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NATURAL HEALTH PRODUCTS
PROTECTION ASSOCIATION

There's more than one way of looking at health

Draft Discussion Paper on the Amendments to Bill C-51

Bill C-51 was debated during second reading in the week ending June 13, 2008. During second reading the Government introduced amendments to the Bill.

Bill C-51 has become a significant issue for persons in the Natural Health Community. Because of this, it is important for the amendments to be analyzed so that Canadians can understand the impact of Bill C-51 as it is now amended.

Discussion Paper Only

This is a discussion paper only and does not reflect the position of the NHPPA or of the NHPPA advisory board. The thoughts and comments are those of the author, Mr. Shawn Buckley and are intended to foster discussion.

The NHPPA will formulate its position after feedback from the Natural Health Community.

The Government is Claiming Victory for the Natural Health Community

One of the key demands of the Natural Health Community is for the Government to stop regulating Natural Health Products as drugs. According to the media, the Government is now claiming that with the amendments to Bill C-51 they have listened, and have now given Natural Health Products their own distinct category.

As an example of how the amended Bill C-51 is now being represented as creating a separate third category for Natural Health Products, the following quote from a June 13, 2008 article in the Vancouver Sun titled “About-face on natural health products” is instructive. The article includes:

When Clement proposed amendments to the Food and Drugs Act in April, natural medicines were lumped in with pharmaceutical drugs, raising concerns they would be subject to the same type of oversight. He now admits it was a mistake not to create a separate category under the law.

“My attitude is a bill is a work in progress. Let’s see whether we are clearly getting out the things we want to do in a particular bill. In this case, obviously protecting the health and safety of Canadians was and remains the motive for the bill,” Clemente said in an interview Friday.

But he added it “became clear that some things that we thought were implicit in the bill” needed to be spelled out.

“So, I listened to that, I listened to my own caucus who were getting the feedback from people as well, and to me it was a no-brainer. We can make the bill a better bill. We can make it explicitly, as well as implicitly, more balanced, and we still achieve our goals, which is protecting the health and safety of Canadians,” said Clement.

The government is now proposing to insert a definition of natural health products into the Food and Drugs Act to “clearly recognize” that they’re distinct from foods and drugs under the law.

Highlights

- The goal of a “third category” is to protect and increase access to Natural Health Products.
- The amendments do not advance the goal of the Natural Health Community to protect and increase access to Natural Health Products.
- There is no change in how Natural Health Products will be regulated. Putting a definition in the Act by itself does not change how a thing is regulated.

- Despite the new definition Natural Health Products are still drugs under the *Food and Drugs Act*. Indeed, **rather than creating a third category that is “distinct” from the drug category, the amendments actually entrench Natural Health Products as a subset of the drug category.**
- The few amendments do not address the concerns found in our original Discussion Paper on Bill C-51 which can be found at www.nhppa.org.
- Bill C-51 continues to pose a significant threat to the Natural Health Community.

Before Addressing Whether the Amendments Really Create a “Third Category” it is Necessary to Understand the Reason for the “Third Category”

The Natural Health Community has asked for a “third category” for a long time. It must be understood that when the Natural Health Community calls for a “third category” it is asking the Government to stop regulating Natural Health Products as drugs. **The point of asking for a “third category” is to protect and increase access to Natural Health Products.** The Natural Health Community asks for a “third category” distinct from the drug category because the current approach of regulating Natural Health Products as dangerous drugs is driving many Natural Health Products from the market and is stifling innovation on new products.

When discussing a “third category” the goal of protecting access to Natural Health Products must be kept in mind. A “third category” that does not protect and increase access to Natural Health Products does not address the goal of the Natural Health Community. A “third category” is not the goal of the Natural Health Community. A “third category” is a means by which the Natural Health Community believes the goal of protecting and increasing access to Natural Health Products can be achieved.

Do the Amendment’s Advance the Goal of the Natural Health Community to Protect and Increase Access to Natural Health Products?

The biggest amendment is to add a definition of “Natural Health Product” to the *Food and Drugs Act*. The current definition of “Natural Health Product” is found in the *Natural Health Product Regulations*. The new proposed definition is similar but not exactly the same. To show the differences, both are reproduced below.

Current NHP Regulations Definition	Bill C-51 Definition
<p>"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in</p> <p style="padding-left: 40px;">(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;</p> <p style="padding-left: 40px;">(b) restoring or correcting organic functions in humans; or</p> <p style="padding-left: 40px;">(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.</p> <p>However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.</p> <p>SCHEDULE 1 – Included Natural Health Product Substances</p> <ol style="list-style-type: none"> 1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material. 2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation. 3. Any of the following vitamins: biotin; folate; niacin; pantothenic acid; ribovlavin; thiamine; vitamin A; vitamin B6; vitamin B12; vitamin C; vitamin D; vitamin E. 4. An amino acid. 5. An essential fatty acid. 6. A synthetic duplicate of a substance described in any of items 2 to 5. 7. A mineral. 8. A probiotic. <p>SCHEDULE 2 – Excluded Natural Health Product Substances</p> <ol style="list-style-type: none"> 1. A substance set out in Schedule C to the Act. 2. A substance set out in Schedule D to the Act, except for the following: (a) a drug that is 	<p>“natural health product” means, subject to regulations made under paragraph 30(1)(c.1), any of the following that is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or for use in restoring, correcting or modifying organic functions in human beings:</p> <ol style="list-style-type: none"> a) a homeopathic medicine, b) a plant, any plant material, an alga, a bacterium, a fungus or any non-human animal material, c) any substance that is extracted or isolated from a thing referred to in paragraph (b) if the primary molecular structure of the substance is identical to the primary molecular structure of the substance before being extracted or isolated from the thing, d) a vitamin, e) an amino acid, f) an essential fatty acid, g) a synthetic duplicate of any thing referred to in any of paragraphs (c) to (f), h) a mineral, i) a probiotic, and j) any product whose medicinal ingredients consist entirely of things referred to in any of paragraphs (b) to (i);

<p>prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy.</p> <ol style="list-style-type: none"> 3. A substance regulated under the <i>Tobacco Act</i>. 4. A substance set out in any of Schedules I to V of the <i>Controlled Drugs and Substances Act</i>. 5. A substance that is administered by puncturing the dermis. 6. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic. 	
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Although the two definitions are not the same, they are similar in meaning. Schedule 1 in the *Natural Health Product Regulations* has been worked into the new definition proposed in Bill C-51. Schedule 2 has not been included into the definition but will continue to apply unless the *Natural Health Product Regulations* are amended. Despite the different wording in the new definition, the overall meaning is the same as the current definition. The changes to note are:

1. **the new definition does not include Traditional Medicine such as Chinese or Native medicine.** This is a significant departure which could affect various ethnic groups if the new definition is also adopted in the *Natural Health Product Regulations*;
2. the new definition contains:

“subject to regulations made under paragraph 30(1)(c.1)”.

Section 30 of the Act is the section that allows the Government to pass regulations. Paragraph 30(1)(c.1) reads:

“subject to subsection (1.01), specifying any thing or class of things as not being a Natural Health Product”.

Subsection (1.01) reads:

“In specifying any thing or class of things as not being a Natural Health Product in regulations made under paragraph (1)(c.1) the Governor in Council must take into account the risk of injury to health and the intended use of the thing or of things in that class.”

These changes will work together to permit the Government to exclude any thing or class of things from the new definition. This means that

despite the new definition being in the Act, it can in effect be changed by regulations which exclude single Natural Health Products or classes of things from the Natural Health Product definition.

To understand how this could operate, the Government could pass a regulation exempting the things that are currently listed in Schedule 2 of the *Natural Health Product Regulations* from the Natural Health Product definition proposed in Bill C-51. Schedule 2 is a list of things that are excluded from the current definition of Natural Health Product in the *Natural Health Product Regulations*.

The ability of the Government to exclude things or classes of things from the Natural Health Product definition is not new. Because the current definition is in a regulation the Government can change it by regulation at any time. The new definition is simply maintaining the ability to use regulation to change what is a Natural Health Product. **This means, however, that Natural Health Products are not afforded any “new” protection by the addition of a definition in the Act. The Government can still change what is considered to be a Natural Health Product by a simple regulation.** By contrast the definitions of the other categories such as “food” or “drug” cannot be changed by regulation;

3. the new definition does not limit vitamins to the twelve listed in Schedule 1 of the Regulations. Unless the current Regulations are changed, however, the Schedule 1 limit will continue to apply, and
4. the wording in the current definition:

“(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health”

has been changed to:

“restoring, correcting or modifying organic functions in human beings.”

The current wording “such as modifying those functions in a manner that maintains or promotes health” makes it clear that products that maintain or promote health are Natural Health Products. It may be that the wording in the new definition “mitigation or prevention of a disease, disorder or abnormal physical state” also covers such products and that

the current definition is repetitive. If this is the case, then the new definition is not as clear on this point as is the old definition. Alternately the change in wording could be interpreted by a Court as an intention not to include products that simply maintain or promote health. As indicated below, the new wording is identical to the wording in the definition of “drug” in the Act.

Putting a definition in the Act by itself does not change how a thing is regulated. For example, the Government could take the entire *Natural Health Product Regulations* and put them into the *Food and Drugs Act*. This would not in any way change how Natural Health Products are regulated. Indeed, the effect of this would be to entrench how Natural Health Products are regulated, as it is much more difficult for the Government to change an Act than to change regulations.

Amending Bill C-51 to add a definition of Natural Health Product to the Act, will not change how Natural Health Products are regulated. Natural Health Products will still be covered by the definition of “drug” in the Act. The current *Natural Health Product Regulations* will still continue to apply in their current form. **In short, if Bill C-51 passes, it will be business as usual except that the other provisions in Bill C-51 will pass allowing things like:**

- **making it an offence not to follow the instructions of an Inspector. This will make it an offence for Natural Health Practitioners to continue to treat patients with a treatment if an Inspector tells them not to (i.e. the Inspectors can make health decisions);**
- **Inspectors will be given unprecedented powers of search and seizure without Court supervision;**
- **penalties designed for large pharmaceutical companies will be imposed on Natural Health Practitioners and Natural Health Product manufacturers, distributors and retailers. Few if any in the Natural Health Community are likely to survive a successful prosecution, and**
- **treaties or the laws of other countries or international bodies can be adopted as Canadian law by regulation without Parliament’s approval.**

Prescription drugs provide another example of how adding a definition to the Act does not change how a thing is regulated. Currently prescription drugs are not defined in the Act. Rather, they are defined in the regulations (see Regulation C.01.041 and Schedule F to the Regulations). Under Bill C-51 the definition

“prescription therapeutic product” is added to the Act. This new definition does not, however, mean that the current prescription drugs will cease to be drugs under the amended Act. Nor does it mean that the current prescription drugs will be regulated differently. If the Government decides to amend the regulations governing prescription drugs, they are unlikely to make substantive changes.

The Government is not claiming that prescription drugs have been given a distinct category under Bill C-51. Despite the new definition of “prescription therapeutic product”, prescription drugs will continue to be “drugs” under the Act. The current Regulations governing them will continue to apply unless and until they are amended by the Government.

Natural Health Products will Continue to be “Drugs” under the Act

The term “drug” is defined in the *Food and Drugs Act* as:

“drug” includes any substance or mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- b) restoring, correcting or modifying organic functions in human beings or animals, or
- c) disinfection in premises in which food is manufactured, prepared or kept.

Bill C-51 proposes a minor tweaking of part (c) of the definition so that it will read:

“(c) disinfection of premises in which a food is manufactured, prepared or kept”.

The use of the words “includes any substance or mixture of substances” makes this term very broad in its application. It covers “any substance” used for the purposes set out in (a) to (c) of the definition. Currently there is no question that Natural Health Products are “drugs” under the Act. The *Natural Health Products Regulations* are drug regulations that treat Natural Health Products as a subset of drug.

Placing the proposed new definition of Natural Health Product into the Act does not change that Natural Health Products, as defined in Bill C-51 will continue to fall within the definition of “drug” in the Act (i.e. they will still be “drugs”).

Indeed, **the new definition which is being touted as creating a category separate from the “drug” category is deliberately drafted to make it clear that Natural Health Products are drugs.** To illustrate this, consider the following table. Note that the text in bold is identical except for the words “or animals”.

Definition of “Drug”	First Part of New Natural Health Product Definition
<p>“drug” includes any substance or mixture of substances manufactured, sold or represented for use in</p> <ul style="list-style-type: none"> a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, b) restoring, correcting or modifying organic functions in human beings or animals, or c) disinfection in premises in which food is manufactured, prepared or kept[.] 	<p>“natural health product” means, subject to regulations made under paragraph 30(1)(c.1), any of the following that is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or for use in restoring, correcting or modifying organic functions in human beings:</p>

When looking at the new definition of Natural Health Product, it is obvious that **the wording from the “drug” definition was used verbatim with the exception that the words “or animals” were taken out and the words “or for use in” were added.**

Rather than create a third category of Natural Health Products that is separate than “drugs”, the amendments to Bill C-51

entrench Natural Health Products as “drugs”. Because this is so clear when looking at the definitions and the amended Act, one wonders if the media are misquoting the Government when reporting that there is now a distinct “third category” separate from drugs. If this is the case, efforts should be made to correct the media so that the Government is not misrepresented.

Another possibility is that there is misunderstanding between the Natural Health Community and the Government concerning what a third category means or what it is to accomplish.

The Presumption that Natural Health Products are Dangerous May be Reinforced

In the First Discussion Paper on Bill C-51 which can be found at www.nhppa.org it was explained that Bill C-51 will require Natural Health Products to demonstrate that their benefits outweigh their risks. Natural Health Products can only be exempted from this requirement if the federal cabinet is satisfied that their nature is such that a risk assessment is not necessary. It was also explained that the federal cabinet could only exempt Natural Health Products or a class of Natural Health Products from the new proof of efficacy requirement “if” they are satisfied that “by its nature” it does not need to be subject to a benefit and risk analysis. This is very vague and there is no mechanism in place for making submissions to the cabinet.

Many in the Natural Health Product Community believe that it is inappropriate to presume that Natural Health Products are dangerous and that the presumption that they are dangerous has led to inappropriate regulations. Indeed, they point to the regulatory environment in the United States where by law the same products are deemed to be safe unless the U.S. Food and Drug Administration has evidence that they are not safe (see the *Dietary Supplements Health and Education Act*).

The NHPPA’s own Advisory Board has given the NHPPA the goal of obtaining a regulatory environment where, among other things, Natural Health Products are presumed to be safe and that as in the United States a Natural Health Product cannot be taken off of the market unless the Government has evidence that it is unsafe.

If Bill C-51 passes, those in the industry such as our advisory board who would like to see Natural Health Products to be presumed safe until proven to be dangerous will be disappointed. It would require a change to the new Act as opposed to a change to the regulations. Further, the amendments to Bill C-51 may reinforce the presumption that Natural Health Products are dangerous.

As indicated earlier the new Natural Health Product definition allows the Government to exclude things or classes of things from the definition by passing a regulation. The criteria for doing this is found in the new subsection 30(1.01) which reads:

“In specifying any thing or class of things as not being a Natural Health Product in regulations made under paragraph (1)(c.1) the Governor in Council must take into account the risk of injury to health and the intended use of the thing or of things in that class.”

This gives the Government two mandatory criteria:

1. the risk of injury to health, and
2. the intended use.

When read in the context of the entire Act, it is likely that the phrase “the risk of injury to health” will be narrowly interpreted to mean the risks of injury to health by allowing the thing or class of things to remain on the market. This would reinforce the presumption in the Act and Regulations that Natural Health Products are dangerous until proven safe.

There is no requirement that the Government consider the risk of excluding a thing or class of things from the Natural Health Product class. This is curious as Natural Health Practitioners as well as manufacturers of Natural Health Products are required to consider the risk of removing a product from the market before they do so. In many circumstances, if persons have come to rely upon a Natural Health Product for serious health conditions, then the providers of the product can be committing criminal negligence if they withdraw the product from the market. For public policy reasons, we have made it criminal to provide a treatment that people come to rely upon and then to withdraw the treatment (see sections 217 and 219 of the *Criminal Code*).

Because of the legal duty not to withdraw a product people rely upon for their health, it is necessary for persons in the Natural Health Community to balance the risk of removing a Natural Health Product with any risk of leaving it on the market, in both:

1. determining the safest course of action, and
2. satisfying the often competing duties under the *Food and Drugs Act* and the *Criminal Code*.

I would be interested in getting feedback on whether it would be better public policy to mandate that the Government consider both the risks of products and the risk of removing products before an exclusion decision is made. In considering this, it is important to keep in mind that a decision to exclude a thing or a class of things from the Natural Health Product definition is tantamount to declaring it

illegal. Most Natural Health Products cannot get approval under the chemical drug regulations.

Some Clarification on New Market Authorization Requirement

As indicated in the original Discussion Paper, Bill C-51 introduces a mandatory pre-approval condition for all therapeutic products. If Bill C-51 passes, Natural Health Products (which are therapeutic products in Bill C-51) will be deemed in the Act to be unsafe and illegal to sell without Health Canada's pre-approval. See the original Discussion Paper for more detail.

One of the amendments is to make it clear that in the case of Natural Health Products, traditional knowledge and the history of use of a product may be considered in a market authorization application. This is found in the new subsection 30(1.3).

If the Government is going to impose the pre-approval provision by passing Bill C-51, it is definitely better that regulations relating to the information required for an authorization may include traditional knowledge and history of use. In this sense this amendment is positive.

On the other hand, those in the Natural Health Community that seek to obtain a regulatory environment where Natural Health Products are presumed to be safe (such as in the United States), will not be consoled by this amendment. If Bill C-51 passes it will be much harder to obtain the goal of a presumption of safety. It would require an amendment to the Act itself, as opposed to the Natural Health Product Regulations. It is not progress to amend a provision that still moves the Natural Health Community away from the goal of a reasonable regulatory environment.

The “Therapeutic Product” Definition is Amended by Adding Natural Health Products

As discussed in the original Discussion Paper, Bill C-51 adds the term “therapeutic product” into the legislative scheme as a catch-all phrase for anything

used for a therapeutic purpose such as drugs, medical devices, cells, tissues or organs. One of the amendments is to add the term “Natural Health Product” into the list of things covered by the “therapeutic product” definition.

This addition is cosmetic only, and does not change the meaning of the term or its application to Natural Health Products. As discussed above, despite the addition of the definition of “Natural Health Product”, they are still “drugs” under the Act. Because “drugs” were already covered by the “therapeutic product” definition, Natural Health Products were already “therapeutic products” in Bill C-51.

This amendment gives the appearance that Natural Health Products are now distinct from drugs under Bill C-51. This is misleading. The Government is not saying that Natural Health Products were not covered by the original definition of “therapeutic product” in Bill C-51. They were covered because they clearly fit within the definition of “drug” in the Act. Put another way, if the term “Natural Health Product” had not been added to the definition of “therapeutic product”, Natural Health Products would nevertheless fall under the definition because they are “drugs” under the Act.

This amendment by itself should not cause any concern as it is only cosmetic and does not change the meaning of the “therapeutic product” definition.

The Meaningless Interpretation Committee

Bill C-51 originally proposed a new subsection 20.4(1) which read:

“20.4(1) the Minister may establish committees for the purpose of seeking advice.”

One of the amendments is to change this to:

“20.4(1) The Minister shall establish one or more committees for the purpose of providing advice to the Minister concerning the development of guidelines that relate to the interpretation of this Act or the regulations and may establish other committees for the purpose of providing advice to the Minister concerning any other matter.

(1.1) The membership for each committee established for the purpose of providing advice to the Minister concerning the development of guidelines that relate to the interpretation of this Act or the regulations must reflect a

range of experience or expertise relevant to the committee's mandate including, but not limited to,

- a) experience or expertise in consumer issues;
- b) experience or expertise in patient or caregiver issues;
- c) specialized knowledge, such as the knowledge possessed by scientists and academics;
- d) practical or clinical experience as a health professional; and
- e) experience or expertise in industry issues.

This amendment mandates that the Minister "shall" establish one or more committees to provide him/her with advice on guidelines relating to the interpretation of the Act and Regulations. Further, the committees are to contain persons with the expertise listed in (1.1) (a) to (e) as listed above.

I have to say that I have found this amendment to be completely puzzling. We have the rule of law and it is the Courts that interpret the meaning of Acts and Regulations. So in the real world, if there is a dispute, the Courts will tell us what the Act and the Regulations mean. As a lawyer who deals with statutory interpretation issues in Court, I can tell you that Courts have specific rules and approaches to statutory interpretation. What a committee established under section 20.4 says **will probably not even be admissible let alone relevant. In other words, they will be engaging in a completely meaningless exercise.**

It is also curious that these committees will be staffed by the list of persons set out above, all of which know nothing about how Courts interpret Acts and Regulations.

I am quite concerned that this amendment gives the impression that Natural Health Community stakeholders will have a say in how the Act and Regulations are interpreted when in reality they will have no say. I am also concerned that people will be asked to spend their valuable time on completely meaningless committees.

I am looking forward to input from others as to why the Minister would make these amendments.

The Seizure Power Still Circumvents the Courts

The current seizure power in the Act was declared unconstitutional by the Federal Court in 1987 (see *C.E. Jamieson & Co. v. Canada*, [1987] F.C.J. No. 826 (T.D.)). Since then Health Canada Inspectors have needed to apply for search warrants to legally seize property. Search warrants can be obtained over the phone (the telewarrant process) if there is an emergency or it is inconvenient to attend in front of a Court. The advantage for citizens with the Court process is that property cannot be seized without an independent analysis of the reasons for the seizure. Further, everything seized has to be promptly reported to the Court. A Court will require the Inspector to come back within 30 days to explain why anything seized should be held any longer. Within a short time if Health Canada has not applied to have the property forfeited to the Crown or has not laid charges, the property will be ordered returned. Courts do not let the State hold private property for undefined periods.

I am not aware of cases where the current Court supervised process was insufficient. If the current system was working, one has to wonder why it was necessary to introduce into Bill C-51 broad powers to search and seize private property without the protection of Court supervision.

The purpose of this paper is not to repeat the points raised in the original Discussion Paper on Bill C-51. For those interested in the analysis of the seizure powers contained in Bill C-51, please see the original Discussion Paper.

One of the amendments to Bill C-51 is to revise the broad seizure power. A criticism of Bill C-51 is that it allows Inspectors to seize property without any specified reasons. Now Inspectors can seize if they reasonably believe the detention is necessary

- a) to prevent a risk of injury to health;
- b) to prevent inaccurate representations of the article, or an article in the receptacle, package or conveyance, as the case may be; or
- c) to determine whether the article, or an article in the receptacle, package or conveyance, as the case may be, poses a risk of injury to health.

It appears to be progress to have Inspectors limited to these three grounds rather than having a blank slate. That said, the grounds are still so broad as to almost amount to a blank slate. For example, under the *Hazardous Products Act* there has to be a “significant” health risk before private property can be seized. Because everything carries some “risk”, anything can be seized under the amended Bill C-51 which permits a seizure to prevent any risk of injury to health. If it is necessary to move away from the current Court supervised process, we may want to consider whether there should be safeguards such as the “significant” risk threshold as we have done in the *Hazardous Products Act*.

The power to seize over “inaccurate representations” is also troubling. Under the current s. 9 of the Act, a product is deemed to be misleading (i.e. inaccurately represented) if the label is not in full compliance with the regulations. This is found in section 9 which is being replaced by a new section 14. However, Bill C-51 will give the Government the power to make regulations specifying what is to be considered misleading for the purposes of section 14 (see subparagraph 30(1)(o)). This means that the Government can pass regulations that will affect the scope of this seizure power. At the present time, the scope is unknown. If a similar approach to the old section 9 is taken, then we can expect that the seizure power as amended, will allow the seizure of property for minor violations that do not pose a risk. Currently, the Court supervises seizures for “inaccurate representations”. Again it is necessary to consider whether it is in anyone’s interest to move away from the current system.

Finally, the power to seize to determine if an article posed a risk really is a blank slate to seize private property that poses no risk. As it is currently worded, there is nothing that is covered by the Act that could not be seized under this wording just to check for a risk. A Court would not permit this without some evidence of a significant risk. A Court would not permit this because Courts are also charged with protecting our Constitutional right to be free from unreasonable search and seizure (see s. 8 of the *Charter of Rights and Freedoms*).

Another concern raised about Bill C-51 was that Inspectors can seize property for any amount of time (unlike property seized under the current Court supervised process). There is now an amendment that reads:

“An article, receptacle, package or conveyance seized under paragraph (1)(c) may be detained only for so long as it is necessary to prevent a risk of injury to health or to determine whether the article, or an article in the receptacle, package or conveyance, as the case may be, poses a risk of injury to health.”

If someone came to me and asked for my legal opinion as to how long Health Canada could hold property under this amended wording, I would have to say “I don’t know”. There is no outside limit. If Health Canada deemed that there was a theoretical risk due to something like a labeling violation, when would that risk end? This is still very broad and open-ended. There is no need to report the seizure to a Court. There is no outside time limit.

Considering that the current system was working, I look forward to input from others as to whether or not it is appropriate to move away from having independent Courts balance the interests of the State and the citizens and instead

implement a system in which the State is not supervised in the seizure and detention of private property.

In this Discussion Paper I am only covering the “amendments”. There are search and seizure provisions in Bill C-51 such as the abolition of the law of trespass that are not subject to amendments and so are not discussed here. Suffice it to say that there are only a handful of amendments to a very long, broad and complicated legislative scheme contained in Bill C-51. For an analysis on the other search and seizure provisions refer to the original Discussion Paper at www.nhppa.org.

The State can Still Destroy Private Property Without Court Supervision

The new 23.3(c) was amended. The first version in Bill C-51 was:

“if the inspector believes on reasonable grounds that the thing could be injurious to human health,

- (i) dispose of it on notice to and at the expense of the owner or the person having possession, care or control of it at the time of its seizure, or
- (ii) direct its owner or the person having possession, care or control of it at the time of its seizure to dispose of it at their cost.”

The amended Bill C-51 version is:

“if the inspector reasonably believes that the thing could be injurious to human health, and that the thing must be disposed of to prevent injury to health

- (iii) dispose of it on notice to and at the expense of the owner or the person having possession, care or control of it at the time of its seizure, or
- (iv) direct its owner or the person having possession, care or control of it at the time of its seizure to dispose of it at their cost.”

The first change is that “believes on reasonable grounds” is replaced with “reasonably believes”. Both these phrases refer to a similar standard and so this amendment does not affect the meaning.

The second change is to add the condition “that the thing must be disposed of to prevent injury to health”. I have mixed feelings about this amendment. On the

one hand, I see it as an improvement as it imposes on the Inspector a second condition before he/she has private property destroyed without Court supervision. On the other hand, because it is solely up to the Inspector and not the Courts, I am concerned that it will not have much practical effect. An Inspector had to already believe that the “thing could be injurious to human health”. Once this belief is held how can he/she be faulted for then concluding that the private property must be disposed of to prevent injury to health?

Currently Health Canada needs Court approval or the consent of the owner to destroy private property. In this way the interests of Health Canada is protected as the property is already seized and hence does not pose a safety risk. The interests of the citizens are protected as an independent Court determines if it is in the public interest for the property to be destroyed. If Health Canada is found to be wrong in their risk assessment the property is returned.

Bill C-51 as amended is still setting a dangerous precedent where there is a move away from the rule of law where the Courts adjudicate between the citizen and the State concerning private property. I look forward to input from others concerning whether it is prudent to set a precedent where it is the State alone that decides whether it was correct in seizing and destroying private property.

Other Amendments

The few other amendments do not in any way affect how Natural Health Products will be regulated. For example, some section numbers are changed and the preamble to Bill C-51 is changed. Preambles do not become law and are meant as explanatory introductions only.

Summary

The much hyped amendments do not change how Natural Health Products will be regulated. That would require changes to the *Natural Health Product Regulations* which will still apply in their current form unless amended.

Natural Health Products are entrenched as “drugs” in the amendments. They fit squarely within the definition of “drug”. Further, the new definition borrows the “drug” definition wording almost verbatim in a move away from the current definition in the *Natural Health Product Regulations*.

The issues raised in the original Discussion Paper on Bill C-51 which can be found at www.nhppa.org have not been addressed by the amendments. Indeed, the few amendments that were made to Bill C-51 are more of form than of substance.