Draft Discussion Paper on Bill C-17
An Act to amend the Food and Drugs Act

Prepared by Shawn Buckley, LL.B., president of the Natural Health Products Protection Association (NHPPA) on December 12, 2013.

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Background

On December 6, 2013, the Minister of Health introduced Bill C-17 in the House of Commons.

The Bill passed first reading.

The following is a link to the text of the Bill:

http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6375723

Bill C-17 is a partial return of Bill C-51 which had been introduced on April 8, 2008. Because Bill C-51 became a matter of significant public interest, we believe that all those involved in the natural health community should study Bill C-17 to determine how it may affect them.

Discussion Paper Only

This is a discussion paper only and does not necessarily 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 encourage Canadians to read Bill C-17 and to foster discussion.

This is an initial discussion paper only. The author expects that as feedback is received and further study of the Bill is undertaken, that the opinion of the author will broaden.

The NHPPA is inviting comments on this discussion paper. Feedback and comments can be forwarded to the attention of Shawn Buckley at info@nhppa.org.

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Olive Branch or Trojan Horse?

Bill C-51 created significant public backlash from Canadians who were concerned about their access to natural health products. We were told by some long-term Members of Parliament that it was the largest public reaction they had ever experienced. During the Bill C-51 fight I attended a meeting at the Prime Minister's Office. At this meeting the then number two at the Ministry of Health was asked if he had read the NHPPA discussion paper on Bill C-51. We were told that people writing to the Minister would staple the discussion paper to their letters and as a consequence the mail had to be moved with wheel barrows.

Because the public reaction to Bill C-51 was so severe, we believe that the Government has been reluctant to threaten natural health products with legislation.

On our first read of Bill C-17, our initial reaction was that it was drafted to ensure that natural health products are not threatened. In other words, it appeared to be an olive branch to the natural health community. After further reflection, we became concerned that Bill C-17 could later act as a Trojan Horse that surprises the natural health community with Bill C-51 provisions.

Bill C-17 also gives the Minister significant power to take control over property, and to potentially adversely affect health, without any court oversight. Philosophically we understand that any move away from the rule of law is dangerous. This is doubly so in the area of health.

Re-introduction of the term "therapeutic product" – the olive branch and the potential Trojan Horse

Bill C-17 creates the following definition of "therapeutic product":

> "therapeutic product" means a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*".

As discussed below, the Bill goes on to give the Minister significant powers in relation to therapeutic products. It also creates new offences concerning therapeutic products with dramatically higher penalties than are currently in the *Food and Drugs Act*.

Whether this Bill affects natural health products depends upon the "therapeutic product" definition. The definition does not currently apply to natural health products, but the way it is written leaves a back door, like that in a Trojan Horse, that could come back to haunt us. This back door would be closed if Bill C-17:

1. added the current definition of natural health product into the *Food and Drugs Act*, and

2. defined "therapeutic product" as:

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> "therapeutic product" means a drug or device or any combination of drugs and devices, but does not include a natural health product"

If the definition of natural health product was put into the Act, the definition could not be changed without an amendment to the Act. In that way, if the Government wanted to change the law to make the strong powers and harsh penalties in Bill C-17 apply to natural health products, they would have to amend the Act. This would require three readings in the House of Commons and three readings in the Senate. There would be ample opportunity for citizens to communicate to the law makers that they do not want these changes. That was the protection that stopped Bill C-51.

If Bill C-17 passes, we do not have the protection of the Government having to change an Act to affect natural health products. Rather, all they have to do is change a regulation. The definition of "natural health product" referred to in the "therapeutic product" definition, is only a regulation. Regulations can be changed by simply publishing the change twice in the *Canada Gazette*. There are no votes by either the House of Commons or the Senate to regulation changes. Even an unpopular minority government can change regulations with impunity.

The potential danger of Bill C-17 is that Canadians will not take any notice because the return of the Bill C-51 powers and penalties it represents do not appear to apply to natural health products. The Bill could easily pass because the public does not care. Later even a minority government can apply the Bill C-17 provisions to natural health products by simply changing or abolishing the natural health product definition in the regulations.

We are not saying that this is the intention of the current Government. Nor do we want to speculate that a future government may do this. Our point is that Bill C-17 creates a significant risk. If the Government's true intention is to exempt natural health products from the effects of Bill C-17, it would be easy to make the changes outlined above to protect them.

Expanded Injunction Power

Although not written into the *Food and Drugs Act*, the Government has always had the ability to apply to a superior court for an injunction to prevent anyone from violating the Act or Regulations. Bill C-17 expands on this by creating the new section 21.5.

Under Bill C-17 if anyone has or will violate the Act or Regulations the Minister can apply for an Injunction. If there is urgency there does not even have to be notice to obtain a court order. The court can order the offending person to stop doing anything, such as selling. The court can order remedial action, such as a recall.

We do not have a difficulty with this part of Bill C-17. The ability of the Minister to apply for an injunction can serve to protect the public when the Minister believes that health is at risk. The public can also be protected by the Minister applying for an injunction when health is not at risk, but there is non-compliance with the law the Minister wants corrected.

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The persons subject to the court application are protected in that their property and livelihood will only be interfered with by an impartial court that will arbitrate between the Minister's interest in enforcing the law and the person's interests. That is what the rule of law looks like.

Abandoning the Rule of Law – Giving the Minister Dictatorial Powers to Control Property without Court Supervision or Any Safeguards

Benjamin Franklin is often credited with saying something to the effect that those who give up essential liberty to obtain temporary safety deserve neither liberty nor safety. Bill C-17 moves us away from the fundamental protection of the rule of law. The rule of law protects you because it mandates that the Government cannot take control over your person or your property, except as supervised by an impartial court. The rule of law is essential for the long-term functioning of a democracy. It should never be sacrificed for any reason, let alone for safety. Indeed, history students could well instruct us that the most dangerous thing a populace can do is to permit the rule of law to be undermined.

Bill C-17 gives the Minister the power to order persons who sell a product to recall it or to transport it to a place of the Minister's choosing (the new section 21.3). It is an offence to defy an order to recall or to transport your property to a place in the Minister's control. Under Bill C-17 the new penalty for each day an order is defied is a maximum of a $5,000,000 fine and two years of imprisonment.

There is no appeal process for Ministerial orders taking control over your property. There are no safeguards. There is no supervision by any court or independent body. The orders are exempt from the *Statutory Instruments Act* which means that:

- they will not be examined to see if they unduly encroach upon your rights;
- they will not be published in the *Canada Gazette* which permits public scrutiny, and
- they will not be subject to review in Parliament.

This power is a dramatic move away from the rule of law. It raises the question: are we so unsafe with the existing law that we need to sacrifice the rule of law to protect ourselves? To answer this question consider the following:

1. the Minister has always had the right to apply to court for an injunction to ensure compliance with the law;
2. as outlined above, Bill C-17 also expressly contains an injunction provision which permits a court to order a recall or such other remedial action as is necessary;
3. section 23 of the *Food and Drugs Act* permits Inspectors to seize any drug or device the inspector believes is involved in a contravention of the Act (if there was a danger the Minister can revoke the product licence and the inspectors can seize if there are any further sales);

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4. section 30.1 of the *Food and Drugs Act* already enables the Minister to make interim orders, which includes the power to stop the sale of a product. Although these orders are not supervised by a court, there are the following safeguards:

    a. the orders expire after 14 days unless approved of by the federal cabinet;

    b. even if approved by the cabinet there is a one year limit on the order;

    c. they must be published in the *Canada Gazette* within 23 days which allows public scrutiny, and

    d. they must be tabled in the House of Commons within 15 days to permit scrutiny by Parliament.

As outlined above, there are already significant powers to ensure safety and compliance with the law. Bill C-17 is not new in enabling the Minister to protect us. It is new only in giving the Minister dictatorial powers over property without any supervision. In effect we lose freedom and gain no safety.

There is no justification for this dramatic move away from the rule of law.

Be Careful What You Wish For – The Best Intentions Without Supervision Can be Dangerous

In my law practice I have extensive experience assisting persons and companies when they are targeted by Health Canada. Often there are demands for product recalls. When this occurs the first thing we do is a risk analysis to see if more harm would be caused by removing a product from the market than by leaving it on the market and by managing the risk in another way. In some cases the evidence was that more harm would be caused by a recall. In those cases, civil and *Criminal Code* obligations kick in to mandate against a recall. A person cannot put an effective treatment onto the market, let others become dependent on it, and then pull it from the market. Aside from being ethically wrong, it is dangerous and could lead to severe criminal and civil consequences. In one case I was involved with the court found that if the company had listened to Health Canada it would have led to deaths.

My point in this is simply to communicate that sometimes the regulator gets it wrong. We are all human and are prone to mistakes. Health Canada is no exception. Despite the best of intentions, they will not always be right. However, because their decisions can have a direct impact on treatments, it is safer for all involved if there is some supervision when treatments are interfered with (be this by a court or by Parliament). In all cases the public should be informed. The new power of the Minister to take control of treatments without supervision or publication can by itself create a dangerous situation when the Minister gets it wrong.

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It is a rare occurrence for a person or a company to ignore a demand by Health Canada to recall a product. There is almost a 100% compliance with such demands. For those rare occasions where a person or company is not willing to recall, the Minister has the tools listed in the previous section to ensure compliance. They can also charge the person or company criminally and use the *Criminal Code* and *Food and Drugs Act* seizure powers to seize any offending treatment. For the few persons and companies that have refused to recall to protect health (when Health Canada was wrong), the stress of having property seized and facing court proceedings was daunting. Under Bill C-17 it will be unbearable. The fiscal penalties have been raised dramatically. Under Bill C-17 every day of non-compliance with things like Ministerial orders is a separate offence. Under Bill C-17 it is less likely that persons or companies will be able defy the Minister even when that is the safest course.

Pharmacists and Doctors Beware – Diligently Watch Health Canada Advisories

If the Minister orders a recall of a product, it is an offence for anyone to sell it, regardless of whether they were informed of the recall. Under the Act, giving a product away is also selling. So, for example, doctors who give patients drug samples are selling.
Under section 21.3, a person who did not know about a recall can still be convicted providing "reasonable steps had been taken to bring the purport of the recall order to the notice of those persons likely to be affected by it."

This could mean that someone like a pharmacist who sells a product that has been recalled could be convicted despite being unaware of the recall. Similarly doctors who give drugs samples to patients could be convicted despite being unaware of the recall.

Because the potential penalty includes two years of jail, it is unclear whether this provision would stand up in court. Offences with significant incarceration usually require a guilty mind, or recklessness. People like pharmacists or doctors would be well advised to regularly study Health Canada's website for product recalls. Failure to do so could lead to fines and incarceration.

Disclosure of Information without Information and Privacy Safeguards

Section 21.1 created by Bill C-17 gives the Minister the power to order any person to provide the Minister with information the Minister believes is necessary to determine whether a product presents "a serious risk of injury". Note that a "serious risk of injury" is different than a "risk of serious injury". It is not clear what a "serious risk of injury" is. It is likely that it means a probable risk of injury (whether serious or non-serious).

Note that the person does not have to be a person selling the product or connected to the product. It can be a doctor being told to disclose all information on patients who use a product. It could be a university doing a study. It could be the manufacturer. In no case are there safeguards for individual privacy. Nor are there safeguards for intellectual property. There are no limits on the use of any information obtained.

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We think there needs to be information and privacy safeguards. We also think that the standard for ordering the disclosure of information should be changed so that an order can be made only if the Minister has reasonable and probable grounds to believe there is a risk of serious injury. Inspectors already have the power under s. 23 of the *Food and Drugs Act* to search any place where drugs are manufactured, sold or stored and to examine and copy all records. Further, if there was evidence of an offence, a search warrant can be obtained. With these powers already in place, the real change is that persons not connected with manufacturing or selling can be compelled to disclose information without any privacy safeguards or compensation.

If your doctor or research university is ordered to disclose your records most likely they will. Failure to do so could result penalties up to a $5,000,000 fine and two years imprisonment for each day they refuse to do so.

No Backing Out – You can be forced to test for products no longer being sold regardless of the absence of any health risk

Bill C-17 defines "therapeutic product authorization" as follows:

> "therapeutic product authorization" means an authorization – including a licence and a suspended authorization or licence – that is issued under the regulations and that authorizes, as the case may be, the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product.

One thing to note about this definition is that it covers licences that are suspended. A licence can be suspended because the person selling a product has decided to no longer sell the product. A licence can be suspended for a violation of the Act or Regulations.

Bill C-17 gives the Minister the power to order the holder of a "therapeutic product authorization" to conduct an assessment of the product and to give the Minister the results. There are no limits to the types of assessments that can be ordered. There are no limits on the number of assessments that can be ordered. There is no threshold, such as evidence of a safety risk, required to order an assessment. Basically the Minister has absolute power to order assessments (see the new section 21.31).

Under Bill C-17 it is a separate offence for each day an assessment order is ignored. The maximum penalty for each day is $5,000,000 and two years of jail.

In effect the Minister has absolute power to order assessments, even if the product is not being sold. For small companies, assessments could potentially bankrupt them. Small companies are, however, in a no-win situation if punitive assessments are ordered. They will go bankrupt if they obey the order or they will be bankrupted with fines if they do not. If safety was a requirement for an assessment, this might be more justifiable.

The new section 21.32 allows the Minister to order the compilation of information, and/or tests and studies concerning a product's effects on health or safety. As with section 21.31 just discussed, there is no threshold for ordering such information or tests.

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My experience with Health Canada is that they are never concerned with the economic effects of their actions on small companies (I have never acted for a large company so cannot comment on whether they are concerned about the economic effects of their actions on large companies). If this trend continues, we could have a situation where a small company that has an effective treatment on the market is ordered to conduct tests it cannot afford. The company goes bankrupt and the effective treatment is lost to those who depend on it. All of this could occur without Health Canada having any meaningful evidence of risk.

Bill C-17 can affect access to treatments. It will give the Minister tools to take treatments away without the requirement of a balanced risk analysis. One of my greatest criticisms of the *Food and Drugs Act* is that it does not require a balanced risk analysis before Health Canada takes steps that remove products from the market. If we were really concerned about health, we would ensure that before any therapeutic product is removed by the regulator, that the regulator does a balanced risk analysis which includes the risk of removing the product. It is precisely because of the importance of balanced risk analyses, that groups seeking to ensure a balanced regulatory environment had the requirement put into the *Charter of Health Freedom* (http://www.charterofhealthfreedom.org).

Unfortunately Bill C-17 will move us further along the road where products are removed without a balanced risk analysis.

Bill C-17 also exempts these testing and information orders from the *Statutory Instruments Act* so that there can be no scrutiny to ensure that they do not unduly encroach upon the rights found in the *Charter of Rights and Freedoms* and in the *Bill of Rights*. Nor will they be published in the *Canada Gazette* (they will be secret) or be subject to Parliamentary scrutiny.

An Improvement on Health Canada's Ability to get Safety Information from Clinical Trials and From those with Authorization to Manufacture and/or Sell in Canada

Bill C-17 gives the Minister the power to make regulations requiring holders of therapeutic product authorizations to provide the Minister with:

- safety information from clinical trials;
- safety information they become aware of after a clinical trial;
- information in respect of any serious risk of injury they receive from outside of Canada;
- information in respect of any serious risk of injury that has resulted in a labeling change outside of Canada;
- information concerning any recalls, reassessments and suspensions or revocations of authorizations taking place outside of Canada.

(see the new section 30(1.2), paragraphs (c-d)).

Considering the high risk profile of pharmaceutical drugs, We view this as a positive part of Bill C-17. This should enable Health Canada to better manage the risk of pharmaceutical drugs.

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Moving away from Parliamentary Supervision of Drugs and Medical Devices

Bill C-17 permits the Minister when making regulations concerning medical devices and drugs (other than natural health products) to incorporate by reference any document, regardless of its source, either as it exists on a particular date or as it is amended from time to time (see the new section 30.5)

There are dangers to listing other documents as binding in regulations. Those other documents, from other sources, even foreign governments, or trade bodies can be changed without any involvement of our Parliament. Under our current law (see the *Statutory Instruments Act*) we have many procedural safeguards by requiring changes to be made by regulation. These protections include:

1. the public is alerted to all proposed changes which are published in the *Canada Gazette*;
2. the public is given an opportunity to comment on all proposed changes after their publication in the *Canada Gazette*;
3. the *Statutory Instruments Act* requires the Clerk of the Privy Council in consultation with the Deputy Minister of Justice to examine all proposed changes to ensure that:
   (a) they are authorized by the *Food and Drugs Act*;
   (b) they are not an unusual or unexpected use of the regulation power under the Act;
   (c) they do not trespass unduly on existing rights and freedoms, and
   (d) they are consistent with the purposes and provisions of the *Canadian Charter of Rights and Freedoms* or the *Canadian Bill of Rights*;
4. all final changes must be published in the *Canada Gazette*;
5. under the *Statutory Instruments Act* all regulations are permanently before committees of both the House of Commons and the Senate who can present resolutions in Parliament to revoke all or part of the regulation, preserving Parliaments' supervision over regulations made by the Government.

Incorporation of "any document, regardless of its source, either as it exists on a particular date or **as it is amended from time to time**" also creates a significant democratic deficit. For example, the proposed amendment would permit the Minister to incorporate by reference European Union regulations. How would persons affected in Canada go about seeking changes to those regulations? Would we petition the European Parliament or its Member States? If trade association documents were referenced, would we petition the trade association? Either way, the supervision and relevance of Parliament is excluded.

It is easy for the Government to pass or amend regulations. We see no advantage for the Canadian Consumer for the protections listed above for regulations to be circumvented by allowing the Minister to incorporate documents of other governments or trade associations as regulations. It is in the interest of Canadians for Parliament to maintain its supervision over the regulation of drugs and medical devices.

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Dramatic Increase in Penalties

It is very rare to see any *Food and Drugs Act* charges against a pharmaceutical company. Because of its extreme rarity, it is unclear whether the increase in penalties ushered in by Bill C-17 are a public relations exercise or whether they are intended to be used. For small companies, the changes are a death knell if they come into conflict with Health Canada.

Currently for offences concerning drugs or medical devices the maximum fine is $5,000. The maximum imprisonment is 3 years.

Under Bill C-17, the maximum fine for offences that do not endanger life is raised by 1000 times to $5,000,000. The maximum jail for pharmaceutical drugs and medical devices is reduced to two years.

The increase in penalties is magnified dramatically by a new provision which makes each day that an offence takes place a separate offence, and hence subject to the maximum fine and incarceration for each calendar day there is non-compliance.

The penalties are so dramatically increased and severe, that I will have to change my legal advice to companies that want to defy Health Canada when to listen would cause harm. I will now have to advise them that they will be totally destroyed. It will no longer be possible to keep a needed treatment on the market unless the company and directors and officers and managers are willing to be bankrupted and jailed.

I mention the directors and officers and managers because under Bill C-17, the corporate veil is pierced. Every director, officer or agent that authorizes, assents to or participates in the commission of an offence is deemed to be a party to the offence and can be personally charged and held accountable.

For multi-billion dollar pharmaceutical companies the fine increases are small change. For small and medium firm they may be insurmountable. A more balanced approach would be to have a sliding scale of fines dependent upon sales. In this way large pharmaceutical companies that caused harm could have a meaningful fine over $5,000,000, but small companies would not be bankrupted for minor transgressions. The fines and jail outlined above apply where there is not a serious "risk" of injury (let alone injury). Where there is a serious risk of injury the fine is left the discretion of the court and imprisonment is up to five years (the new section 31.4).

Little Gain with Significant Downside Risk

There are a couple of parts of Bill C-17 that we support, such as the explicit injunction sections allowing a court to step in and order recalls or other remedial action. We also like the expanded power to regulate the disclosure of safety information (providing individual privacy is protected).

The few parts of the Bill we support are overwhelmed by the rest of the Bill that we have severe concerns about. Considering the extensive powers that already exist to ensure consumer safety, we see the new powers in the Bill as largely unnecessary and as

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dangerous. We view them as dangerous in two ways. First, the move away from the rule of law towards absolute discretion is always dangerous in and of itself. Second, the lack of oversight combined with draconian penalties for small firms will likely lead to the removal of effective products in those cases where Health Canada gets it wrong.

Then there is the Trojan Horse problem. Unless changes such as those set out above concerning the addition of the natural health definition into the *Food and Drugs Act* are made, the possibility exists that the Bill C-17 provisions could be made to apply to natural health products by a simple regulation change. This is a risk that is very dangerous to allow. Indeed, if the Government is sincerely trying to exempt natural health products from the ambit of Bill C-17, then it would be very easy to make the changes we outline to ensure that natural health products are protected.

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