

# The NHP Licensing Crisis

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# Executive Summary: The Problem

Natural health products (nhp's), which are a subset of drugs in Canada, require a licence in order to be sold to Canadians, and Health Canada is currently in charge of this licensing activity. Presently, nhp's are being regulated as drugs — they require randomized clinical trials as the benchmark standard, and Health Canada is compelling every product to carry at least one claim.

Nhp's cannot be patented; there is little inherent research incentive to produce such randomized clinical trials, and most nhp suppliers are small- to medium-sized companies and cannot afford to carry out their own studies. Licence applicants must therefore rely on what evidence already exists in the public literature, which is strongly lacking for most nhp ingredients.

Right now Health Canada also reverses the burden of proof in demonstrating safety. The starting assumption for every licence application is that the product is dangerous until proven safe. "Proving" safe is achieved by providing published studies from the public literature that that exact ingredient, source, preparation method, daily dosage and subpopulation were used in at least one randomized controlled human study; finding an exact match is nearly impossible.

Nhp's have a remarkable history of safe use. There is no evidence to support a policy on this reversed safety burden — only one in a million nhp's might have a safety problem, but these are all fairly well known in advance. The absence of data cannot be used as a basis for assuming danger.

Health Canada has struggled to achieve any significant output since 2004; their backlog of around 10,000 applications has been relatively constant since 2006.

Further, the Inspectorate is now in the final stages of implementing the enforcement of the licensing requirements (June 1, 2011 is the theoretical enforcement start date). Even though temporary licences are offered for backlogged applications, it takes nearly nine months to achieve such temporary licences, and a company can lose them as quickly as they received them because of the evidence barrier.

The net result is that most companies who used to offer a broad selection of innovative products, are now cutting their product line down by at least 50%. New products coming to market are no longer innovative — and small businesses are going out of business. The black market for unlicensed nhp's is expanding enormously, and consumers are being forced to order from other markets (such as the USA) instead of buying locally.

None of this is what the Standing Committee on Health envisioned in their 1998 recommendations to Parliament. We were promised a "new vision" that would help preserve innovation and freedom of choice — not the bureaucracy filtering our choices.

# Executive Summary: The Solution

Canadian consumers are intelligent and capable of making informed decisions for themselves. Health Canada must not prevent market access to safe products simply because there is not a high level of certainty for efficacy or safety. Canada now has the international reputation of being the most difficult country in the world to achieve regulatory success for dietary supplements. This is not a “new vision” of nhp regulation.

Health Canada must stop presuming nhp's are dangerous; there is no precedent for that level of regulatory involvement. Ginseng should not require a randomized clinical trial to be “proven” safe. It should be Health Canada's burden to demonstrate that nhp's are dangerous, and such evidence should be compelling and rigorous. Health Canada must also stop assuming that “safety” is a separate issue from “purity”.

Health Canada must stop compelling suppliers to make health claims. A consumer walking into a health food store and buying chromium picolinate should not have their choices limited simply because Health Canada insists on a health claim. Consumers are intelligent, they can educate themselves about efficacy. If a product has limited evidence for efficacy, tell the consumer — let the consumer decide. Product labels can carry disclaimers if necessary, and the wording of the claim can be qualified according to the strength of the evidence.

Health Canada needs to back away from being a rigorous academic powerhouse, which they clearly are not. Not only do they not understand these products, but their staff lack the necessary qualifications to review these products. The idea of “academic certainty” as being the necessary pre-requisite for allowing consumers to choose their own safe health products, is preposterous. We wouldn't allow the government to choose our clothing for us, why would we allow them to choose our health products?

Health Canada must become more transparent to its stakeholders in terms of licensing requirements, and they must also provide a workable appeal process for the “finer points” of their evidence requirements. Currently there is no ministerial appeal if a supplier disagrees on evidence requirements — the most crucial aspects of product licensing have no ministerial appeal. This must change, and it must change immediately.

# Discussion Topics

## The Presumption of Safety

Health Canada should not have the authority to restrict market access to natural health products (nhp's) without substantial scientific evidence demonstrating a known serious potential for harm. NSAID's such as aspirin have an annual mortality rate of 7,500+, yet aspirin is still widely available as over-the-counter and has mild efficacy effects. If aspirin were the benchmark for safety, every nhp on the market would receive an NPN.

If the onus is on the seller to "prove" safety, any innovative ingredient or product would be hard-pressed to demonstrate this. There was a time not very long ago, when glucosamine had no clinical research behind it — and was freely available on the market — and now there are over 250 clinical trials on glucosamine. But we only knew about its immense benefits after it became a market success, not before.

The Standing Committee on Health, in their report *A New Vision* (1998), fully acknowledged that by and large these products are safe and pose no immediate harm to consumers. Every Minister of Health since then has affirmed this statement, and the Natural Health Products Directorate (NHPD) acknowledges this statement.

We must switch the burden of proof for safety — if our products are indeed safe by and large, then fair regulation would be for the onus to be reversed, i.e. Health Canada must prove (with solid evidence) that the ingredient is harmful.

Any decision which Health Canada makes regarding the market restriction of nhp ingredients based on safety, must be held to a high stakeholder accountability. Consumers, retailers, practitioners, manufacturers and distributors must all agree on what type / how much evidence should be required to ban an ingredient from the marketplace. These standards must be transparent and equal across all directorates — including the Therapeutic Products Directorate, in the management of OTC medicines. If aspirin can stay on the market after thousands of annual deaths definitively linked to aspirin intake, then nhp's must not be held to a higher standard than aspirin.

## The Efficacy Mandate

Health Canada must absolutely revoke its policy stating that every nhp carries a health claim. The *NHP Regulations* do not require that nhp's carry a health claim, and the Standing Committee on Health made no such recommendation compelling sellers to advertise a health claim.

Health Canada cannot have it both ways — if an "nhp" is an nhp because it has a claim, then naturally the absence of a claim would remove the product from Health Canada's jurisdiction. Health Canada cannot refuse a licence based on efficacy and still insist that the product is a "natural health product" by definition. If indeed an nhp is defined by what it is and the fact that it has health claims, then the absence of a claim would certainly annul the definition.

But Health Canada cannot continue compelling companies to make claims. We believe that Health Canada should play a role in assessing the plausibility of health claims (especially claims against serious health conditions), but efficacy is not always related to safety — and an nhp for sale in Canada cannot be compelled to make claims.

A company choosing to sell cranberry extract capsules should not be required to tell Health Canada “what it is for” if the seller has no intention of advertising a health claim. Should safety be a non-issue, then efficacy substantiation must not be forced on a company.

In the *NHP Regulations* (Section 7), it reads that a licence will be issued for a product so long as (i) the applicant submits the requested information and documentation on efficacy and safety etc; (ii) the information is truthful and not misleading; and (iii) “the issuance of the licence, as the case may be, is not likely to result in injury to the health or a purchaser or consumer”. In other words, Health Canada has no written authority to refuse a licence if efficacy were not substantiated — and the *NHP Regulations* make no provision for an applicant being compelled to make any health claims.

In fact, in the *NHP Regulations* (Section 5), an applicant simply has to forward “information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use” (Section 5g). In no way do the *NHP Regulations* require an applicant to make any health claim whatsoever.

## Efficacy & Scientific Plausibility

Currently, Health Canada reviews each and every health claim and requires that every health claim has a high level of certainty. Everything from healing bruises to treating anxiety requires the same level of assurance of efficacy.

**Efficacy**, the health benefit perceived by the consumer, is not equivalent to “scientific certainty” of any kind — all products work differently for all people, and efficacy is relative to the consumer.

Efficacy could also be defined as the “contract” between the seller and the buyer. If the product fails to achieve its intended benefit, the buyer will not continue buying the product — and the product will eventually disappear from the marketplace. Sellers and buyers enter into a business relationship defined by the product's efficacy. But this relationship is not defined by any demonstrated/proven/scientifically assessed process; it is defined by trust and the plausibility of benefit.

Even with the most researched ingredients do we see varying efficacy success. But this does not detract from the consumer's perception of health benefit — and the wonderful thing about the human spirit is that sometimes even faith is enough to cure, as has been demonstrated even in the scientific community by what is called the “placebo effect”. Health Canada must tread lightly with regards to efficacy — in assessing efficacy with too high a standard, they are violently treading over the buyer-seller relationship.

Buyers and sellers always live with the disappointment of expected results. A honeymoon getaway promising to re-kindle a dying marriage, could have more a more devastating aftermath than an antioxidant juice not “working” as it should. As buyers and sellers of products that could benefit us, we must constantly live with the possibility of disappointment — it defines us as

a society, and natural health products are no different simply because the expectation is within a health context.

We cannot protect Canadians against disappointment or ignorance. Preventing market access because we want to protect Canadians against having to do their own homework, is not a free market system. We believe that Canadians are intelligent consumers capable of making their own informed decisions — and that “informed choice” depends on having choices to choose from. Health Canada does not have the right to restrict access owing to efficacy before consumers are allowed to choose their health products.

In the academic community there is no such thing as “certainty”. A theory becomes more believable with increasing evidence; but it is never “certain”. Health Canada cannot claim a higher vantage point than the scientific community — and must certainly not use published evidence as a filter for market access. Such a “police state” mentality can never promote true freedom of choice.

Canadians deserve access to information, to make their own choices. The Standing Committee on Health firmly believed this — they stated that “**Committee members feel that the availability of substantive, accurate, and up-to-date information about products is the prerequisite for true freedom of choice**” (*A New Vision*, House of Commons Standing Committee on Health;1998). We believe that this statement is at direct odds with the current licensing behaviour of Health Canada, and that Health Canada is limiting true freedom of choice by regulating products off the market on account of “certainty”.

If the evidence for a claim is scientifically plausible — i.e., the totality of evidence suggests that it could play a role in the purported benefit — then the health claim should be permitted. One of the Health Committee’s 53 recommendations in *A New Vision* was that the label clearly state the evidence that backs up the claim. Presently this is not required by Health Canada, but it needs to change. Canadians have the right to read qualified health claims and make informed decisions for themselves — and if a health claim is not supported by rigorous evidence, then the claim should still be permitted but the label should clearly indicate what the evidence is.

Today, Health Canada recognizes traditional medicine from many different cultural paradigms. But traditional medicine is what it is today, not because human society conducted formal clinical trials over the last 10,000 years, but rather because we had the freedom to experiment. And from these millennia of experimenting, undoubtedly we had side effects and even deaths over our history — and today, “traditional medicine” is the collective knowledge which we inherited from this health freedom. It is only in recent times that a government of any kind has insisted on taking control over individuals’ health freedom over their own bodies.

This millennia-old experiment with nhp’s does not end because of the advent of modern science. We do not “know better” simply because we “know more”. The discovery of new treatments for the health problems of society arise from our collective ability to freely exchange information and our collective ability to experiment with products we think can help us. It’s our bodies, it must be our choice.

No distant bureaucrat in Ottawa has a better insight into the health of my own body than I do. I am the governor of my own body, and I resist the idea that any governing body has any authority to tell me otherwise.

# A Simple Licensing System

With every added complexity that Health Canada adds to the regulation of nhp's comes an added expense to the Canadian consumer. Not only do we pay dearly for this complex regulation through our taxes, but in the future we will most certainly pay for this complexity directly through external charging.<sup>1</sup>

When the Standing Committee on Health discussed product licensing in 1997, there was concern expressed over potential costs to the industry. It was mentioned to the Committee that in Australia the review fee was only \$250 and that this could be a similar fee for nhp licensing in Canada. Today, the complexity of nhp licensing is so grand and drawn-out, that \$250 would never recover even a tenth of the budget required to license products based on their current system.

Health Canada must relax its efforts on nhp licensing. Reversing the burden of proof for safety will reduce review time, and licensing with a "scientific plausibility" will empower Health Canada officers to make decisions faster and with less assessment time.

Health Canada must also drastically change their internal operations. It is not sustainable. There are such tremendous differences in their performance between their officers, that it can make/break a submission depending on which officer is reviewing the file. This must stop. There must be a centralization for records of decisions, for all officers to compare notes.

## Transparency and Ministerial Appeal

At present, a licensing decision cannot be appealed on the basis of disagreeing with standards of evidence. Under the NHPD's current "reconsideration" process, an appeal can only be made when a clerical mistake has been made by the NHPD. But fundamentally this is inappropriate.

According to the *NHP Regulations*, an applicant can appeal to the Minister (Section 9) on any grounds, not just clerical grounds. So long as the applicant is given "an opportunity to be heard", the NHPD must reconsider the decision. But today we effectively have no appeal process with regards to the fundamental reasons why a submission is not licensed.

Health Canada has issued over 24,000 product licences to date, but since 2004 their standards of evidence for licensing have been elusive and poorly defined. Furthermore, their standards of evidence for safety and efficacy substantiation have changed frequently since 2004 — and even today, we have no clear indication of how much evidence / of what type / is required for what types of claims. If asked, Health Canada only respond that it is on a case-by-case basis, and that there are no evidence standards predictable rules.

Health Canada must publish predictable and transparent licensing requirements, and must make better efforts at cooperating with stakeholders.

Our industry needs a third-party appeal process that mediates licensing decisions with Health Canada, and such an appeal process must have clearly defined performance standards and permitted appeal reasons.

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<sup>1</sup> "External charging" is what Health Canada calls cost recovery, i.e. they charge stakeholders fees for reviewing applications. Currently the NHPD is not recovering any of its expenses from external charging, though we are told it is coming in the future.

# Cooperation with Health Canada

Since 2004, Health Canada has become less and less cooperative in dealing with our industry. They refuse submissions at the drop of a pin — and it seems that every week they discover new justifications for refusing submissions. Health Canada has not only made the product licensing process too complex and burdensome for the average supplier to comply, but they have also ceased working within a cooperative spirit with the supplier.

Health Canada must stop interacting with licence applicants with a hostile attitude. We are trying to comply — and Health Canada must not be so difficult and burdensome to deal with. The ridiculousness of most of Health Canada's licensing decisions and unwillingness to open a dialogue, creates hostility between government and industry, and which is not beneficial for Canadians.

# Endangered Examples

The following are samples of medicinal ingredients that are endangered from being removed from the Canadian market.

## Grapefruit Seed Extract

Nutribiotic contains **grapefruit seed extract** as its key medicinal ingredient, made from plain ordinary grapefruit seeds. It was developed in the 1960's, and has sold millions of units in the USA and Canada in the last thirty years. This ingredient is one of the most effective products against candida infections and for treating internal parasites.

The key problem is there are no controlled human clinical trials, and there is no traditional evidence. It is truly an innovative product in every way.

Without serious changes to the standards of evidence, grapefruit seed extract will disappear from the Canadian market after 2011.

## Oregano Oil

**Oil of Oregano** is a popular remedy in the Canadian marketplace, and it is derived from good old oregano leaves distilled to extract their oil. It is commonly used to relieve symptoms of the common cold.

Reputable sources such as *Physicians Desk Reference* and *Commission E Monographs* support the use of oregano oil as being both safe and efficacious.

Health Canada has rejected every single application for this ingredient to date. Without serious changes to the standards of evidence, oregano oil will most assuredly disappear from the Canadian market.

## Adrenal Tissue

**Adrenal tissue** from animals is commonly used to help people with low adrenal output, supplementing the body's lowered production of stress hormones.

Adrenal tissue has been used since the 1930's, and there have been no published studies to date showing any harmful effects on oral consumption.

There are no human controlled trials on adrenal tissue, however, and so adrenal tissue will most assuredly disappear from the Canadian market if serious changes are not made to the evidence standards.

## Buffered Vitamin C

**Buffered vitamin C** is an innovative form of vitamin C, in that it uses multiple delivery forms of ascorbic acid that in the end are easier on the body to digest.

Unfortunately, many of these unique types of delivery forms (such as chromium ascorbate or zinc ascorbate) have no evidence in that exact form, and would therefore not receive a licence given the current requirements.

Even though both ascorbic acid and zinc have great safety profiles and have been licensed by Health Canada thousands of times, if we put them together to form “zinc ascorbate” it somehow doesn't qualify for a licence. There are no safety or efficacy issues with these forms of vitamin C — and if our evidence standards are not changed in a major way we will lose this product.

## Ribose

**Ribose** is a naturally occurring sugar, similar to glucose, and it is a fundamental building block used in the human body. It is ubiquitous in nature, and lately it has been heralded as the next great leader for treating symptoms of fibromyalgia.

Over 13 human clinical trials have been conducted on ribose, but recently Health Canada has ruled against its licensability based on their drug-like standards for licensing. There are absolutely no safety concerns with ribose, it is as harmful as sugar.

Without changes, this product will be lost from the Canadian market, affecting many thousands of people who depend on ribose to support their health.

## Stevia

**Stevia** is a sweetening agent, it is naturally occurring — and it has zero calories. The *Stevia rebaudiana* plant grows naturally in the Asian Pacific. It is growing incredibly fast in popularity, and already major commercial producers are using stevia instead of artificial sweeteners. It is not allowed as a food.

Stevia has two clinical studies published for efficacy — one for diabetes and the other for hypertension. Both of these claims are illegal in Canada (*Schedule A, Food and Drugs Act*), based legislation that goes back to the 1930's. Because health claims are mandatory, however, this ingredient could never achieve a licence on its own.

Currently Health Canada compels all suppliers to make at least one substantiated health claim — as long as the claim is not itself prohibited through legislation (such as diabetes or hypertension). Even if the product works marvellously at helping with such illegal claims, it is not allowed.

## Plant-Based Enzymes

**Plant-based enzymes** (also called “fungal enzymes”) help digest food, and they are great alternatives to animal-based enzymes for vegetarians. Currently plant-based enzymes outsell animal-based enzymes.

Presently there is no evidence on individual plant-based enzymes, and Health Canada has recently announced that unless new clinical trials are published on plant-based enzymes they will not issue licences to these products. Various industry experts, including the *Enzyme Technical*

Association in the USA, have argued that plant-based enzymes are safe and very efficacious, despite the limited research.

Without serious changes to the standards of evidence, Health Canada will begin restricting access to these products in 2011.

## Manuka Honey

**Manuka honey** is a honey from New Zealand, and it is special in what kinds of flowers the bees use for pollination — tea tree flowers (the same plant that we get tea tree oil from). The honey has medicinal properties against bacteria, and people use the honey as a kind of “medicinal food”.

Health Canada has not licensed any manuka honey products since 2004, and so far many applications have failed. Without serious changes to the standards of evidence, this valuable product will be lost to the Canadian market.