
- Chief Food Safety Officer, Chief Veterinary Officer, Chief Plant Health Officer and Chief Science Operating Officer
- Senior management structure

Date modified:

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Home

Anil Arora

Anil Arora was appointed Chief Statistician of Canada in Septem

.Mr ..(Mis..t. r.).Arora has led significant transformational initiatives throughout his career, with experience and partnerships spanning all three levels of government, the private sector and international organizations, including the UN..(U ni ted..Nations) and the OECD(Orgar,izatio nJor..Econo mic .G9.9.P. r.9Ji9.Q..<3..r.i9..P Y.E?/.QP!I.1. r1n. He has led projects on high-pro issues, legislative and regulatory reform, and overseen large national programs.

In 1988, Mr...(Mist r) Arora joined Statistics Canada where he served in several positions, including regional operations, corporate services and the redesign of the dissemination function. In 2000, he became Director of Census Management Office and subsequently the Director General responsible for all aspects of the 2006 Census. In this role, Mr..(Mister) Arora led the most comprehensive redesign of the Program, including the introduction of an online questionnaire. Following the successful delivery of the 2006 Census he became the Assistant Chief Statistician of Social, Health and Labour Statistics from 2008 to 2010.

In 2009. , Mr..(Mister) Arora received the prestigious APEX Leadership Award in recognition of his exceptional leadership skills and management· excellence.

In 2010, Mr. .(Mister) Arora joined Natural Resources Canada as Assistant Deputy Minister of the Minerals and Metals Sector, and in 2013 was appointed Assistant Deputy Minister of Science and Policy Integration . He moved to Health Canada in 2014, becoming Assistant Deputy Minister of Health Products and Food Branch and leading a complex organization overseeing regulation of food, drug and health products for Canada. He also served as chair of the International Coalition of Medicines Regulatory Authorities.

Mr.J Mister) Arora attended the University of Alberta, where he earned a Bachelor of Science, followed by further education in computing science and management, including a graduate certificate in Advanced Public Sector Management at the University of Ottawa, and the

Advanced Leadership Program at the Canada School of Public Service.

Chief Statistician of Canada

Contact information

anil.arora@canada .ca
Statistics Canada
100 Tunney's Pasture Driveway
Ottawa, Ontario
K1A OT6

Appendix 5

Pierre Sabourin

Otta wa, Canada Area Government Admini stration

500 + connec tions

Current Health Canada I Sante Canada, University of Ottawa

Previous Canada Mortgage and Housing Corporation, Canada BorderServices Agency, Foreign Affairs and International Trade Canada

Education University of Ottawa / Universite d'Ottawa

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Deputy Commissione deleguee at Canada I Agency - Agence du r Canada


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Director General, Ass


Executive Bureau, GI Canada


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Chauffeur chez STM


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Jeff Heynen
Director, Trade Policy


Canada - Transports


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Congratulations to Glenn Moran, EMBA 2017, on his new role...

Tina Namiesniows Executive Vice Presic Border Services Ager

Kendal Weber Associate Assistant C Health Products and I Health Canada

Lindy Van Amburg Assistant Director at f Sante Canada

Lisa Campbell Associate Deputy Mir /Proudparent /Sous-n deleguee/Av ocate/Pa

Ken Sunquist

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Pierre Sabouri

A r e a

I• I **Assistant Deputy Minister** - **Health Products and Food Branch**

C. H ea lth Canada ISante Canada anada March 2016 - Present• 2 years 8 months Ottawa, Canada

m.,

(1) a broad range of health products that affect the everyday lives of Canadians, including pharmaceutical drugs, biologies and radiopharmaceuticals, medical devices, and natural health products;

(2) the safety and nutritional quality of food.

II **Professor (part time) - Telfer School of Management**
University of Ottawa
1999 - Present • 19 years

Leads the courses "IT for managers". Designed and delivered the "Innovation and entrepreneurship" course (which includes a working trip to Silicon Valley) . University of Ottawa part-time professor of the year in 2004.

Senior Vice-President, Corporate Services
Canada Mortgage and Housing Corporation 2013 - 2014 • 1 year
Ottawa. Canada Area

I led the provision of corporate services in human resources, communication, marketing, corporate relations, information technology and administrative services. Member of CMHC Management Committee.

Vice President, Operations
Canada Border Services Agency
April 2010 - May 2013 • 3 years 2 months

I led all customs and immigration border operations including an international network, all Canadian border inspection points and "post border" operations (criminal

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investigations, intelligence, removals). 10.000 employees and $1B budget accountability. Led operationalization of Beyond the Border CDA-USA agreement, various immigration legislative changes and operational improvements. Champion for Front Line service delivery in CBSA Change agenda. Member of CBSA Executive Committee. Chair of CBSA Modernization. Innovation and Transformation Committee. Co-chair Beyond the border Committee.

Foreign Affairs and International Trade Canada
5 years

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Created and led the "international platform" branch providing common services to DFAIT and 21 Other Government Departments delivering international programs for the Government of Canada. Common services includes property abroad, IT, officer re-location program and supply chain management.
Implemented corporate savings targets as part of DFAIT strategic review including establishment of regional service centres.
Member of Executive Committee, Co-chair of Resource Management Committee.

Chief Information Officer
Foreign Affairs and International Trade Canada 2005 - March 2008 • 3 years

Accountable for providing IM and IT services to 10,000 employees in 170 locations worldwide. Over $1OOM bud get. 500+ employees. Key accomplishments: redesign of IM/IT governance, development of an integrated IM/IT planning and budgeting process, creation of a "CIO Fund" dedicated to systems integration - recognised as an industry best practice by Gartner Group.

Director PEMD and eServices
Foreign Affairs and International Trade Canada 2000 - 2004 • 4 years

Responsible for the Program for Export market Development, a contribution program supporting small business and industry associations to do business internationally. Also responsible for electronic channel

development for the Trade Commissioner Service at Foreign Affairs. In support of government expenditure reductions, terminated the PEMD program for small business and re-engineered PEMD association program tripling the number of applicants and substantially increasing export impact.

Project manager
Foreign Affairs and International Trade Canada
1997 -1999 •
2 years
Ottawa,
Canada Area

Reporting to the Assistant Deputy Minister, managed a team to design and implement a corporate performance measurement framework (balanced scorecard approach) as part of a major corporate renewal and change exercise.

Employee, Project manager and Deputy Director
Foreign Affairs and International Trade Canada
1993- 1996 • 3 years Ottawa, Canada Area

Participated in the worldwide deployment of local area networks and the WINExports system for the Trade Commissioner Service.

Consultant
Private consultant
1989-1992 • 3 years
Montreal , Canada and Paris. France

Information technology and project evaluation assignments for Kraft Inc, Asian Development Bank and the Canadian Embassy, Paris (France).

Consutant
CEGIR
1986- 1988 • 2 years Montreal

Participated in market studies financial analysis projects. On-site project experience includes: Ministry of Industry and Small Scale Enterprise - Guinea Republic (World Bank). As part of a multi-disciplin ary team, designed and implemented a survey of the informal private manufacturing sector to determine its characteristics and potential for growth.

Education

University of Ottawa/ Universite d'Ottawa

MBA, International Business
1991 - 1993

Universite de Montreal - HEC Montreal
Certificate, Finance
1984 - 1984

Bachelor, Engineering

Skills & Endorsements

Join LinkedIn to see Pierre's skills, endorsements, and full profile Join now

Honors & Awards

Part-time Professor of the Year
University of Ottawa
2004

Minister International Trade Award : eServices
Foreign Affairs and International Trade
2003

Queen's Jubilee Award
Foreign Affairs and International Trade
2002

Minister International Trade Award: Change Management
Foreign Affairs and International Trade
2000

Minister International Trade Award: Performance Measurement
Foreign Affairs and International Trade
1999

Languages

English
Native or bilingual proficiency

French
Native or bilingual proficiency

CBSA: The re-organization Case
(A) University of Western Ontario
Ivey Business School May 2013
Authors: Pierre Sabourin

High Value, high Risk: Managing the Legacy Portfolio
Gartner EXP Premier
Report September 2006

CIO Fund mentioned as
industry best practice Authors :
Pierre Sabourin

CRM and eGovernment
Summit Magazine
February 2003
Authors: Pierre Sabourin

Lessons Learned ... and Being Learned: Implementing Performance Measurement in the Canadian Trade Commissioner Service i
Optimum - Journal of Public
Sector Management June 1999
Authors: Pierre Sabourin

Wastewater Technology Centre - Cases (A) and (B)
University of
Ottawa 1993
Authors: Pierre Sabourin

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