DRAFT DISCUSSION PAPER ON Bill C-51

Prepared by Shawn Buckley, president of the NHPPA on April 9, 2008.

Purpose of the Paper

Yesterday the Minister of Health introduced Bill C-51 into the House of Commons. The Bill passed first reading. The following is a link to a version of the Bill:
http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=3398126&

Although this only occurred yesterday, upon our reading of the Bill it became apparent that it may have wide ranging negative implications for the Natural Health Product industry. We are of the opinion that it would be prudent to draft an initial discussion paper to be circulated to stakeholders and more importantly to other stakeholder groups to begin discussion on the issues raised in this Bill.

Need for a Broad Consensus

We feel that Bill C-51 has such broad implications for the Natural Health Product Industry that it would be prudent for all of the various stakeholder groups to collaborate to see if an industry consensus can be reached in how to approach Bill C-51. If Bill C-51 poses a threat to the industry, unless there is consensus, efforts to protect the industry will fail.

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 industry feedback.

Invitation to Other Stakeholder Groups

We will be forwarding this discussion paper to other stakeholder groups such as the CHFA and consumer groups.

We would like the other stakeholder groups to analyze the Bill. We would then like to get representatives of the various groups together to see if a consensus can be reached concerning Bill C-51. We believe that it is important for the various stakeholder groups to take a leading role with their members on this issue in the event that their leadership is required to protect the industry.

Initial Points of Discussion

Scope of Discussion Points

Because we feel it is necessary to get this Discussion Paper out immediately to stimulate examination and discussion on Bill C-51, I will only focus on what I consider to be major points. I fully expect that as others examine this Bill and take part in the discussion that they will identify other significant issues.

Preamble to the Act

The preamble to the Act is not part of the Act and does not become law if the Bill is passed. What the preamble does is explain why the Bill is necessary.

The second last paragraph of the preamble reads:

> "Whereas the Parliament of Canada recognizes that it is the responsibility of regulated persons to ensure that only products that meet legislative requirements are available to the public;"

My initial thoughts is that this is a classic case of what George Orwell calls doublespeak. That is, a case of saying the opposite of what you are doing.

What is communicated:

> that it is the responsibility of "regulated persons" to ensure that only products that meet the legislative requirements are available to the public.

What the Act does:

> the Act gives broad power and responsibility to Health Canada inspectors to force "regulated persons" to take whatever measures the inspectors deem necessary to ensure safety. For example, see section 23.8 of the Bill.

I am troubled by this due to the following scenario developing:

1) currently roughly 60% of natural health product license applications are failing. The majority of these license applications are for single ingredient products which are easier to licence then multi-ingredient products. The percentage of failed license applications is expected to increase as more multi-ingredient product license applications are considered. My estimate is an overall failure rate of 70%. **This means that over 60% of the natural health products on the market will fail the licensing process and will become illegal.** At that point the manufacturer can wilfully withdraw them from the market or Health Canada can take enforcement action;

2) the NHPD has been given more resources to process license applications which means that the majority of the products will become illegal sooner rather than later;

3) Health Canada is currently going to universities to recruit university graduates as inspectors because Health Canada anticipates an increased need for enforcement, and

4) Bill C-51 gives inspectors new powers to force products off of the market.

I am not aware of Health Canada having enforcement problems with chemical drug pharmaceutical companies. My belief is that when Health Canada asks a pharmaceutical company to take a product off of the market, the pharmaceutical company does. I expect that this occurs because pharmaceutical companies would face huge liability issues if they failed to comply with a Health Canada request and then someone was injured. **If I am incorrect in this I am inviting correction as it is important for us to determine "who" the new enforcement powers are directed to.**

If Health Canada is not having compliance problems with pharmaceutical companies, then should we interpret the new powers in Bill C-51 as necessary to force the natural health product industry into compliance? I do not know the answer to this. I would ask you to analyse this as you work through the Bill.

The Move to the term "Therapeutic Products"

Bill C-51 moves away from the use of the term "drug" and introduces the term "therapeutic products". Indeed even the name of the "Food and Drugs Act" will be changed to "An Act respecting foods, therapeutic products and cosmetics."

The definition of "drug" remains unchanged but a new definition of "therapeutic product" is added which includes drugs, medical devices and cells, tissues or organs. However, the term "drug" is replaced throughout the old Food and Drugs Act with the term "therapeutic products".

Natural Health Products remain "drugs" under the Act. The only change is that now all drugs are referred to as "therapeutic products" in the Act instead of as drugs.

I have found this to be a very interesting change, and perhaps the most significant of all of the changes. I think this is perhaps the most significant of all changes as I asked myself the following questions:

1) why is a language change away from the word "drug" and to the term "therapeutic product" important to Health Canada, and

2) what part of the industry is this change for?

We think and communicate in language. The terms we use to define and refer to things affect how we think about them. That is why advertising firms exist.

The term "drug" in the Food and Drugs Act is not substance specific in that any substance is considered a "drug" if sold or manufactured for a therapeutic purpose. However, many people think of the word "drug" as referring to chemical drugs as opposed to plants sold for therapeutic purposes.

There is no confusion in the public's mind concerning pharmaceutical drugs. When the public thinks of pharmaceutical drugs they are comfortable with the word "drug".

There is confusion when the word "drug" is applied to natural health products.

Because there was no confusion concerning pharmaceutical drugs and the word "drug", is the change of terminology directed at the Natural Health Product industry or are there other reasons?

The change certainly affects the dynamics of the debate over regulating NHPs as foods or as a third category separate from drugs. Let's use the NHPPA's position on regulatory change as an example. The NHPPA Advisory Board has given the NHPPA the goal of obtaining a regulatory environment where:

(1) NHPs are presumed to be safe. A NHP cannot be taken off of the market unless the Government can prove that it is unsafe;

(2) there are different claims structures so that:

a) manufacturers do not have to make claims;
b) manufacturers can make limited claims, such as structure function claims with a low evidence threshold, and
c) manufacturers can make specific health claims if they can meet a higher evidence threshold;

(3) NHPs are not regulated as drugs. They are either regulated as food or as a third category separate from drugs and food;

(4) there are Good Manufacturing Processes that are appropriate for the low risk profile of NHPs, and

(5) there is a conflict resolution mechanism to settle disputes between the Government and industry members.

The last time consumers and the industry rebelled against Health Canada enforcement actions against NHPs, the rallying cry was "don't treat our foods as drugs". That rallying cry created the most successful petition drive in Canadian history. It was a large factor leading then Minister of Health Allan Rock to refer the issue to the Standing Committee on Health. The result was the 53 Recommendations which the industry would still like to see implemented.

Would the rallying cry have been successful with the new term: "don't treat our foods as therapeutic products"? Or to be more accurate: "don't treat or natural health products as therapeutic products"?

My point in all of this is simply to communicate that terms and language are important as they determine the parameters of how we think and can affect debate. The change in terms is being introduced deliberately by Health Canada and we need to consider what the implications for the industry are.

Expanded Definition of "Sell"

The old definition of "sell" is:

> "'sell' includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration."

The new definition of "sell" is"

> "'sell' includes offer for sale, expose for sale or have in possession for sale or distribute **to one or more persons**, whether or not the distribution is made for consideration and in relation to a device, includes lease, offer for lease, expose for lease or have in possession for lease."
>
> (emphasis added).

The lease provision is not going to affect the NHP industry.

The change that is interesting is the new if you distribute to "one or more persons" you can be prosecuted for selling under the Act. Under the old definition, although you did not have to get paid if you gave product away, it is fair to say that the definition of "sell", especially when considered in the context of the Act as a whole, would be considered to be referring to a commercial venture. So for example a manufacturer giving out free samples would be selling.

Now the term "selling" will apply to a single isolated giving of a therapeutic product. So if I give my child a natural health product I am now selling under the Act and can be prosecuted. I doubt that the intention is to prosecute parents for giving their children NHPs, although that could happen under the new definition. Rather, as a lawyer who defends people and companies charged with violating the Act and Regulations, I see this as an open door to prosecute natural health practitioners, including naturopathic and homeopathic doctors.

Changes to legislation are supposed to solve a problem. When we analyse this change to the definition of "sell" we need to ask, what is the problem that Health Canada feels needs to be addressed by significantly widening the scope of selling under the Act?

It is going to be vital to obtain the input of natural health practitioners concerning this change.

Introduction of the term "Controlled Activity"

The Bill creates the following term:

> "'controlled activity' means
>
> (a) in relation to a therapeutic product manufacturing, collecting, processing, preserving, labelling, packaging, importing for sale, distributing, wholesaling or testing, and
> (b) in relation to a designated therapeutic product manufacturing collecting, processing, preserving, labelling, packaging, importing, distributing or testing.

My initial thoughts on the introduction of this term is that it is again directed at natural health practitioners such as naturopathic and homeopathic doctors.

The Bill introduces the following section:

> "13. No person shall conduct a **controlled activity** unless they are authorized by an establishment license to do so."

The change from our current regulatory scheme is the expansion of the site licence requirements. Section 27 of the Natural Health Products Regulations does not include: collecting, processing, preserving. Section 27 already includes manufacturing. By adding processing and preserving Health Canada is targeting something other than manufacturing.

Allowing Trade Agreements to become law without Parliamentary Approval – and the Sharing of Confidential Information with Foreign Governments and Agencies.

The following term is added to the Act:

> "'government' means any of the following **or their institutions**, as applicable:
> (a) the federal government;
> (b) a corporation named in Schedule III to 10 of the Financial Administration Act,

(c) a provincial government **or a public body** established under an Act of the legislature of a province,
(d) an aboriginal government as defined in subsection 13(3) of the Access to Information Act,
(e) **a government of a foreign state or of a subdivision of a foreign state, or**
(f) **an international organization of states.**

(emphasis added).

Defining "government" to include foreign states or international organizations of states such as the United Nations, is important because of a change to section 30 of the Act. Bill C-51 adds the following to the regulation making power of the federal government:

"30(7) A regulation may incorporate by reference documents produced by a person or body other than the Minister of the Canadian Food Inspection Agency including
(a) an organization established for the purpose of writing standards, including an organization accredited by the Standards Council of Canada;
(b) an industrial or trade organization; or
(c) **a government**."

This addition allows the federal government to make documents prepared by foreign governments or bodies law in Canada by simply passing a regulation incorporating the document**. So for example, the CODEX treaty could become law without Parliamentary approval by simply passing a regulation saying it is now part of our regulations.**

Just so that everyone understands what this means I will explain the difference between Acts and Regulations. Acts are documents introduced into either the House of Commons or the Senate. They must pass three readings in both before they can become law. This process ensures that Canadians and their representatives become aware of proposed changes, have them debated in Parliament, and have time to contest them.

Regulations on the other hand are simply published in the Canada Gazette twice and then can be signed into law. Parliament does not vote on regulations.

This change to allow the federal cabinet to incorporate documents from foreign governments or organizations as law by referring to them in

regulations will remove Parliamentary scrutiny on issues that could fundamentally change the ground rules for our industry.

Because these changes were not made by accident, the questions are raised:

> **what purpose is served by removing Parliamentary scrutiny to the adoption of documents from foreign governments and institutions into Canadian Law, and**
>
> **does the federal cabinet already have specific foreign documents in mind?**

There are also significant confidentiality issues associated with the new term of "government" in the Act. Bill C-51 also gives the Minister authority to disclose personal and business information without consent to a person or "government" that carries out functions relating to the protection or promotion of human health (see sections 20.9, 21 and 21.1). There are some safeguards, but at the same time the Minister has new power to share personal and confidential business information with a wide range of bodies, both Canadian and foreign, without consent.

Product Monographs are "Deemed" to be part of your Label

Bill C-51 adds:

> 2.1 For the purposes of this Act,
>
> a) a product monograph of a therapeutic product is deemed to be a label even if it is not attached or included in or does not accompany the therapeutic product;

Approaching this from a defence counsel perspective, my immediate concern is that this will subject companies to misrepresentation and fraud charges.

I will need input from industry stakeholders concerning the implications when manufacturers disagree with the Health Canada monographs.

It would also be helpful to get feed-back as to why Health Canada wants this change. Put another way, what is broken that this is intended to fix?

A New Purpose of The Act

The Food and Drugs Act (i.e. the Food and Therapeutic Products Act) is given a new purpose which is:

> 2.3 The purpose of this Act is to protect and promote the health and safety of the public **and encourage accurate and consistent product representation** by prohibiting and regulating certain activities in relation to foods, therapeutic products and cosmetics.
>
> (emphasis added).

Section 3 Prohibiting Schedule A Claims is Removed

Section 3 of the Act which prohibited Schedule A claims is removed. I expect that this is in response to the CanWest lawsuit to have s. 3 declared unconstitutional.

New Restrictions on the Importation and Transportation of Food

Section 4 of the Act is amended to include restrictions on the "import for sale" of foods that are poisonous, unfit, injurious or adulterated. I do not see a difficulty with this.

This is part of a general change in the Act towards prohibiting importation and shipping.

Sections 5.1 to 5.4 are added which place restrictions on "prescribed food". A prescribed food will be a food put on a list by the federal cabinet. These sections prevent the importation from another country and the shipping across provincial borders of a prescribed food unless they have a "registration or a license". These foods can only be sent to registered establishments.

It is not clear to me at this point what danger or purpose these new provisions are directed to addressing. What foods currently need these types of restrictions?

Bill C-51 represents a tightening of restrictions and the increasing of Health Canada powers in all areas covered by the Act.

Importing is added to prohibitions in the former sections 8 and 9.

The new sections 8 and 9 are similar in nature to the old ones except that the prohibitions are expanded to include importing and conveying for sale.

Is Health Canada Approval now required for clinical trials involving food?

Prior to the creation of the NHPD universities did not get Health Canada approval to do nutrition research. So for example, if a university wanted to run a clinical trial to better understand the effect limes have on scurvy, they did not get Health Canada approval. Even with the creation of the NHPD, it is not clear to me that Health Canada approval would be necessary to study the effect of limes on scurvy.

It has also been the case that some clinical trial businesses did not feel they needed Health Canada approval for natural health products that had been in the food chain for a long period of time.

The new Act adds a definition of "clinical trial" as well as a prohibition on conducting a clinical trial for a therapeutic product without Health Canada authorization.

As I read the new provisions, I think that a study of limes for scurvy would now require Health Canada approval.

I would like input as to whether the current regime needs to be widened?

The need for pre-market approval becomes part of the Act as opposed to part of the Regulations – And the Criteria Changes.

The new section 12 provides:

> 12(1) No person shall advertise, sell or import for sale a therapeutic product that does not have a market authorization or is not a designated therapeutic product.

The Act does not currently require Health Canada pre-approval for the sale of drugs. For there to be a pre-approval requirement, it has to be added in the Regulations. So for example, the NHP Regulations require pre-approval.

This change will mean that there is a blanket need for pre-approval and any exception needs to be added to the Regulations.

What has changed is that the Act will now presume that all "therapeutic products" are dangerous and need pre-approval unless specifically exempted.

Again part of the general tightening in Bill C-51.

Concerning the criteria change: section 18.7 will only enable Health Canada to issue market authorization if satisfied "that the benefits that are associated with the therapeutic product outweigh the risks." Risks are not defined and so it is unclear if Health Canada will continue to use risk factors such the risk people will not seek "proper" (i.e. read mainstream medical) treatment if they take an NHP.

This criteria change is legislating an efficacy requirement. The NHPD will have to have evidence of efficacy before they can determine that the benefits outweigh any risks.

This balancing is appropriate for chemical drugs that carry a high risk profile. The industry will have to discuss whether it is appropriate for the NHP industry which has never caused a single death in Canadian history. **In any event, if Bill C-51 passes, the goal posts for the NHP industry will change which should require re-licensing of NHPs.**

After the Act is changed to require NHPs to demonstrate their benefits outweigh their risks, NHPs 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

I have just discussed how the Act will now require proof of efficacy before a product can be licensed unless it is specifically exempted. It needs to be appreciated, however, that there are limits on exempting products from this requirement. The new subsection 30(1.1) contains this limit as follows:

> 30 (1.1) a regulation may be made under paragraph (1)(d) [the section governing the designation of therapeutic products] **only if** the Governor in Council is satisfied that the therapeutic product is one that by its nature does not need to be the subject of an assessment of its benefits and risks.

This means that the federal cabinet could only exempt NHPs or a class of NHPs 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.

If Bill C-51 passes, those in the industry such as our advisory board who would like to see NHPs 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.

"Import for sale" is added to the old drug provisions.

The old drug provisions of the Act which are now the "therapeutic product" provisions now include a prohibition for importing for sale although this addition is not highlighted in the proposed Bill as other changes are.

A Prohibition against selling prescription "therapeutic products" without a prescription is added to the Act.

The Regulations currently provide that prescription drugs (that is those listed in Schedule F of the Regulations) are only available by those authorized to write prescriptions. This is now being put as part of the Act as opposed to the Regulations.

There are other changes and it is not clear to me yet whether or not it will now be Health Canada as opposed to the provinces who will be determining who is eligible to write prescriptions, although I view that as an area of provincial jurisdiction.

Why the prescription drug issue is important to the NHP industry is that Health Canada currently has a policy that if you can extract a prescription drug substance from a plant or animal, then that plant or animal can only be sold by prescription. So for example, green and black tea contain a prescription substance but Health Canada has not yet started attacking NHPs with tea as an ingredient.

Again part of the general tightening in Bill C-51.

Inspection and Seizure Powers are Increased

The inspection and seizure powers found in s. 23 of the Act are increased to:

- give inspectors authority to enter private property to prevent non-compliance with the Act or Regulations;

- enter conveyances for the purposes of inspections;

- enter places where even a document relating to the Act and Regulations may be located. Currently inspectors are restricted to places where articles to which the Act or regulations apply are manufactured, prepared, preserved, packaged or stored. Note that document is defined in Bill C-51 to include information that can be read by a computer or device so if your blackberry is in your car the car can be searched;

- take samples free of charge. This is interesting for two reasons. First, there is no limit to the value of the samples. Second, although the current wording of the section does not state that Health Canada should pay for samples they take, it was clearly the intention of the government that they do pay for them. Prior to the current wording the Act specifically set out that Health Canada had to pay fair value for samples they took. When the new wording was introduced the Minister made it clear that although the wording changed that the samples were to be paid for. This can be found in the Hansard for April 21, 1953 where the Minister is asked:

  Q. In the matter of taking samples, the section says that the inspector may take samples and examine them. No provision is made in section 21 for leaving the sample. Later on in the bill we are going to come to the point of a court case on the analysis of a sample.
  A. When an inspector takes the sample he pays for it, of course.

  There is a general principle that the government cannot take property without compensating the owner. Is it necessary to abandon that principle in this case?

- seize and detain **for any time** anything connected to the Act and Regulations, such as your products and equipment. This is a significant change. Currently, an inspector can only seize if he/she "believes on

reasonable grounds" the article is connected to a violation of the Act or Regulations. **Now an inspector can seize all of your property without the pre-condition that he/she believes it is connected to a violation of the Act.**

The addition of "for any time" is also a change. Previously articles could only be held for such time "as may be necessary" and in connection with a violation. So for example, if your property was seized for a labelling problem and you printed correct labels, the property should be released. Now the property can be held for any time and for any reason. This raises a question as to **why such new broad and sweeping seizure powers are necessary?**

Keep in mind that Health Canada always has access to the search warrant provisions found in the Criminal Code. These provisions have been used by Health Canada and seem to work adequately for other federal regulatory bodies. What is going to occur that requires seizure without a warrant, without any reason, without reporting back to a Court or Justice, and without any time constraints?

- enter on and pass through or over private property without any liability and without the owner of the property having the right to object;

- charge the owner for storage of seized property. **Now not only can Health Canada seize property for any length of time, but the new s. 23.3 gives them the right to charge you for the moving and storage**. I am aware of one company that has had product seized for 5 years. Under this new provision they would be liable for ongoing storage costs. This is unprecedented. Usually the government can only seize private property for violations and it is very unusual for their to be fees for the storage of what is then considered to be evidence;

- if inspectors believe on reasonable grounds the seized property could be injurious to human health they can dispose of it **at the expense of the owner or direct the owner to dispose of it.** Currently inspectors have to either obtain the owner's consent or apply to a Court to have product destroyed. This protects the property owner by ensuring that an impartial Judge will make the decision. It is difficult to understand why it is in anyone's interest to take away the current safeguards;

- property is immediately forfeited after 60 days unless an owner is identified. No application to a Court is necessary. I find this interesting as I was involved in a case in which product was seized but for prosecution

purposes Health Canada was going to have difficulty proving ownership. Now if in doubt Health Canada can simply seize enough of your property that you will go bankrupt if you do not claim it and hence solve the proof of ownership issue. It is highly unusual for their to be forfeiture without a Court order. The costs of destruction can be charged to the owner or person entitled to possession.

Inspectors are given apparently unlimited powers to direct your actions and do "anything" for even the slightest suspected violation of the Act or Regulations

The new section 23.8 gives inspectors extremely broad powers. If the inspector believes on reasonable grounds there is a contravention of the Act or Regulations they can direct you to:

a) stop doing something that is in contravention of the Act or the regulations or cause it to be stopped; or

b) take a measure that is necessary to identify or respond to a risk of injury to health that is related to the activity that is the subject of the contravention.

This means that if an inspector who does not understand the NHP industry, and who is not qualified to make health decisions tells a manufacturer to stop selling an essential product, or tells a natural health practitioner not to provide a product their patients rely upon, that the manufacturer or natural health practitioner is committing an offence if they do not comply.

The new section 24 also gives Health Canada the authority to require a product recall. Currently Health Canada cannot require a recall.

I am of the opinion that the recall provision is directed at the NHP industry. As discussed above, I do not think there is a problem with the chemical pharmaceutical industry recalling when Health Canada asks them to recall.

There are problems in the NHP industry with companies refusing to recall. This is because often it is dangerous for a NHP company to issue a recall. The most obvious example is that of Truehope Nutritional Support. The Alberta Court found that Truehope would have caused suicides and hospitalizations if they had listened to Health Canada's demand to take the product off of the market. The decision can be found at: http://www2.albertacourts.ab.ca/jdb%5C2003-%5Cpc%5Ccriminal%5C2006%5C2006abpc0196.pdf

When a NHP manufacturer asks me whether they should follow a Health Canada demand for a recall, I have to first get information from them as to whether or not any Canadians rely upon the product for their health. If they do then I have to advise them about the Criminal Code criminal negligence provisions which would make them liable to criminal prosecution if they removed a product from the market that people relied upon, and for which there were not obvious alternatives.

When Health Canada inspectors demand that NHPs be recalled or removed, they are in effect making decisions that affect people's health. In determining whether these inspectors should be given blanket power to recall and seize products, we need to consider whether we want untrained persons making health decisions. Currently to force a recall Health Canada would need to seek an injunction in Court. Under this procedure the Court would consider the risk of removing the NHP before making an order. In assessing these new powers, we need to consider whether we want to remove the Court's oversight which is currently required.

Bill C-51 adds the right to apply to a Court for an injunction. This right already exists under the Federal Court Act and so this is not a significant change except that it may enable provincial superior courts to consider injunction applications.

You are now told where to keep your documents, which includes computer records

The new section 25 and 26 require you to keep your documents "in Canada at a prescribed place". Remember documents is defined to include electronic documents and would also cover your web-sites.

Again part of the general tightening in Bill C-51.

Expanded powers to make regulations

For the purpose of this discussion paper I am not going to go into the specifics of the expanded powers except to comment that the Minister's powers to make regulations is expanded.

The new offence of not listening to an inspector

Section 31 is amended to make it an offence not to do something that the Minister or an inspector directs you to do. Similarly it is an offence to do something the Minister or an inspector tells you not to do.

As discussed above, this is particularly problematic for natural health practitioners who would be violating the new Act if they failed to take health decision advice from an inspector.

An incredible increase in penalties for violating the Act or Regulations along with New Offences.

There are two types of offences under the Act: indictable offences and summary conviction offences. Indictable offences are considered more serious than summary conviction offences.

The current penalties are:

- for summary conviction offences a fine of up to $500 and/or imprisonment of up to 3 months for a first offence, and a fine of up to $1,000 and/or up to 6 months incarceration for subsequent offences, and

- for indictable offences a fine of up to $5,000 and/or imprisonment for up to 3 years.

The new penalties are:

- for summary conviction offences a fine of up to $250,000 and/or imprisonment of up to 6 months for a first offence, and a fine of up to $500,000 and/or up to 18 months of incarceration for subsequent offences, and

- For indictable offences a fine of up to $5,000,000 and/or imprisonment of up to 2 years.

This is not a doubling or tripling of fines. In the case of indictable offences the fine is increased by a multiple of 1000 times. In the case of summary conviction offences the fine is increased by a multiple of 500 times.

This raises the question as to why it is necessary to raise the primary penalty by multiples of 500 and 1000. This is probably unprecedented in Canadian history.

Again, we need to ask who the changes are directed towards and whether they will be beneficial for the industry.

There are also new offences for wilfully or recklessly violating the Act or Regulations or not listening to the Minister or an inspector. The penalties for these new wilful or reckless offences are higher. They are:

- For summary conviction offences a fine of up to $500,000 and/or imprisonment for up to 18 months for a first offence, and a fine of up to $1,000,000 and/or imprisonment of up to two years for subsequent offences, and

- for indictable offences "a fine the amount of which is at the discretion of the court or to imprisonment for a term of not more than five years or to both".

Please note that in all of my years defending companies in Court, I have never seen Health Canada charge only one offence. In one case there were 73 charges. Under ten would be an exception. So when considering whether a company could survive sentencing, do not calculate a single fine for a single offence. Rather assume multiple fines for multiple offences.

These are penalties that few manufacturers or natural health practitioners could survive. **Small and medium manufacturers along with natural health practitioners now face bankruptcy for violations of the Act or Regulations.**

Directors and officers of corporations are now also personally responsible for violations of the Act and Regulations and so are also facing personal bankruptcy if there is any violation of the Act or Regulations.

Need for input

This draft document is admittedly only a cursory consideration of Bill C-51. However, because the Bill presents significant changes that may be extremely damaging to the NHP industry, we felt that it was necessary to prepare an initial discussion document to get the various stakeholders aware of the issues presented by the Bill.

It is essential that stakeholders and stakeholder groups take the time to examine Bill C-51 and to draw their own conclusions.

We will be inviting the various stakeholder groups to discuss the issues to see if there is consensus on how the industry should proceed and how they can take a leadership role in protecting the industry.

I anticipate that my very quick analysis will contain errors and that some of you will correct them. I thank you in advance for your input. I am also looking forward to issues that I missed or avoided being brought forward.

For those of you who would like to send their comments by email, probably the best email address to use is shawn@buckleyandcompany.net. **Please restrict your use of this email address to your comments on this Discussion Paper.**

Shawn Buckley