Natural Health Products Under Siege in Canada
By John Biggs

For any who think that stricter regulation of natural health products (NHPs) is a good idea, consider the bureaucratic manipulation that has occurred in Canada since the Natural Health Product Regulations went into effect in 2004.

NHPs are Drugs

After massive public and industry protests in 1997 against classifying NHPs as "Drugs," the Canadian government Standing Committee on Health went through a multi-year investigative process, and decided that NHPs should have their own unique third category, distinct from either "Foods" or "Drugs." In essence, this should have turned the Food and Drugs Act into the "Food, Drugs, and Natural Products Act."

However, when it came down to drafting the legislation, the bureaucracy in charge, Health Canada, "pulled a fast one." They created a separate directorate and a new set of regulations for NHPs, but still classified them as a subset of "Drugs." This allowed Health Canada to apply basic drug criteria to NHPs that they knew the majority would never be able to meet, while claiming to any who asked, "No, no, no, NHPs are regulated separately from drugs." Although it is true that NHPs are regulated separately from ***pharmaceuticals***, actually ***both*** groups are regulated as drugs. But this wording effectively confused the Canadian MPs, many of whom still mistakenly believe that NHPs have a distinct category, and repeatedly assure their constituents that they have nothing to worry about.

The NHP Classification is an Elimination Tool

This bureaucratic sleight of hand has served Health Canada's agenda well. Behind the scenes from a total of over 70,000 NHPs on the market prior to 2004, well over 40,000 have been eliminated, including over 20,000 ***documented*** U.S. imports, and over 21,000 that have failed the licensing process. This total does not include the thousands of products that have been voluntarily discontinued, either because they were slow-sellers, or because it was deemed they had no chance of getting a license. Meanwhile, fewer than 30,000 have been licensed and have their NHP number.

You see, each NHP sold in Canada must now submit a detailed product license application and assembling them for every product is, of course, very costly. This means that a product's sales have to justify the cost of its application, and thousands of slow-sellers, including many longstanding formulas, became unavailable as pricelists were shortened. Next, the majority of U.S. companies, many of whom had been here for decades, simply left Canada, taking their

products with them, because they could not justify the expense or hassle, and/or they refused to detail the exact amount of each ingredient in their proprietary formulas, which the regulations demand.

Next, domestically manufactured products, particularly multi-ingredient formulas, came under fire. In their new classification as "Drugs," each product is now ***forced*** to make a claim as to its "intended use," and then has to prove that claim, while meeting Standards of Evidence for safety and efficacy set by Health Canada. Although this may sound reasonable to some, the devil is in the details, and not surprisingly, these Standards of Evidence are an unreasonable bottleneck for approval.

Health Canada Demands Impossible Evidence

Health Canada claims to accept a broad range of evidence supporting efficacy, including traditional use. But any traditional claim must be based on use that can be shown to have been in place for at least fifty years. If scientific evidence is used to support a claim, then it has to be ***human*** evidence, not test-tube or animal. Furthermore, (and here's the rub), you cannot mix science and traditional use to support a claim. It has to be one or the other. That makes no sense at all. Perhaps the authorities are afraid that if you put them together, they might reproduce and take over the Universe.

Of course, this has put countless NHPs between a rock and a hard place for proving their claims. On one hand, until 2004, the majority of NHPs were classified as "Foods," so human trials were rarely performed because they are prohibitively expensive, and there was no point, especially given the non-patentable status of NHPs. Hence, for a majority of NHPs, scientific evidence ***in humans*** was not pre-existing at all.

On the other hand, neither is it feasible to create it now. Given the expense of the double-blind trials that Health Canada is demanding, and the non-patentability of NHPs, meaning anyone can use your work and copy your product after you have incurred all of the proving expenses, such studies are now largely the domain of large pharmaceutical firms, because they are the only ones with enough resources to both conduct studies and then protect their economic interests.

The Natural Health Market is Shrinking!

Not only has this slowed health-product innovation in the Canadian natural-health industry down to a crawl, it has also eliminated products like popping balloons on a dartboard, as applications are denied or withdrawn. Practically every time retailers phone in orders, they are informed of new products that are no longer available, as the industry is streamlined, being stripped of both well-known and innovative specialty formulations and leaving only me-too, commodity products common in mass-market behind. Hundreds of botanicals and ingredients introduced by the industry after 1960, such as oregano oil, resveratrol, and essential oils are out in no-man's land, having neither adequate traditional nor scientific evidence to meet Health Canada's requirements. And this does not even address issues of potency, dosages, and safety, which are all additional parameters upon which Health Canada bases application denials. (Recently, one manufacturer's application for ***parsley*** was denied for failing to ***prove*** safety.) Moreover, if the Agency does not want to approve an application, then it simply does not approve it.

You might think this applies only to ineffective products; but, actually, if your product ***really*** does work and you provide too much evidence for this, then the chances are high that it will have

its application denied, or be forced to water-down its formula or potency until it is ineffective. Multi-ingredient products in particular have been hit hard, and to avoid a revolt Health Canada has now come up with temporary licenses called Exemption Numbers, which allow products to be sold until their applications are assessed. But given that this group of products represents the bulk of the remaining truly effective, unique, and innovative products on the market, and that Health Canada has had more than seven years to assess them, many feel that the plan is to continue picking them off a few at a time, until any temporary licenses still in place expire in early 2013.

How did the Agency achieve this, you wonder? The answer is: Slowly, in phases, so as not to get too many people upset all at once, and so everybody had time to forget the great products we used to be able to get. It was achieved with an ongoing, deceitful appearance of complete reasonableness and willingness, all the while with an underlying intention bent on an agenda. And, of course, it was achieved relying on the overarching assumption by public and industry that Health Canada is going to be reasonable, and this would and could never happen in Canada … the land of the free.

Time to Take a Stand

With the upcoming free-trade deal between Canada and the European Union (set to be signed in the Fall of 2011), and the striking resemblance of these regulations to the EU's Traditional Herbal Medicinal Products Directive, and the fact that Bayer is represented on every possible advisory or input board for the NHP regulations, not to even mention the fact that Bayer reportedly holds hundreds of use patents on isolated constituents from botanicals and that this is to become the new frontier in drug development, does anyone actually have to question where this agenda for all this is coming from? (Virtually all of this was predicted by skeptics back in 2002, if not even longer ago than that.)

So Canadians have a choice to make. Either they rise up in unison and say "NO!" or else they remain complacent as their markets are over-run by trans-nationals and their ability to care for themselves is flushed down the drain. Which will you pick?

John Biggs has been in the health industry for many years now and owns three health-food stores in British Columbia. He has also worked for health freedom in Canada, most notably in lobbying Canadian Parliament with others such as Marilyn Nelson, when she was president of Freedom for Choice in Health Care.