



**Canadian Science Policy Conference 2015  
Evidence Based Decision Making  
Symposium: Case Study of EBDM at The  
Natural and Non-Prescription Natural  
Health Products Directorate**

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## Case Study at NNHPD

### Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy.

The following was prepared by volunteers and represents what we believe to be an honest, fair, and science-based evaluation. We are an independent body that is funded by private donations and we do not represent any corporate interests.

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# Case Study at NNHPD

## Preface

This brief summary of our concerns about the state of natural health product regulation at Health Canada was presented at the Canadian Science Policy Conference 2015 as part of a pre-conference symposium on evidence-based decision making on November 25<sup>th</sup>, 2015 at the Delta City Centre in Ottawa, Ontario, Canada.

## Background

In 2012, when Bad Science Watch was just getting started, we attended the Health Canada (HC) presentations on the new “Pathway to Licensing” program for the approval of Natural Health Products (NHPs). Given the strict, evidenced-based regulation of pharmaceuticals, we had assumed that due to the common therapeutic claims that NHPs made the Natural and Non-prescription Health Products Directorate (NNHPD) would hold similar values to that of the Therapeutic Products Directorate. It was immediately obvious, however, that this was not the case. The NNHPD appeared to be more focused on ensuring market access for the NHP distributors and manufacturers than ensuring their products were effective and safe. In the following paragraphs, we will lay out our analysis in brief as a case-study on how values, both overt and covert, effect an organization’s choice to use evidence as a decision making tool.

## Values at Health Canada

Health Canada (HC) is the government body tasked with ensuring that health products, including pharmaceuticals and NHPs, are safe and effective for Canadians. In order to achieve this, HC states that it uses “a broad base of evidence and the best science available to make consistent and predictable decisions” (Health Canada, 2012a) regarding the regulation of these products to protect Canadians from harm. HC makes a distinction, however, between NHPs and pharmaceuticals providing different levels of regulation based on the assumption that NHPs are safer, and requiring of less oversight than drugs as defined by the Food and Drug Act.

With respect to NHPs, the NNHPD states that its role is “to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity” (Health Canada, 2014). A number of investigations have been undertaken, including some by us and the Canadian Broadcasting Corporation (CBC 2015a, 2015b), that not only call into question this last claim by HC, but also show that the oversight of NHPs has become increasingly lax over the years to the point where even bogus products can be easily approved by HC, and receive a label that suggests that the product has been reviewed: even when this is not the case.



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### The Pathway to Licensing

In 2012, the NNHPD instituted a new regulatory regime to approve NHPs after a very large backlog had accrued. The changes, while allowing products to be approved faster, also lowered the standards of evidence and decreased the time of the review process. This change showed that contrary to HC's commitment to approving products that are "safe, effective and high quality" they were more committed to getting products approved more quickly. They announced in 2014, just two years later, that they had approved over 70 000 products and their backlog had been cleared. Investigations by the CBC, among others, have shown that there has been very little screening of these products that have been approved by HC.

In the risk category of "traditional use" the situation is even more grim. Often, the manufacture is not required to show any evidence of efficacy at all, just that the product has been used traditionally for a certain time period. Using "general health claims" the licence applicant need only show general trends in evidence or low level animal studies to support a claim like "helps maintain heart health" (Health Canada, 2012b). The bar for efficacy of these products that number, based on our best estimates, in the tens of thousands is set very low indeed.

### Risks of NHPs

During the committee hearings for Bill C-17, the Protecting Canadians from Unsafe Drugs Act, MP Rona Ambrose dismissed criticisms of the decision to exempt NHPs from the law with a number of reasons including that Canada already regulates NHPs, that NHPs would make the legislation too complicated, and that NHPs are safer in general than prescription drugs.

A quick review of the scientific evidence with respect to the safety of NHPs indicates that they are not only *not* inherently safer, but it is not uncommon for NHPs to contain fillers or active substances not on the label, to be contaminated with heavy metals or micro-organisms, and/or to be adulterated with other botanicals or pharmaceutical drugs (Chen et al, 2009, Ernst, 2002, Genuis et al, 2012). It has also been found that there is a lack of toxicity data on NHPs, which means physicians have difficulty knowing how to treat overdoses or drug-NHPs interactions (MacDonald et al, 2009, Bagnis et al, 2004).

The nature of NHPs make it difficult to do controlled studies of their safety and efficacy; they are often multi-ingredient products, and naturally-sourced herbs suffer from variable levels of active ingredients (Garrard et al, 2003). It should be noted that an Ipsos Reid survey found that most Canadians want to have more information about the safety of NHPs, including their potential side effects (Health Canada, 2011). None, the less, the majority of Canadians use NHPs (Health Canada, 2011) and, therefore, ensuring their safety and efficacy is extremely important.



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### Conclusion and Recommendations

As a result of this analysis, it is clear that despite the claim that the NNHPD has approved licensed NHPs as safe, effective and of high quality, this value is subordinate to the value of facilitating access to the market for Canadian NHP manufacturers. The pressure from the manufacturers to approve their products during the earlier years of the program led the NNHPD to lower its evidentiary standards and ignore obvious risks of NHPs.

To solve this problem, we suggest the following changes be made:

- 1. The institution of an Office of Evidence Based Policy to set evidentiary standards and assist departments in developing processes to support the use of evidence when developing regulations and approving products for sale in Canada.**
- 2. The prompt institution of a mandatory quality assurance program for all manufacturers and distributors of NHPs in Canada.**
- 3. The removal of the exemption of NHPs from the updates to the Food and Drug Act that were added with bill C-17.**

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