

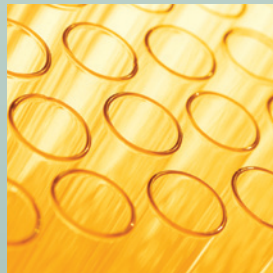
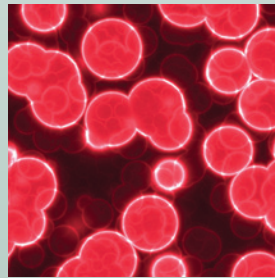
# Studies in Health Care Policy



September 2009

## Unnatural Regulation: Complementary and Alternative Medicine Policy in Canada

by Cynthia Ramsay



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## Executive summary

According to Health Canada, Canadian sales of natural health products (NHPs) were estimated to amount to about \$4.3 billion and to number around 40,000 to 50,000 products in 2004 (Health Canada, 2004b). A 2006 survey on the use of complementary and alternative medicine (CAM) found that more than one-half of Canadians had used at least one alternative therapy in the year prior to the survey, a four percentage-point increase over the rate of use in 1997 (Esmail, 2007).

The fact that more people are using NHPs and CAM—and thus more people are exposed to the potential adverse effects of such treatments—is the main reason given by Canadian and other governments for broadening the regulatory framework covering these products and therapies. However, the data do not support a public safety argument for government regulation of either NHPs or CAM practitioners.

Worldwide, there are relatively few adverse reactions associated with the use of NHPs, the vast majority of which are self-care products (i.e., they do not require the buyer to see a health practitioner). Nonetheless, the Canadian government implemented the Natural Health Products Regulations (NHPR) in 2004. Since the regulations came into effect, there has been no apparent increase in the safety, efficacy, or quality of NHPs, yet there has been a demonstrated decrease in the availability of such products. Moreover, the new regulatory process has resulted in substantial costs for both consumers and producers of NHPs.

The Natural Health Products Directorate (NHPD), which regulates NHPs in Canada, has received 36,127 product license applications and, of this total, has issued 11,007 licenses since the NHPR were created (NHPD, 2009d). Some critics claim that most of the products approved to date have been single-ingredient products (i.e., the easiest to evaluate), yet less than half of the products submitted to the NHPD have been granted licenses (Buckley, 2008).

It is estimated that 60% to 75% of NHPs will disappear from the market because of the NHPR (Buckley, 2008). For example, one study that examined just 12 companies found that the new regulations have cost the companies and the Canadian economy more than \$440 million (Stiefelmeyer et al., 2008: 2). This figure includes the employment that would have been created had rejected and not-yet-approved NHPs been permitted to be made or sold here. The NHPD itself has cost more than \$90 million since its inception in 1999 (NHPD, 2009c).

While NHPs fall under federal jurisdiction, CAM practitioners are a provincial responsibility. Different practitioner groups are regulated

differently among the provinces, and this imposes barriers to labor mobility (i.e., the ability of a practitioner trained in one province to work in another). While recent intergovernmental and inter-professional agreements have mitigated such barriers to a certain extent, obstacles still exist. Perhaps more critically, studies of the American labor market have shown that the use of licensure is associated with about 14% higher wages (and thus higher costs for consumers) without necessarily improving patient outcomes (see, for example, Kleiner and Krueger, 2009, and Svorny, 2008).

This study examines the validity of the public safety argument for licensing NHPs and CAM practitioners. It concludes that the cost of licensure far outweighs the benefits and recommends that:

- ❧ The Natural Health Products Directorate be abolished and the monitoring of NHP safety and effectiveness be left to various nongovernmental organizations.
- ❧ All current health practitioner licenses, including physician licenses, be replaced with certification, with the opportunity for various organizations to become certifying agencies.

# Introduction

More people are using natural health products [1] (NHPs), the vast majority of which are self-care products that do not require the buyer to see a health practitioner. More people are also choosing to use the services of complementary and alternative medicine (CAM) practitioners such as chiropractors and massage therapists. The increasing popularity of such treatments is the main reason given by Canadian and other governments worldwide—as well as the World Health Organization—for broadening the regulatory framework covering these products and therapies.

For decades, various CAM practitioners in Canada have been lobbying to become government-sanctioned, licensed professionals. Many groups have been successful in gaining this status, in part because of the argument that public safety is better protected by practitioners with defined scopes of practice and the exclusive use of a specific title—midwife and acupuncturist, for example—if they have met certain standards.

In 1999, after extensive public consultation, the federal Natural Health Products Directorate was created. Its mandate 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” (NHPD, 2008a: 6).

However, the fact that an increasing number of Canadians were using NHPs and CAM therapies before governments licensed these treatments indicates that consumers were comfortable even when there was little regulation. The available data on the health risks posed by NHPs and CAM treatments support this perception, and other evidence indicates that the regulatory measures implemented to date have decreased Canadians’ access to NHPs and CAM therapies, while imposing substantial costs.

This study provides an overview of the use of NHPs and CAM treatments in Canada. It discusses how NHPs and complementary health practitioners are currently regulated in Canada and examines the validity of the

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1 Canada’s Natural Health Products Directorate defines a natural health product as a substance, or a combination of substances, described in Schedule 1 of the NHPR (see Appendix A), a homeopathic medicine or a traditional medicine that is intended to provide a pharmacological activity or other direct effect in (a) diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physiological state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

public safety argument, as well as the costs of government regulation. It offers recommendations as to how the government should proceed if it is truly concerned with the safety and quality of NHPs and CAM, and with the availability of such treatments in Canada.

# Natural health products and complementary medicine:

## An overview

According to Health Canada, Canadian sales of natural health products (NHPs) amounted to about \$4.3 billion and numbered around 40,000 to 50,000 products in 2004, with vitamins representing more than half of retail sales and comprising more than 18% of Canadian companies involved in the NHP industry; herbs and botanicals accounted for another 30% of sales (Health Canada, 2004b). Some have conservatively estimated that the NHP market numbered at least 70,000 products at one point, but that the NHPR has reduced that total to fewer than 40,000 products available for Canadians to purchase domestically in 2009 (John Biggs, personal communication, June 1, 2009).

Sales of natural health products in Canada were an estimated \$2.5 billion in 2005, in addition to more than \$2.7 billion spent on functional foods [2] (Nutri-Net Canada, 2008). The global functional food market grew almost 10% between 2005 and 2006 and was expected to grow 50% between 2005 and 2010 (Stiefelmeyer et al., 2008: 7). Yogurt, fruit, vegetables, cereals, whole grains, organic grains, and tea all performed well up to 2005 and were expected to continue to do so as the public became more aware of the links between diet and specific health issues (SMC, 2005).

The issue of health claims is central to whether an item is regulated as a food or a drug. While there are certain allowable claims for foods, what product should belong to which category is not always clear. For example, the US Food and Drug Administration (FDA) sent a letter released on May 12, 2009, to General Mills, producers of the cereal Cheerios®. The FDA contended that the packaging of and Internet ads for Cheerios® Toasted Whole Grain Oat Cereal made inappropriate health claims—claims that can only be legally made by FDA-approved drugs—about the cereal’s ability to lower cholesterol (*CBC News*, 2009, May 12).

The complaint against Cheerios® was filed by a so-called consumer advocacy group, the National Consumer League, while at least one other so-called consumer group—the Center for Science in the Public Interest—which

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2 A functional food is a conventional food that has physiological benefits and/or reduces the risk of chronic disease.



campaigns for stricter limits on food health claims, applauded the FDA's actions (Birchall, 2009, May 12).

Such classification issues may become more prevalent as more foods are shown to have health benefits. *Canadian Food Trends to 2020: A Long Range Consumer Outlook* (SMC, 2005), a report prepared for Agriculture and Agri-Food Canada, provided numerous examples of foods that have been shown to have physiological benefits or to reduce the risk of chronic disease. These examples include eating carrots to prevent eye diseases; drinking cranberry juice for urinary tract infections; consuming dairy products to counter osteoporosis; increasing fibre intake to prevent colon cancer and improve intestinal health; eating blueberries and certain vegetables with anti-oxidant properties to prevent cancer or slow the effects of aging; consuming fish oils (containing omega-3 fatty acids) for normal growth and development, and improved mental capacity and cardiovascular health; eating tomatoes (lycopene) for prostate health; and drinking red wine for cardiovascular health (SMC, 2005: 13).

Table 1 comes from a report prepared for Agriculture and Agri-Food Canada called *Integrating Food Policy with Growing Health and Wellness Concerns: An Analytical Literature Review of the Issues Affecting Government, Industry, and Civil Society* (Cash et al., 2004). It presents the number of studies that have shown various foods to have protective effects, no effect, or detrimental effects on coronary heart disease, cancer, stroke, and diabetes.

**Table 1: Number of studies showing associations between foods and diseases**

	Coronary heart disease			Cancer			Stroke			Diabetes		
	P	NE	D	P	NE	D	P	NE	D	P	NE	D
Fruit and vegetables	16			8	2		2					
Meat					34	82						
Eggs		1										
Whole grains	15	1		29	4		1			3		1
Alcohol (moderate consumption)	5				5	25	2	1		1		
Sugar												
Dairy	3						2					11
Fish	8	3		24	6		2	1				
Pulses	3			1								
Soy protein	41	5										
Soy isoflavones				4	1							
Nuts	11											

Note: P = Protective; NE = No effect; D = Detrimental

Source: Cash et al., 2004: 25.

While there are few studies that show a connection between certain foods and stroke and diabetes, there are many studies showing that certain foods have a protective effect on coronary heart disease and cancer.

The evolving evidence concerning the relationship between various foods and health can sometimes cause confusion to both consumers and regulators. Scientists deem something healthy one day, and then find something detrimental about it in subsequent research, or vice versa. For example, the consumption of egg yolks was linked to coronary heart disease in the early 1960s, but by the late 1990s, eggs were no longer considered that unhealthy (Cash et al., 2004: 118).

## **Do natural health products and complementary therapies work?**

The lack of evidence regarding the effectiveness of natural health products and complementary medicine treatments makes sound public policy and consumer choices difficult in this area. But while many medical professionals have argued against the effectiveness of CAM and/or herbal remedies, there is research indicating that certain treatments are beneficial. For example, there is significant support for the use of acupuncture for pain relief, but the scientific literature offers little about the efficacy of traditional Chinese medicine (TCM) as a whole; studies generally investigate only specific TCM herbs (Mackay, 2007).

The Nonprescription Drug Manufacturers Association (NDMAC) claims that there is a growing body of studies in Canada and the United States showing that increased use of self-care health products can result in savings to the health care system. The NDMAC gives a number of examples of disease reduction resulting in lower costs: for example, an annual savings of \$6 billion in the treatment of cardiovascular diseases with daily use of omega-3 fatty acids, flaxseed, and folic acid; and a US\$13.9 billion net savings over five years through daily use of a calcium supplement with vitamin D among people aged 65 and over, to prevent hip fractures (NDMAC, 2007).

Furthermore, a 2000 retrospective [3] study of Quebec health insurance enrollees found that transcendental meditation (TM) may reduce health costs. The study compared a group of TM practitioners with a group of non-meditators and found that, after learning TM, the annual change in average payments to physicians was a decline of 1% to 2% for the TM group, and an increase of up to 12% for non-meditators, with a potential cost savings of up to \$300 million per year (Bodeker et al., 2007: 25).

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3 A retrospective study looks backward in time; in this case, it used insurance records to examine the relationship between physician costs and the use of transcendental meditation.

Another report, conducted by Deborah A. Kennedy and her colleagues (2007), analyzed studies of perioperative [4] nutrition and enriched enteral nutrition [5] for critical illnesses, cardiovascular incidents, gastrointestinal disorders, and other illnesses. The researchers found that eight of the nine studies examined demonstrated that when a NHP was part of the care patients received, there was a 3.7% to 73% reduction in costs compared to the control group, as well as positive health outcomes.

The effectiveness of NHPs and CAM in curing an ailment or improving health or well-being can be influenced by other factors. As Gerard Bodeker and his colleagues write in *Traditional, Complementary and Alternative Medicine: Policy and Public Health Perspectives*, “Belief and attitude have an influence on treatment outcomes in all therapeutic settings, western and other traditions. A ‘placebo’ or ‘meaning response’ effect is an important component of many therapies. The extent to which therapeutic outcomes are based on expectancy is an important area of study.”

While more evaluation of the effectiveness of complementary medicine, in comparison to or in combination with allopathic (i.e., Western or conventional) medicine, in treating various conditions is needed, there are issues with the underlying assumptions and methodology of the investigative approach favored in Western countries: the randomized control trial (RCT). A RCT involves the random allocation of different interventions to subjects who are unaware of which treatment they are receiving. When this type of trial is used, the placebo effect should be mitigated so that it does not confuse the data on the effectiveness of the various interventions being tested.

There are a few problems with using RCTs to measure the efficacy of complementary and alternative medicines and treatments. One is the cost associated with conducting RCTs on products that generally have ingredients that are not patentable (for example, plant material). As well, the composition of herbal remedies, for example, can be especially challenging as a single plant can contain hundreds of constituents and the isolation of active ingredients is an integral part of a RCT. According to the World Health Organization, such obstacles help explain why clinical trials of CAM have been few, small, and often inadequately controlled, and why there have been few reliable and full economic analyses of traditional medicine and/or complementary and alternative medicine (TM/CAM) (WHO, 2002: 22).

Regarding non-medication therapies, the WHO pointed to a 1999 *British Medical Journal* series on CAM which found that RCTs offered evidence that hypnosis and relaxation techniques can reduce anxiety and prevent panic disorders and insomnia (WHO, 2002: 23). The WHO also noted

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- 4 Perioperative is the period of time from when a patient is admitted for surgery to when that patient is discharged.
  - 5 Enteral nutrition is tube feeding.

that evidence from RCTs is persuasive for many uses of acupuncture, as well as some herbal remedies and manual therapies (WHO, 2002: 3). Overall, however, the WHO contended that the increased use of TM/CAM has not been matched by an increase in the quantity and quality of medical evidence to support its claims (WHO, 2002: 3).

## **The use of natural health products and complementary therapies**

Regardless of the ongoing debate over the effectiveness of various NHPs and CAM, an increasing number of Canadians are using them—sometimes instead of prescribed drugs or conventional treatment. That Canadians are willing to pay for these products and services privately clearly shows that NHPs and CAM provide perceived benefits to individual Canadians. Thus, a reduction in the availability of CAM or NHPs could negatively affect a large number of Canadians.

The Fraser Institute conducted surveys on the use of complementary medicine in Canada in 1997 and 2006. With respect to self-reported health, little changed between 1997 and 2006. In both years, more than 60% of respondents reported their health to be very good or excellent, and only 11% reported their health to be fair or poor. However, those surveyed still suffered from various ailments; the most common health conditions experienced in the 12 months prior to both of the surveys were allergies, back or neck problems, and arthritis or rheumatism (Esmail, 2007).

Other studies have also found that, on the whole, Canadians describe their health in positive terms; however, 92% report that, in a given year, they suffer from at least one of a wide variety of illnesses: respiratory, dermatological, and digestive system conditions; conditions requiring pain relief; and other conditions such as obesity, depression, and high blood pressure (NDMAC, 2004c: 3). Approximately one-third of adults will have a sore throat, cold, or flu in any given month and, of those adults, 63% will initially react by using some type of self-treatment (NDMAC, 2004c: 3). In a 2001 survey, about 7% of Canadians reported that they took NHPs instead of a drug prescribed by a doctor, up from 2% in 1999 (CIHI, 2005: 115). Furthermore, the number of Canadians who reported substituting a NHP for over-the-counter (OTC) medication doubled from 15% in 1998 to 30% in 2000 (CIHI, 2005: 115).

According to 2000 data, at the onset of a new medical problem or illness, 55% of Canadians will “tough it out, and wait and see if it gets worse,” 21% will go to their family doctor, 9% will self-medicate with over-the-counter drugs, and 4% will try a natural remedy (NDMAC, 2004c: 3). Over the course of a year, 83% of adult Canadians take OTC medications, 59% take multivitamins or minerals, and 27% take herbal remedies (NDMAC, 2004c: 5).

A 2003 Statistics Canada survey estimated that 3.3 million Canadians aged 12 or older (12%) used a CAM provider in the year prior to the survey (CIHI, 2005: 114). In addition, a 2005 Health Canada poll found that 71% of Canadians used alternative health products, and that the most commonly used NHPs were vitamins (57%), echinacea (15%), and herbal remedies, algal and fungal products (11%) (Ipsos Reid, 2005a: 8).

There have been studies indicating that only one in 40 symptoms ever results in a medical consultation (Jones, 2000). But despite the prevalent use of NHPs and other self-care products, the Nonprescription Drug Manufacturers Association of Canada (2005b) has estimated that if 10% of the people who seek formal care first when treating a self-treatable illness were to treat themselves, billions of dollars could be saved, as 50% of physicians say that 25% of their consultations are unnecessary or inappropriate, and that 65% of their consultations are for minor complaints.

A now dated but no less relevant study by Simon Rottenberg showed that self-care in the treatment of minor upper respiratory illness could reduce by a factor of 15 the cost of treatment compared to what the cost would have been if a doctor had been visited (Rottenberg, 1990: 27). The explanation for this result remains valid: physicians are expensive to train and the delivery of medical care by physicians is very resource intensive. Consequently, more limited use of such a costly resource saves the system money and frees physicians to focus on more serious cases. In reference to the United States, the Rottenberg paper noted that “if only 2% of nonprescription drug consumers had chosen to seek professional care rather than to resort to self-medication, the demand for the services of doctors would have risen by 53%” (Rottenberg, 1990: 27–28).

Once Canadians decide to seek treatment from a health provider, doctors are still their main choice. In the Fraser Institute’s 2006 survey regarding complementary medicine use, 73% of respondents said they had “total” or “a lot” of confidence that their doctor could help them manage their overall health. As well, 73% of respondents suffering from a medical condition listed in the survey [6] sought medical attention for their health problems during the previous year. Nonetheless, 74% of Canadians said that they had used at least one alternative therapy at some time in their lives, and that they used alternative therapies an average of 8.6 times during the year prior to the survey (Esmail, 2007).

The Fraser Institute’s 2006 survey found that more than one-half (54%) of Canadians used at least one alternative therapy in the year prior to the survey, an increase over the rate of use in 1997 (50%). The five most commonly used complementary and alternative medicines and therapies were massage, prayer/spiritual practice, chiropractic, relaxation, and herbal

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6 The survey listed 28 medical conditions.

therapies. The top-five list was the same in 1997, although the order was different (Esmail, 2007).

Most people who used alternative therapies in the 12 months preceding the 2006 Fraser Institute survey did so to prevent future illness from occurring or to maintain health and vitality (Esmail, 2007). Similarly, in a 2004 survey, more than half of all NHP users cited the following reasons for use: prevention of illness or disease (55%), nutritional purposes (54%), and the alleviation of symptoms/to treat a specific condition (52%) (NDMAC, 2004c: 16). Furthermore, in a 2005 survey for Health Canada, the majority of respondents agreed that NHPs could be used to maintain or promote health (77%) or to treat an illness (68%), but only 43% of respondents agreed that NHPs were better than conventional medicines (Ipsos Reid, 2005a: 9). The 2005 survey also found that 18% of users of NHPs used such products for reasons related to the belief that natural health products are better than conventional drugs, 18% used NHPs because of personal health concerns, and 14% used NHPs to help or promote personal health (Ipsos Reid, 2005a: 8).

The HealthLink BC website has a fairly extensive amount of information on complementary and alternative medicine, including some of the common reasons why people may choose to use CAM: for example, a desire for a more holistic approach, a desire for a more active role in one's health care, or because conventional treatment has not provided relief from a chronic condition. Reasons why people may choose not to use complementary medicine could include the lack of scientific research on the safety and effectiveness of some of the therapies, the interactions complementary medicine may have with conventional medicines, the high cost of some therapies that are not covered by provincial health plans or private health insurance, and satisfaction with conventional treatments (Curtis et al., 2007).

Among respondents to the 2005 Health Canada survey who had not used NHPs, the primary reasons for not doing so included: no need (20%), a lack of information on natural health products (17%), the attitude "I am healthy" (13%), a lack of belief in the efficacy of NHPs (11%), and a sense that the products were too expensive (5%) (Ipsos Reid, 2005a: 9). However, 81% of respondents predicted growth in the use of NHPs in Canada, and 72% said that Canadians should have the right to use NHPs if they choose to (Ipsos Reid, 2005a: 9, 44).

Most Canadians pay out-of-pocket for many complementary and alternative medical services and therapeutic products. In 2004, governments and government agencies financed 98.9% of physician services, whereas the private sector funded 91.2% of expenditures on the services of other professionals, including CAM providers (CIHI, 2006: 14).

The Fraser Institute survey data suggest that during the latter half of 2005 and first half of 2006, Canadians spent more than \$5.6 billion out-of-pocket on visits to providers of alternative medicine. If all the money spent on



health books, medical equipment, herbs, vitamins, and special diet programs is included, out-of-pocket spending on alternative medicine increases to an estimated \$7.84 billion. Despite the expense, the majority of respondents (59% in 2006 and 58% in 1997) believed that CAM should be covered privately and should not be included in provincial health plans. Notably, the highest level of support for private payment (62%) was found among 18- to 34-year-olds, the group that used alternative therapy the most (Esmail, 2007).

In a 2004 NDMAC survey, more than four-fifths (84%) of Canadians said they were covered by some type of drug plan that covered all or some of their medications, and all respondents said they used more nonprescription medications than prescription drugs (NDMAC, 2004c: 11). With the caveat that half of the government plan users were aged 65 and over, NDMAC noted that those covered by a government plan tended to use prescription drugs the most and to visit a family doctor, specialist doctor, and pharmacist most frequently.

In 2002, Statistics Canada surveyed Canadians aged 20 and older who had stopped consulting a health professional about their mental health and/or addiction problems in the previous year about why they had stopped. Many (29% to 53%, depending on the type of professional consulted) reported that they had stopped seeing a health professional because they felt better (CIHI, 2005: 107). Cost was not an important factor except with respect to “other professionals” (acupuncturists, chiropractors, herbalists, hypnotists, and other CAM professionals); 16% of respondents said that they stopped using those services because they could not afford them.

## **Where people turn to find out more about natural health products**

A 2004 NDMAC survey reported that the people who chose nonprescription medications based their decision most often on information they received from their pharmacists (24.7%). The next most common sources of information were doctors (21.4%), family or friends (14.4%), product labels (12.2%), and advertising (4.5%). However, respondents who chose herbal remedies based their decisions primarily on information from family or friends (35.5%), health books (17.6%), professionals other than doctors (8.7%), and print articles (7.4%) (NDMAC, 2004c: 14).

A similar difference was revealed in a 2005 Health Canada survey, which found that, overall, 71% of Canadians agreed that it is important to talk to a medical doctor before using a NHP. However, the importance of consulting a medical doctor was lower among those who had used a NHP (36% completely agreed) and was higher among those who had not used a NHP (57% agreed). Those who had not used a NHP were more likely to

say that they completely trust medical doctors as sources of information on NHPs (56%, compared to 44% for those who had used a NHP), while those who had used a NHP were more likely to report that they completely trust NHP information provided by naturopaths or naturopathic doctors (28%, compared to 16% for those who had not used a NHP) (Ipsos Reid, 2005a: 12).

Data from other sources demonstrate that a person's beliefs affect his or her trust in a particular provider or kind of treatment. For example, consumers who are not confident in the safety of the food produced in Canada, although few in number, are twice as likely to report suffering from a food-borne illness in the past year; consumers who believe the quality of food produced in Canada is only of average or poor quality are also more likely than the average to say that they have suffered from a food-borne illness in the past year (32%) (Ipsos-Reid, 2006: 73).

The most significant trend, however, is that more and more people are seeking health information on the Internet. Despite the variability in information quality, the percentage of adults in the United States who have sought health information online grew from 27% (54 million) in 1998 to 53% (117 million) in 2005 (National Association of Boards of Pharmacy, 2009). Data from the Pew Research Center's Internet and American Life Project, which has conducted surveys on Internet use in the United States since 2000, show how fast the importance of the Internet is growing. In 2000, 46% of Americans had access to the Internet; by 2008, 74% were online (Fox and Jones, 2009: 6). The 2008 survey found that 8 in 10 Internet users, or 61% of US adults, had looked online for health information. Pew Internet Project surveys conducted in 2002, 2004, 2006, 2007, and 2008 have consistently found that between 75% and 83% of Internet users look online for health information (Fox and Jones, 2009: 6).

This does not mean that traditional sources of health information are no longer being used. Among American adults who need information or assistance in dealing with health or medical issues, the most popular source of information is a health professional. The second most popular source is friends and family, while the Internet, books, or other printed reference materials are tied for third most popular (Fox and Jones, 2009: 7). Canadians also have access to a wide range of resources on the quality and safety of health products and services, including resources provided by governments, health insurance companies, and renowned health care providers. This abundance of resources calls into question the need for additional government intervention in these areas.



## The regulation of natural health products

In 1997, Health Canada established an advisory panel on natural health products (NHPs), which at the time fell under a regulatory “grey area”; sometimes NHPs were considered foods, but when health claims were made they were considered drugs.

In November 1997, the federal government set up a Standing Committee on Health to conduct a full public review of the issues surrounding the manufacture, distribution, and use of NHPs. In 1998, the committee made 53 recommendations, including an amendment to the Food and Drugs Act—which has not been done—and the creation of a new regulatory authority.

The Office of Natural Health Products, now called the Natural Health Products Directorate (NHPD), was created in 1999. The Directorate’s new Natural Health Products Regulations (NHPR) came into effect on January 1, 2004. Total operating costs for the NHPD from 1999 to fiscal year 2008/2009 were just under \$30.8 million, with salaries and wages consuming about \$57.4 million and transfers slated for the Natural Health Products Research Program accounting for \$3.2 million (NHPD, 2009c).

The Health Products and Food Branch (HPFB) of Health Canada, in which the NHPD is situated, spent \$307.9 million in 2007/2008, while total Health Canada spending that fiscal year was almost \$4.3 billion (Treasury Board of Canada Secretariat, 2008). In an overview of the department’s performance report for that fiscal year, the health minister noted:

Health Canada continued its effort to renew the regulatory framework and programming for natural health products, with a view to reducing the application review backlog and further enhancing product safety. We expect more progress this year and beyond, with the 2008 government investment of \$82.5 million over five years. (Treasury Board of Canada Secretariat, 2008)

In October 2006, the HPFB launched its *Blueprint for Renewal*, the aim of which is to “moderniz[e] Canada’s regulatory system for health products and food” (Health Canada, 2009a). The *Blueprint’s* numerous initiatives include a review of the NHP regulations, as well as reforms to the cost recovery regime that covers the regulation, licensing, and post-market surveillance of health products in general.

Currently, the Food and Drugs Act (FDA) classifies products as a food, drug, cosmetic, or device. Before the Natural Health Products Regulations (NHPR) were implemented on January 1, 2004, NHPs were sometimes considered foods and sometimes considered drugs. Under the NHPR, these products are now recognized as a sub-category of drugs and must undergo pre-market evaluation and receive product licenses in order to be marketed in Canada. To receive a license a product must be appropriate for consideration as an over-the-counter (OTC) product and must not require a prescription. Homeopathic medicines are treated differently under the NHPR as they can contain or be manufactured from substances listed in Schedule D (biological drugs) of the FDA that are otherwise not regulated by the NHPR (Health Canada, 2004a).

Health Canada considers NHPs to be more similar to drugs than to foods, partly because NHPs are taken for therapeutic reasons and not for caloric purposes or to address hunger (Health Canada, 2004a). Most of the supporters of the new NHP regulations wanted the products to be regulated separately from drugs or foods; however, as stated in various consultation documents, it was not possible to create a third category without substantial amendments to the Food and Drugs Act, so Health Canada chose to make NHPs a sub-category of drugs, but with their own set of regulations (Smith et al., 2007: 39–40).

That decision created clarity in some respects, but vagueness remains, particularly with respect to products that could be considered foods or NHPs (Farrell et al., 2009: 389). For example, nutraceuticals—a product derived from foods that has a physiological benefit or provides protection against chronic disease and is usually sold in medicinal forms—are classified as NHPs. A product like probiotic yogurt, however, is currently available for sale in Canada as a food product without a health claim, even though probiotics are included in the definition of a NHP (Farrell et al., 2009: 390). Clinical trials are not required for food products, nor do foods generally require pre-market approval, but functional foods—that is, conventional foods that have physiological benefits and/or reduce the risk of chronic disease—are considered drugs and are required to undergo a pre-market evaluation to demonstrate their safety and the validity of their claim. Under the current regulations, as long as no health claims are made about probiotic yogurt, the product is treated as a food.

Since the implementation of the NHPR, Health Canada has received several hundred product license applications for products in a food format, such as energy drinks, vitamin or mineral supplements in the form of candy, and some juices or waters with added vitamins and minerals. A product that is both a NHP and a food is subject to the NHPR but is exempt from the FDA and its regulations as they apply to food (NHPD, 2009a). According to the FDA, a food is “any article manufactured, sold, or represented for use as

food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.”

NHPs are usually sold in a format that allows them to be consumed in controlled amounts. Consequently, if a product is sold in a particular food format (e.g., a beverage) that lends itself to dosing (e.g., it is sold with a measure that indicates it should be consumed in specific amounts), then it is likely that the product is a NHP as defined in the NHPR. Such classification decisions are made by a committee with experts from both the Food Directorate and the Natural Health Products Directorate (NHPD, 2009a).

The distinction between food and NHPs is important because most health claims for foods are prohibited for disease conditions listed in Schedule A (Section 3) of the Food and Drugs Act, which was recently amended. The revisions to Schedule A [7] came into force on June 1, 2008, and the updated Schedule A list is now shorter and more specific; for example, “liver disease,” which covers all liver diseases, disorders, and abnormalities, is now listed as “hepatitis” (Health Canada, 2008a).

Amendments to the Food and Drug Regulations (FDR) [8] and the NHPR, which also came into force on June 1, 2008, now permit NHPs and nonprescription drugs regulated by the FDA to label and advertise approved preventative claims for the diseases listed in the revised Schedule A (Health Canada, 2008a). However, the only health claims permitted on food labels are specifically exempt from Section 3 of Schedule A. As part of new nutrition labelling regulations published in January 2003, provision was made for five generic health claims on food labels: sodium and potassium for hypertension; calcium and vitamin D for osteoporosis; reduced saturated fat and trans fat for heart disease; vegetables and fruit for some types of cancer; and reduced dietary sugar alcohols for dental caries (tooth decay) (Smith et al., 2007: 67–68; Brosens, 2009: 7).

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- 7 Regulations amending Schedule A to the Food and Drugs Act (FDA) and the Medical Devices Regulations (Project 1539) repealed the references in the FDA to alcoholism, alopecia (except hereditary androgenetic alopecia), anxiety state, arthritis, bladder disease, disease of the prostate, disorder of menstrual flow, dysentery, edematous state, epilepsy, gall bladder disease, gout, heart disease, hernia, hypotension, impetigo, kidney disease, leukemia, liver disease (except hepatitis), pleurisy, sexual impotence, tumor, and venereal disease. The new regulations added references to acute alcoholism; acute anxiety state; acute infectious respiratory syndromes; acute, inflammatory, and debilitating arthritis; acute psychotic conditions; addiction (except nicotine addiction); congestive heart failure; dementia; haematologic bleeding disorders; hepatitis; sexually transmitted diseases; and strangulated hernia.
  - 8 Both the NHPR and the FDR are regulations under the Food and Drugs Act. Prior to the NHPR, the FDR regulated foods and drugs; NHPs were sometimes treated as foods and sometimes treated as drugs.

In comparison, the US Food and Drug Administration approved 10 advertising claims regarding the reduction of disease risk in 1996 and has added several since so that there are now 27 permissible health claims in the United States. These claims include—in addition to the five claims allowed in Canada—green tea for cancer; fruit, vegetables, and fibre containing grain products for cancer; walnuts for heart disease; omega-3 fatty acids for coronary heart disease; B vitamins for vascular disease; chromium picolinate for diabetes; and folic acid for neural tube birth defects (Brosens, 2009: 8).

## The Natural Health Product Regulations

The Natural Health Product Regulations that came into force in 2004 are very similar to those dealing with drugs in the Food and Drug Regulations. The NHPR includes provisions for product licensing, site licensing, good manufacturing practices, adverse reaction reporting, clinical trials, labelling, and importation for sale. [9] NHPs that had drug identification numbers (DINs) when the NHPR came into effect were permitted to maintain their DINs, if so desired, and to be sold for six years before obtaining a NHP product license (Health Canada, 2008b). However, all NHPs for sale in Canada must comply with all of the new NHP regulations by January 1, 2010.

As per the NHPR, all NHP advertising must respect Section 9(1) of the Food and Drugs Act: “No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety” (Health Products and Food Branch, 2006). While pre-clearance from Health Canada is not mandatory, “approved” advertising is assigned a clearance number that signifies that the advertising has been assessed and is considered compliant with the applicable legislation and regulations (Health Products and Food Branch, 2006).

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9 The following provisions from Part A and Part C of the Food and Drug Regulations were incorporated to allow for the administration (including compliance and enforcement) of the Natural Health Products Regulations:

- A.01.022 to A.01.026, A.01.040 to A.01.044, A.01.045, A.01.050, and A.01.051 (general administration);
- A.01.061 to A.01.063 (pressurized containers);
- C.01.001(2), C.01.001(3), and C.01.001(4) (definitions);
- C.01.012 (release of medicinal ingredients);
- C.01.015(1), C.01.015(2)(d) to (f) (disintegration of tablets); and
- C.01.028(1), C.01.028(2)(b) and (c), C.01.029, C.01.031(1), C.01.031.2(1)(a) and (c) to and (g), C.01.031.2(2), and C.01.031(2)(3)(a) and (c) (cautionary statements and child resistant packaging) (NHPD, 2003).

Herbal remedies, homeopathic medicines, vitamins, minerals, traditional medicines, probiotics, amino acids, and essential fatty acids fall under the purview of the NHPR, as do self-care products such as some toothpastes, antiperspirants, shampoos, facial products, and mouthwashes because of their medicinal ingredients and intended uses (Health Canada, 2009d). Before any of these types of products can be sold in Canada, each product must obtain a product license (NHPD, 2003). Obtaining a product license requires submitting to Health Canada detailed information about the product, including its medicinal ingredients, source materials, recommended use(s), and the potencies of each medicinal and non-medicinal ingredient (see Appendix B for more information about the difference between medicinal and non-medicinal ingredients).

The NHPD's Standards of Evidence framework allows for a range of evidence to be submitted in support of the safety and efficacy of a natural health product and the quality of a NHP or homeopathic medicine (Health Canada, 2009d). Should a product developer wish to hold a clinical trial—an investigation involving human subjects that is intended to ascertain a product's clinical, pharmacological, or pharmacodynamic effects and its safety and efficacy—the regulations set out requirements for conducting such a trial.

Once a product has been assessed and granted market authorization by Health Canada, the product label will bear an eight-digit product license number preceded by the letters NPN (natural product number) or DIN-HM (drug identification number-homeopathic medicine). A NHP label must also include the brand name of the product, the product's medicinal and non-medicinal ingredients, the quantity of product in the bottle, the recommended conditions of use of the product, and any special storage conditions. The NHPR require product license holders to monitor all adverse reactions associated with their product and report any serious adverse reactions to Health Canada.

In addition to a product license, a site license is required in order to manufacture, package, label, and import for sale a NHP. Sites must prove that they meet the good manufacturing practice (GMP) requirements—rules that dictate how their products are manufactured, packaged, labelled, imported, distributed, and stored.

## The continuing evolution of the Natural Health Product Regulations

In response to concerns raised by respondents to the NHPD's 2007 consultation paper, *Charting a Course: Refining Canada's Approach to Regulating Natural Health Products*, as well as the NHPD's product license backlog, the directorate developed a risk-based approach (RBA) to the regulation of NHPs (see Appendix C).

The RBA envisions two classes of product licenses: Class I, for which there are readily available, authoritative, and high-quality sources of evidence (pre-cleared information, or PCI); and Class II, which includes products and/or claims that are considered higher risk due to a lack of existing evidence. PCI allows for a broad range of evidence from recognized reference sources, such as pharmacopeias (i.e., books that describe drugs and medicinal preparations; for example, the US Pharmacopoeia, British Herbal Pharmacopoeia, or the Pharmacopoeia of the People's Republic of China), monographs and labelling standards, published expert opinion reports (e.g., from the US Agency for Health Care Research and Quality), international standards, and information from other regulatory bodies (Health Canada, 2009b; NHPD, 2007).

Work in this area, which is in the beginning stages, includes consultations and investigation into exchanging PCI with international regulatory bodies and the development of abbreviated labelling standards for a set of efficacy/health claims. The RBA proposes that the site license assessment process be modified to include some form of on-site verification of GMP compliance so that Health Canada can identify risks and potential non-compliance issues earlier in the process (Health Canada, 2009b), though it is not clear how adding on-site verification of GMP would expedite the NHP application process.

Currently, there are no fees associated with the review and assessment of NHP applications under the NHPR, but the NHPD has put forward a proposed cost recovery framework for the NHP industry. [10] In its *Cost Recovery Framework: Consultation Document*, published in 2007, the Health Products and Food Branch (HPFB) notes that it has the authority to collect up to \$41.2 million through cost recovery, although its actual revenues have averaged about \$38 million per year in the past several years. Cost recovery revenues represent about 15% of HPFB's overall budget, the document reports, and approximately 25% of the budget of the program areas that receive cost recovery revenues.

In 1995, Health Canada implemented fees to recover a portion of the cost of its drug regulation activities. In 2003, the HPFB initiated a review of the fee structures, the methodology used to determine the cost of its activities, criteria for excluding or including activities for cost recovery, the impact of the fees on business, fee mitigation, dispute management mechanisms, and service standards and their link to fees.

The implementation of revised fees was supposed to have occurred in April 2008 (Health Products and Food Branch, 2007). However, the HPFB has

10 In 2004 and 2006, the Auditor General of Canada raised concerns about the ability of Health Canada to continue to fulfill its regulatory requirements with the resources available at the time, and recommended that Health Canada consider cost recovery as a source of income (Health Products and Food Branch, 2007).



said that it will delay cost recovery for NHPs until the current submissions backlog is eliminated and the full costs of compliance are better identified (Health Canada, 2007b).

The proposed NHP fees are substantially lower than those for pharmaceuticals. According to the *Cost Recovery Framework*, drug submission fees currently range from \$143,800 to \$264,900 for a new active substance. The cost recovery proposal suggests that this fee be increased to a flat \$303,480, with drug establishment licensing fees starting at \$15,450 for the good manufacturing component, \$10,300 for packaging/labelling fees, and \$6,440 for importation/distribution fees.

For NHPs, the *Cost Recovery Framework* proposes charging \$1,500 for a compendial [11] product license application, \$1,810 for a non-compendial (single-ingredient) product license application (which requires a full evidence package), and \$3,610 for a non-compendial (multi-ingredient) product license; \$2,110 for a site license, \$2,010 for a site license amendment, and \$1,670 for a site license renewal; \$60 for a NHP international trade certificate, a certificate of GMP compliance, or a stamping of documents; \$470 for a NHP master file submission [12]; and \$920 for an annual product license fee to retain a NPN or DIN-HM.

While the suggested fees for NHPs would increase costs for providers, they do not appear to be excessive. According to the results of a 2003 survey of Canada's functional food and nutraceutical [13] industry, though the majority of firms were small (fewer than 50 employees), 30% of respondents reported total earnings from all sources exceeding \$10 million in 2002, and another 40% reported earnings between \$1 to \$10 million (Agriculture and Agri-Food Canada, 2006: 10). For example, Sisu, a manufacturer of vitamins and supplements based in British Columbia, told a *BC Business* reporter in 2008 that it had annual revenues of between \$15 and \$20 million (Werb, 2008, Aug. 1).

On a much smaller scale, one could compare the NHP cost recovery fees with the cost of membership in a professional organization. In British

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- 11 A monograph is a written description of particular elements on an identified topic, while a compendium is a compilation of monographs developed by the Natural Health Products Directorate. The directorate allows applicants to reference a NHPD monograph in support of the safety and efficacy of a NHP as part of their product license application (NHPD, 2007).
  - 12 A master file submission is the registration of reference documents on proprietary information about relevant manufacturing details and/or the technical specifications of the medicinal ingredients or raw materials used in the manufacturing of a natural health product.
  - 13 As stated earlier in this document, nutraceuticals—a product derived from foods that has a physiological benefit or provides protection against chronic disease and is usually sold in medicinal form—are classified as NHPs.

Columbia, for instance, the gross annual income of a midwife can range from \$50,000 to \$90,000 per year, depending on the number of clients a midwife has (*Vancouver Courier*, 2009, Jan. 16). The cost of registering with the College of Midwives of British Columbia is \$1,800 plus a one-time application fee of \$200 and a \$25 annual membership renewal fee (College of Midwives of British Columbia, n.d.).

Nevertheless, though the suggested fees for NHPs seem reasonable, the *Cost Recovery Framework* allows for the mitigation, delay of payment, or reduction of fees if there is sufficient evidence “that a fee is an excessive financial burden, or contrary to public policy objectives” (Health Products and Food Branch, 2007: 17).

Rather than the size of the proposed fees, one of the main problems with the new regulatory process seems to be the length of time the NHPD takes to approve or reject an application, as well as a lack of clarity. For example, one company that produces teas that contain vitamins and natural ingredients, some of which are considered medicinal in Canada, has been trying to get a product license since 2006 and has had to hire a regulatory consultant to help, at a cost of \$10,000 to date (Stiefelmeyer et al., 2008: 39–40). Another company, which produces a beverage that has added vitamins and minerals, applied for a natural product number from the NHPD in 2004 and was still waiting for a response as of fall 2008, despite hours of follow-up activity from its staff. Given that the planned launch of this product line was 2005, the company estimates that this delay has resulted in a total loss of \$7.8 million in potential sales compounded over three years (Stiefelmeyer et al., 2008: 50). Similarly, of the 160 Sisu products submitted to the Natural Health Products Directorate since 2004, 60% had been granted natural product numbers (NPNs) as of mid-2008 (Werb, 2008, Aug. 1).

## The state of the backlog at the Natural Health Products Directorate

Since the Natural Health Products Regulations came into effect in January 2004, Health Canada has received 36,127 product license applications (PLAs). Of this total, 22,227 PLAs have been completed and 11,007 product licenses have been issued.

The NHPD (2009d) reports that during the first quarter of 2009 (January 1 to March 31), a total of 2,743 PLAs were received and 1,675 PLAs were completed. Of those completed, 633 were licensed (37.8%), 485 PLAs were withdrawn (29%), and 557 were refused (33.3%). Among the PLAs that were refused, 43% failed to meet basic application requirements, 26% were refused when applicants did not respond to a request for further information, 26% were refused when the applicant’s response to a request for further



information did not meet the requirements, 3% did not meet the definition of a NHP, and 2% were refused when significant changes were made to the product itself in response to a request for further information.

Table 2 shows that, in the first quarter of 2009, the NHPD was still processing PLAs from as far back as its inception in 2004, while table 3 shows the number of PLAs that were received and completed within the first quarter of 2009. Such processing delays are costly to the Canadian economy. John H. Biggs, owner of Optimum Health in Alberta, has produced a short list of some of the thousands of products that he claims he can no longer get or sell since the NHPR came into effect (Biggs, 2008, June 7). Among his examples are the products of Utah-based Nutraceutical Corporation, makers of the Solaray brand, which he says pulled out of Canada after Health Canada denied its site license renewal four years after the application was submitted (Biggs, 2008, June 7). The loss associated with Nutraceutical Corp.'s departure extends beyond the Solaray brand: according to their website, the company "offers over 3,000 quality vitamin, herb, and specialty products" (Nutraceutical Corporation, 2009).

An analysis of 12 case studies (two of which were natural health products, two of which related to health claim approvals, and the remainder of which involved some form of health-related modification) conducted for Food and Consumer Products of Canada examined the costs associated with Canada's food regulatory system. The calculation included:

direct costs, opportunity costs to the food manufacturing companies looking to develop new food products and/or market products with health claims, potential lost sales for retailers because of lack of product availability and potential lost sales for primary producers. Overall opportunity costs to the economy were also examined; these losses include the food manufacturers and all upstream industries' output (lost sales), wages and salaries, foregone taxes, and employment that would have been created

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**Table 2: Share of product license applications (PLAs) completed (N = 1,675), by year of application, during the first quarter of 2009 (January 1 to March 31)**

2004 PLAs	4%
2005 PLAs	5%
2006 PLAs	23%
2007 PLAs	18%
2008 PLAs	25%
2009 PLAs	25%

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Source: NHPD, 2009d.

**Table 3: Total number of product license applications (PLAs) received and completed during the first quarter of 2009 (January 1 to March 31)**

Type of PLA	Received	Completed*
Homeopathic medicines	933	185
Non-traditional	703	772
Citing a Category IV monograph or labelling standard from the Therapeutic Products Directorate	21	22
Traditional	159	134
Transitional DIN	417	92
Citing a monograph found in the NHPD's compendium of monographs	510	470

\*Note: Includes all submissions that were licensed, refused, or withdrawn by the applicant.

Source: NHPD, 2009d.

due to the economic activity ... Estimated costs associated with the lags outlined in just 12 case studies are more than \$440 million. (Stiefelmeyer et al., 2008: 2)

The backlog at the NHPD continues to build. In the first quarter of 2009, 113 product license amendments and notifications were received and 107 were completed (licensed, refused, or withdrawn by the applicant); 45 site license (SL) applications were received and 41 were completed (licensed, refused, or withdrawn by the applicant). In this same period, the total number of SL renewals received was 119 and 106 were completed, while the total number of SL amendments and notifications received was 96 and 54 of those were completed. As with the other kinds of applications, “completed” submissions include all submissions that were licensed, refused, or withdrawn by the applicant. These numbers demonstrate an increasing backlog as, in each case, the number of new applications exceeds completed applications.

“As defined by the NHPD, the current backlog consists of all PLAs received before April 1, 2008, which were incomplete as of that date. ‘Incomplete’ PLAs includes those for which the NHPD had not rendered a regulatory decision (i.e., the PLA was not licensed, withdrawn, or refused) by April 1, 2008. All other PLAs received after April 1, 2008, are considered regular workload and are not part of the PLA backlog that the NHPD has committed to addressing by March 31, 2010” (NHPD, 2009d). In other words, the growing backlog identified above is not included in the backlog that the NHPD has committed to reduce. Table 4 shows the current status of the PLA backlog.

**Table 4: Total product license application (PLA) backlog as of April 1, 2008\***

Status	Number	Percentage of total backlog
<b>Completed PLAs</b>	4,405	35%
• Licensed	1,780	14%
• Refused	1,676	13%
• Withdrawn	949	8%
<b>Outstanding (remaining backlog)</b>	8,230	65%
• Undergoing an initial assessment against the evidence criteria	3,512	27.8%
• Have been placed in the appropriate review stream and are awaiting a full assessment of their safety, efficacy and quality (this includes PLAs that have undergone an initial assessment against the evidence criteria)	2,712	21%
• Undergoing a full assessment of safety, efficacy and quality	1,503	11.9%
• Assessment complete	503	4%

\*Note: The backlog here includes PLAs for which the NHPD had not rendered a regulatory decision (i.e., the PLA was not licensed, withdrawn, or refused) as of April 1, 2008. All other PLAs received after April 1, 2008, (and the growing backlog thereafter) are considered regular workload and are not part of the PLA backlog the NHPD has committed to addressing by March 31, 2010.

Source: NHPD, 2009d.

## The Natural Health Products Regulations and federal regulatory policy

The federal government's *Cabinet Directive on Streamlining Regulation* (Canada, 2006a) applies to all departments and agencies involved in the federal regulatory process and, therefore, applies to the regulation of foods, foods with health claims, NHPs, and drugs (Smith et al., 2007: 46). In the document, the government states that, when regulating, it will, among other things, protect and advance the public interest, promote a fair and competitive market economy, and make evidence-based decisions:

When determining whether and how to regulate, departments and agencies are responsible for assessing the costs and benefits of regulatory and non-regulatory measures, including government inaction. This analysis should include quantitative measures and, when costs and benefits are difficult to quantify, qualitative measures. (Canada, 2006a)

The regulatory impact analysis statement (RIAS) produced by the NHPD in 2001 dismissed ideas such as voluntary standards on the grounds that they were “not in line with consumer demands for higher safety assurances, more complete and accurate labelling, and consistency of product”

(Ramsay, 2002: 18). The directorate also disregarded the approach taken by the United States, which classifies many NHPs as dietary supplements (though countries such as Australia and those of the European Union consider these products to be drugs). Finally, the NHPD also failed to conduct a credible cost-benefit analysis of the extensive regulatory system it would eventually implement.

The 2001 RIAS was devoid of numbers. All that the RIAS indicated was that, in a competitive market, the costs imposed on manufacturers would be passed on to the retailers, who would then pass them on to consumers. Health Canada's costs were expected to increase initially as the NHP regulations would not be administered on a cost recovery basis right away (Ramsay, 2002: 19). The RIAS also noted that "those NHP manufacturers who also manufacture drugs (and, therefore, hold valid establishment licenses) would not incur significant costs for any additional NHP specific requirements. Manufacturers of NHPs only would probably incur some substantial costs" (Natural Health Products Regulations, Canada Gazette, 2001).

The main anticipated benefits of increased regulation were more information for consumers and increased consumer and health care provider confidence in the safety and efficacy of NHPs. Despite the paucity of data and with a seeming preference for stricter government regulation, Health Canada concluded that the benefits outweighed the cost. It even suggested that "industry may benefit from a resulting increase in long-term, stable demand for NHPs and will be generally better able to compete domestically and internationally through knowledge that Canadian NHPs meet regulatory requirements" (Natural Health Products Regulations, Canada Gazette, 2001: 4927).

In forming the NHPR, Health Canada and the NHPD failed to meet another requirement of the *Cabinet Directive on Streamlining Regulation*, which states that departments and agencies must, among other things, "demonstrate that the regulatory response is proportional to the degree and type of risk" (Canada, 2006a). A later section of this paper will show that the level of danger NHPs pose to consumers is not commensurate with the costs associated with the NHPR.

## **The effect of the Natural Health Products Regulations on the availability of natural health products**

After the passing of the NHPR in 2004, Health Canada focused its activities by dividing NHPs into six priority categories based on the perceived risks associated with the products in each category. Each priority category had its own deadline for submitting product license applications.

A 2006 study by Laeeque and her colleagues looked at companies that sold finished forms of chondroitin and/or glucosamine because those companies had to apply for a NPN by the first deadline, June 30, 2004. The study found that the majority of participants felt that the regulations were necessary for reasons such as establishing industry standards and increasing consumer confidence in NHPs. However, the findings suggested that, because of the regulations, some small firms might not be able to survive and the NHP industry might become more concentrated to ensure economies of scale. Participants in this study seemed to think that smaller firms generally offer specialty products and that if those smaller firms were forced out of business, then many of these specialty products would no longer be available. As with other research on the impacts of regulation, Laeeque and her colleagues found that potential entrants into the Canadian NHP market—particularly small business owners—may encounter greater barriers to entry due to the new regulations, and that the businesses that are already in the industry may have an advantage. [14]

A 2005 survey conducted for Health Canada found that there was low reported usage of Health Canada's new NHP product drug identification number on homeopathic remedy products (DIN-HM) and NPN product information. It also found that 52% of Canadians disagreed that Health Canada was doing a good job of informing Canadians about NHPs (Ipsos Reid, 2005a: 12). Similarly, more Canadians disagreed (60%) than agreed (22%) that they look for a DIN-HM on homeopathic remedy products, and more than three times as many Canadians disagreed (66%) than agreed (21%) that they look for a NPN on natural health products (Ipsos Reid, 2005a: 12).

The findings of the 2005 Health Canada survey suggest that although some Canadians were unclear as to how NHPs are regulated in Canada and by whom, a large majority of Canadians assumed that all NHP manufacturers had to ensure that the products they sold to consumers were safe (91% agreed). Nevertheless, they also expected the federal government to regulate both the claims made by the manufacturers of NHPs (84% agreed) and the products themselves in the same way that the government regulates drugs (76% agreed) (Ipsos Reid, 2005a: 11). At that time, fewer than half (47%) of those surveyed agreed that government regulation of NHPs would make cost a barrier to NHP use, and only 43% thought that regulation would limit access to NHPs (Ipsos Reid, 2005a: 11).

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- 14 There are many studies indicating that small firms bear a disproportionate share of the burden of regulation. Among them is an Organisation for Economic Co-operation and Development study which found that firms employing fewer than 20 employees face an annual regulatory burden that is five times more than the cost faced by a firm employing 50 to 500 employees (Canadian Federation of Independent Business, 2003: 6).

However, in 2008—four years after the new regulations were introduced—one NHP retailer in Canada estimated that health food stores were allowed to sell more than 20,000 fewer natural health products—mostly US imports (Biggs, 2008, June 15). Indeed, there is evidence that when the regulations came into effect, some Canadian NHP suppliers shortened their price list—the number of products they sold in Canada—because of the cost involved in submitting licensing applications for each product (Biggs, 2008, June 15).

Furthermore, in 2008 it was estimated that roughly 60% of all product license applications fail (meaning that the NHP in question must be taken off the market), and that if this trend continues, 60% of NHPs will disappear from the market (Buckley, 2008). That number could even be higher if the following claim is true: that most of the license applications considered by the NHPD from 2004 to 2008 were for single-ingredient products—the easiest to license—and that the failure rate for multi-ingredient products is likely to be higher, perhaps 70% to 75% (Buckley, 2008).

A 2008 NHPD report noted that, of the product license applications that remain with the NHPD for assessment, 70% are of the non-traditional type and 21.1% are of the traditional type [15] (NHPD, 2008b: 2). To reduce this backlog, the NHPD tried to streamline the licensing process. It claims that after doing so, it completed the initial assessment of 80% of the current non-traditional backlog within months (NHPD, 2008b: 3). Where these applications are now in the licensing process has not been made clear.

In 2008, the federal government proposed further regulation for NHPs in the form of Bill C-51, a bill to amend to the Food and Drug Act, which would have greatly strengthened the compliance and enforcement provisions of the act. Not surprisingly, NHP advocates expressed great concern about the future availability of natural health products in Canada. In response, then federal Health Minister Tony Clement told *BC Business*:

I know that 99 percent of natural health products are good products. We want them on the shelves; we want consumers to have more choice. But for the one percent that are the bad apples—that mislabel their products or have some chemicals in them or some compounds in them that could create liver damage or cardiac arrest or increased risk of stroke—we want to get those off the shelf and make sure people know that what they're consuming is safe. (Werb, 2008, Aug. 1)

The irony of Clement's comments is that, irrespective of the NHPR, the Canadian Food and Drug Act prohibits the sale of foods and drugs containing any poisonous or harmful substances or which are adulterated or processed

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15 For more information about these types of licenses, see Appendix C.



under unsanitary conditions, and it is illegal to advertise any food or drug in a false, misleading, or deceptive manner. For the “one percent that are bad apples”—and for actions that were already illegal—the government has taken drastic measures with the NHPR, let alone with any further regulation of the industry.

With no NHP-related deaths on record in Canada, many question why Health Canada and the NHPD are regulating natural health products as drugs. They question the logic of taking products off Canadian shelves when there is no apparent safety risk and when these products are still available for sale in the United States. In addition, due to the extensive—and some would say excessive—licensing process and the resulting backlog that has existed at the NHPD since the NHPR were implemented, additional costs are being incurred.

## **International efforts to regulate complementary and alternative medicine**

Canada is by no means the harshest regulator of natural health products or complementary medicine in general, though it is also not the least harsh, either. In the international realm, lip service is paid to integrating traditional, complementary, and alternative medicine (TCAM) into health care systems, while respecting the fundamental theoretical underpinnings of TCAM. But in practice, most governments are trying to fit TCAM into their Western medicine policy framework.

Traditional medicine is used widely around the world. According to the WHO, up to 80% of the population in Africa uses it to help meet their health care needs, while in China, traditional medicine accounts for around 40% of all health care delivered. Complementary medicine is also popular in many developed countries. For example, 48% of the population in Australia, 70% in Canada, 42% in the United States, 38% in Belgium, and 75% in France have used TCAM at least once, according to a 2002 study by the WHO.

A 2007 study estimated that 40% to 70% of the European population had used some form of CAM; 10% to 20% of the European Union population aged 15 and older had seen a CAM doctor or practitioner within the previous year; and 30% to 50% of Europeans aged 15 and older had used CAM within the previous year (Roberti di Sarsina, 2007).

In developing countries, use of traditional medicine is often attributed to its accessibility, affordability, and its place within the population’s general belief system. In developed countries, influential factors are thought to include concern about the adverse effects of chemical drugs, questions about the approaches and assumptions of allopathic medicine, and the increased prevalence of chronic diseases (WHO, 2002: 2).

The World Health Organization (WHO) is a major proponent of the regulation of TCAM. According to the WHO (2002: 21), a national traditional medicine/complementary and alternative medicine (TM/CAM) policy should include the following key elements: a definition of TM/CAM; safety and quality assurance of TM/CAM therapies and products; the creation or expansion of legislation relating to TM/CAM providers and regulation of herbal medicines; provision for the education and training of TM/CAM providers; promotion of the proper use of TM/CAM; and coverage of TM/CAM by public health insurance, among other things.

At the same time, the organization argues that national policies should benefit patients, and that such policies would fail to do so if they are unable to ensure the safety, efficacy, and quality of TM/CAM products and practices; if they unduly restrict the practice of TM/CAM; lead to higher health care costs; unjustifiably hinder patient treatment options; or reduce the ability of allopathic medicine practitioners to cross-refer patients [16] (WHO, 2002: 21).

In its *Traditional Medicine Strategy 2002–2005*, the WHO set targets for its member states for a national policy on TM/CAM (25% by 2005, up from 13% in 1999) and for laws and regulations on herbal medicines (40% by 2005, up from 34% in 1999). A 2005 WHO survey found that these targets were met or soon to be met: in 2003, 45 (32%) of the responding member states reported having a policy on TM/CAM, and of the states that did not have a national policy, 51 (56%) indicated that such policies were being developed. Furthermore, in 2003, 53 member states (37%) reported having laws and regulations relating to herbal medicines, and of the states without current laws or regulations, 42 (49%) declared that those regulations were in the process of being developed (WHO, 2005: v). Member states that reported having laws or regulations governing herbal medicine indicated that those laws were similar to laws or regulations for conventional medicine (WHO, 2005: 26).

In its 2005 survey, the WHO also asked member states whether a national office for TM/CAM existed and more than half (75 countries, 53%) of the responding states reported having such an office. In most cases, this was a recent development: from 1987 to 2003, the number of national offices throughout the world nearly quadrupled and, from 2000 to 2003, almost twice as many national offices were established as in any other period (WHO, 2005: 19). As Gerard Bodeker and his colleagues note in *Traditional, Complementary and Alternative Medicine: Policy and Public*

16 The fact that, in most countries, patients are paying out-of-pocket for TCAM services that are still not covered by insurance has somehow led WHO to the remarkable conclusion that “adequate government funding is a prerequisite for effective traditional health care services. Under-investment risks perpetuating poor standards of practice and products, and also contributes to maintaining old stereotypes of inferior services and knowledge in traditional medicine” (Bodeker, 2007: 16).



*Health Perspectives*, “the global trend has shifted from being led by consumers and advocacy groups of practitioners, to a situation in most countries where governments are now working towards establishing a full regulatory context for the practice and use of TCAM” (Bodeker et al., 2007: 5). This certainly seems to be the case in Canada.

## **The United States**

The United States defines dietary supplements in a fashion similar to how the Natural Health Products Directorate defines NHPs. However, the US Dietary Supplement Health and Education Act of 1994 places dietary supplements, in whatever form they may take, under the umbrella of foods, not drugs. While the act requires every supplement to be labelled as a dietary supplement, it is the responsibility of the supplement manufacturer to ensure that its product is safe before it is marketed and that its product label information is truthful and not misleading.

By law, manufacturers may make three types of claims for dietary supplements: health claims, structure/function claims, and nutrient content claims. In the United States it is not legal to market a dietary supplement product as a treatment or cure for a specific disease or condition, which is why there was a problem with the claim that Cheerios® cereal could lower cholesterol. The US Food and Drug Administration “declared Cheerios® to be a ‘new drug’ under the act ‘because it is not generally recognized as safe and effective for use in preventing or treating hypercholesterolemia or coronary heart disease’ ” (Brosens, 2009: 3). Such cases show why the US system is not one that Canada should necessarily try to emulate, even though the United States allows more health claims to be associated with food products.

## The regulation of complementary medicine practitioners

In general, there are three forms of occupational regulation: registration, certification, and licensure. In 2001, about 20% of Canadians worked in regulated occupations (Sobkow, 2001: 10).

Registration is the least onerous of the three types. Individuals only have to file their names, addresses, and training level with a government agency before being able to practice their occupation; there may be some fees involved, but there are few specific qualifications required. In the health care field, however, certification and licensure are most common.

Through an examination or another process administered by a government, employer association, or other agency, certification attests that a worker has achieved a certain level of skill, knowledge, and/or ability, and reserves a title for them to use, though it permits others to perform the same type of work a certified worker does. Licensure, however, provides the exclusive right to practice certain tasks, and no matter how skilled someone else may be at those tasks, it is illegal for them to perform those duties without a license.

In the health care field, provincial legislation has created regulatory bodies that define scopes of practice for most professions and reserve the use of a specific title—medical doctor and chiropractor, for example—for practitioners who have passed certain requirements. Provinces differ as to which professions are licensed, and even within licensed professions, the assessment processes, documentation requirements, and licensing processes vary among the provinces. [17]

However, some provincial professional associations have made formal or informal efforts to determine mutually acceptable standards that would allow practitioners in one jurisdiction to practice in another. As well, there are interprovincial agreements that aim to increase labor mobility and eliminate barriers to trade and investment, such as the 1995 Agreement on Internal Trade (AIT), a federal-provincial accord; and the Trade, Investment and Labour Mobility Agreement (TILMA), signed by Alberta and British Columbia in 2006.

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17 The terminology surrounding licensing, certification, and registration can be confusing. For example, a registered midwife in British Columbia is actually licensed, as it is illegal for someone who is not a member of the College of Midwives of British Columbia to perform the work of a midwife.

TILMA requires regulatory authorities in Alberta and BC to recognize each other's certified and/or licensed workers as qualified without requiring additional training or examinations. If an occupation is only regulated in one province, however, a certified worker moving to the province where the occupation is unregulated cannot expect to be certified (British Columbia and Alberta, 2009). For example, before TILMA, chiropractors had to be licensed in the province where they practiced, but under TILMA, chiropractors licensed in British Columbia do not have to obtain a license from the regulatory body in Alberta to practice there, and vice versa (Knox and Karabegović, 2009: 19). This kind of mutual recognition means that, to a certain extent, "government agencies and nongovernment licensing authorities no longer have the monopoly over licensing and certification of professional occupations and trades practicing in their own provinces" (Knox and Karabegović, 2009: 25).

Broadly speaking, it is estimated that interprovincial trade barriers cost from 0.05% to 1.58% of Canada's gross domestic product (GDP), with the lower estimate (0.05%) resulting in a cost of some \$766 million in 2007, or about \$23 per Canadian (Knox and Karabegović, 2009: 1). While the AIT made progress in eliminating barriers to labor mobility, TILMA is a more inclusive agreement in that, rather than listing specific sectors to be covered, it presumes that all measures affecting trade, investment, and labor mobility fall within its purview unless explicitly excluded (Macmillan and Grady, 2007: 8; Productivity Commission, 2009: 352). As well, TILMA has a stronger dispute resolution mechanism than the AIT (Clemens et al., 2006: 19). However, even with TILMA, a province is permitted to require additional measures, such as an exam or course, if it can justify the requirements as serving a "legitimate objective, such as preventing a risk to the public, to the consumer, or the environment" (British Columbia and Alberta, 2009).

Despite its shortcomings, TILMA enhances labor mobility between Alberta and British Columbia. Recognizing this, Canada's premiers committed to amending the labor mobility chapter of the AIT based on the same principles as TILMA at the annual meeting of the Council of the Federation on July 18, 2008, and again on December 5, 2008 (Knox and Karabegović, 2009: 20).

Compared to most international agreements, TILMA has fairly extensive provisions for mutual recognition. For example, TILMA covers much more than the North American Free Trade Agreement between the United States, Canada, and Mexico, which contains limited mutual recognition provisions (Productivity Commission, 2009: 337). European Union member states also have bilateral mutual recognition agreements with a number of other countries, including Canada, but they do not extend to mutual recognition or harmonization of standards or regulations (Productivity Commission, 2009: 349). There is some mutual recognition of selected occupations at a

multilateral level, such as the Asia Pacific Economic Cooperation (APEC) engineer register, launched in 2000, and the APEC architect register, introduced in 2005; Canada is one of the countries that maintains a section of the APEC engineer register (Productivity Commission, 2009: 356–57). However, as Robert Knox and Amela Karabegović (2009: 8–9) note, “most international trade agreements apply to the elimination of tariff barriers and have not progressed very far into the realm of non-tariff barriers, let alone to the small differences in standards, regulations, and administrative practices that do not necessarily restrict trade but might impede trade or make it inefficient.”

## **Licensed complementary medicine practitioners in Canada**

Some professions have a longer history of being licensed than others. Chiropractors have been licensed in all provinces since 1992. Since 2004, all provinces have had legislation requiring registration with a provincial licensing authority as a condition of practising as a dietitian and reserving the title of dietitian for registrants. And physicians have been licensed in all provinces in Canada for more than a century (CIHI, 2006). In 1994, Ontario became the first province to license midwifery; in 2005, the Northwest Territories became the most recent Canadian jurisdiction to do so.

Midwifery is licensed in Alberta, British Columbia, Manitoba, Northwest Territories, Ontario, Quebec, and Saskatchewan; legislation has yet to be implemented in Nova Scotia and is in progress in New Brunswick (Canadian Midwifery Regulators Consortium, 2009a). The seven provinces with licensure have formed the Canadian Midwifery Regulators Consortium and have created the Multijurisdictional Midwifery Bridging Project, a seven-month pilot project that started this spring, which is designed to help qualified midwives educated outside the country to practice in Canada (Canadian Midwifery Regulators Consortium, 2009b).

Most complementary medicine practitioners are licensed only in certain provinces. For example, the occupations of naturopath and naturopathic doctor are licensed in Alberta, British Columbia, Saskatchewan, Manitoba, Nova Scotia, and Ontario (CICIC, 2009). In Quebec, the naturopathic professional association is lobbying for provincial regulation to “offer the highest standard in natural medical therapies to the citizens of Quebec while ensuring practitioners have qualified education and training with a defined scope of practice” (Quebec Association of Naturopathic Medicine, 2004).

The profession of massage therapy is licensed in British Columbia, Ontario, and Newfoundland and Labrador. The regulatory bodies in these three provinces are exploring the different entry-to-practice competencies between the regions, with the goal of moving toward a common standard

(College of Massage Therapists of British Columbia, 2009: 2). In other areas of the country, there are professional associations that have standards for membership that may transfer to other regions. For example, the Massage Therapy Association of Manitoba has received permission from the College of Massage Therapists of Ontario for its members to use the titles of massage therapist, registered massage therapist, and massage therapy [18] (Massage Therapy Association of Manitoba, 2007). But in Nova Scotia, the Massage Therapists Association of Nova Scotia is “the only association in the province of Nova Scotia with the purchased right to use the trademarked title of massage therapist and registered massage therapist” (Massage Therapists Association of Nova Scotia, 2009).

British Columbia and Ontario license both traditional Chinese medicine and acupuncture, while Alberta and Quebec license acupuncture only (CMAAC, 2009b). In addition to those two provinces, the Chinese Medicine and Acupuncture Association of Canada has chapters in Manitoba, Newfoundland and Labrador, Nova Scotia, and Saskatchewan, and there have been discussions between at least Newfoundland and Labrador, British Columbia, Alberta, and Quebec (since Ontario’s regulatory body was only recently created) about the potential for developing standards for mutual recognition and labor mobility between the provinces with licensure and those without (CMAAC, 2009a).

In provinces that do not yet have a regulatory body for a certain profession, employers may still require candidates to be qualified for membership in the provincial association (CICIC, 2009). For example, while aromatherapist is an unlicensed occupation, members of the Canadian Federation of Aromatherapists (CFA) “are entitled to the legal designation of the certification mark CAHP [certified aromatherapy health professional]. Successfully writing the CFA national exam, holding professional liability insurance, and having current CPR/first aid qualifications are all mandatory requirements for professional members of the CFA” (CICIC, 2009). As well, the Quebec Association of Naturopathic Medicine, for example, warns that certain practices may be limited in jurisdictions that do not regulate naturopathic medicine (Quebec Association of Naturopathic Medicine, 2004).

But despite the progress made with various forms of mutual recognition, there are still barriers to labor mobility for CAM practitioners and others in Canada’s health care sector. Interprovincial trade barriers are not the only concern, however, as different types of regulation have different costs. Even if mutual recognition agreements meant that every licensed practitioner across Canada had to meet the exact same standards for their respective

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18 The College of Massage Therapists of Ontario protected these titles under the Trademarks Act of Canada and thus controls their use (Massage Therapy Association of Manitoba, 2007).

profession and, therefore, could practice anywhere in the country, other forms of occupational regulation might be more efficient.

## The regulation of occupations

The main arguments given for licensing and certification include protecting public health, ensuring a highly trained and competent workforce, reducing recruitment costs (the standard serves as evidence that a skill exists, thereby simplifying selection decisions), and increasing the status and compensation of certified/licensed members (Sobkow, 2001: 8–9). While the reasoning behind licensure and certification may be similar, there are several economic studies that point to licensure as the most costly and restrictive form of occupational regulation.

While only qualified practitioners are allowed to use a designated title under a certification scheme and thus there is some form of quality assurance, other people are allowed to perform the same services as a certified practitioner. In general, a certified practitioner's fee is higher than a non-certified practitioner's fee because there are costs to becoming certified (e.g., examinations and fees for association membership) and maintaining one's certification status (e.g., periodic reviews of members' work by the certifying entity). But since consumers also have the choice of using a less expensive non-certified practitioner, there are more practitioners overall and more competition generated between them. Consequently, there are more constraints on wages and prices with a system of certification than there are with a system of licensure.

Under licensure, only licensed workers are legally allowed to do a particular job. As a result, there is less competition within a profession and thus generally higher prices for the services licensed workers provide relative to certified workers. Kleiner and Krueger (2008) estimate that in the United States, where, in 2006, 29% of the workforce was required to hold an occupational license, licensing has about the same impact on wages as unions—and increase of about 15%. A follow-up study found that in 2008, 38% of US employees were or were about to be licensed or certified by the government, and that licensing was associated with about 14% higher wages (Kleiner and Krueger, 2009: 2). That study also found that “the certification variables, although positive, are usually not statistically significant and the coefficients are of a much smaller magnitude than was found for licensing, averaging between 7 and 11 percent” (Kleiner and Krueger, 2009: 14). It concluded that “licensing policies, with regulations that require additional effort to get into the occupation, matter more in wage determination than the government merely giving its approval of a title for an occupation” (Kleiner and Krueger, 2009: 15). Furthermore, in *Licensing Occupations: Ensuring Quality or Restricting Competition?* Kleiner notes that:



State-regulated occupations can use political institutions such as state legislatures or city councils to control initial entry and in-migration, thereby restricting supply and raising the wages of licensed practitioners. There is assumed to be a ‘once and for all’ income gain that accrues to current members of the occupation who are ‘grandparented’ in and do not have to meet the newly established standard ... Individuals who attempt to enter the occupation in the future will need to balance the economic rents of the field’s increased monopoly power against the greater difficulty of meeting the entrance requirements. (2006: 11)

In Ontario, for example, the College of Nurses of Ontario has required a degree in nursing for entry to practice since 2005, but as the requirement changes, diploma graduates who are already practising will be able to continue without mandatory upgrading. In British Columbia, a bachelor’s degree was required to practice as of 2008, and in Alberta, a bachelor’s degree will be required by 2010 (CIHI, 2006: 202).

In Canada, 15.2% of the 2004 registered nurse (RN) workforce began their career with a baccalaureate in nursing, an increase from 11.8% in 2000, and the proportion of RNs with a university degree as their highest education also increased, from 24.4% in 2000 to 32.1% in 2004 (CIHI, 2006: 207).

Provider groups seem to fight for licensure and increased education requirements on the basis that more education translates into greater quality. But since stricter requirements reduce the number of entrants into a profession, increase prices, and reduce access to care, licensure could just as easily lead to worse health outcomes (Svorny, 2008: 5). Furthermore, as Svorny notes, “without legislatively mandated education requirements or scope-of-practice restrictions, hospitals and other providers could better adjust their workforces when demand shifts, or when opportunities arise to reduce costs—either by making care more convenient or by saving patients money—while maintaining quality” (Svorny, 2008: 12).

Critics of licensure also charge that it only benefits those already practising. [19] Barriers to entry into a profession allow licensed practitioners not only to earn a higher income than they would otherwise, but also to restrict or control the complaints and disciplinary procedures against them (Kleiner and Krueger, 2008: 2). Because government regulators generally rely on licensed professions to regulate themselves, it is often left to the professional colleges or associations to screen potential entrants into the profession, investigate patient complaints, and determine how members are to be

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19 It is interesting to note the similarities between licensure and regulation. In many ways licensure benefits those already practicing at the expense of consumers and new entrants. Similarly, regulation in many ways benefits larger incumbent producers at the expense of smaller competitors, new entrants, and consumers.

disciplined. This can lead to conflicts of interest as professional members may not always report a colleague's mistake or misbehavior (Svorny, 2008: 7). For example, a study of US state medical boards found that the boards "may be more likely to discipline older physicians and non-certified practitioners, perhaps in response to special interests of industry members" (Fournier and McInnes, 1997: 113).

There is limited research on the change in productivity or quality of health outcomes before and after licensure has been implemented for a health-related occupation. However, many studies have compared the care provided by physicians and nonphysician clinicians and have found that both resulted in similar patient outcomes, but the latter came at a lower cost (Svorny, 2008; McCord et al., 2009). Some studies have concluded that restrictive occupational licensing may lower service quality, while others have found no correlation at all between licensing and output quality. In addition, there are several economists who suggest that licensing suppresses innovation (Stephenson and Wendt, 2009: 187). In one study, the researchers examined the dental records of US Air Force recruits from different states and found little evidence in output measures, malpractice insurance rates, or complaints to state licensing boards to support tougher licensing; they only found an increase in the prices of some dental services and in dentists' hourly earnings (Kleiner, 2000: 198).

Other research shows that licensing and certification tend to benefit consumers who value quality highly at the expense of those who do not (Shapiro, 1986). Another analysis (Kleiner and Krueger, 2008) compared self-assessments of competency between licensed and union workers and found that individuals in a licensed profession considered themselves more competent, while union members perceived themselves as less competent than other workers. The authors concluded that the contrast suggests that the results are not just due to a higher wage, and that it is possible that quality is improved by licensing. But Svorny (2008) argues that

Quality assurance in today's medical marketplace does not come from state medical boards but from the fear of medical malpractice liability and from market mechanisms such as malpractice insurers; independent certification agencies like the Joint Commission, specialty boards, and credentials verification organizations; consumer guides such as *Consumer Reports* ... and providers' interest in protecting their reputations and brand names.

Many of these same checks on provider behavior exist in Canada, and the safety argument to justify licensing is further undermined when one considers, for example, that the profession of interior designer is licensed in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia,



and New Brunswick. In those provinces, a person must be certified as a full member of the provincial institute or association in order to use the designation “interior design consultant” in his or her practice (CICIC, 2009). This situation is not unique to those provinces. As of 2007, 22 American states had some kind of titling law for interior designers, and three states and the District of Columbia also required designers to acquire government licenses to practice (Carpenter, 2007).

In *Designing Cartels: How Industry Insiders Cut Out Competition*, Dick M. Carpenter (2007) examines the results of the decades-long struggle of lobbyists within the interior design industry to gain stricter regulations on their profession, arguing that a minimum amount of education, experience, and examination—sanctioned by the government—is required to ensure public health, safety, and welfare. The results of Carpenter’s case study indicated that there was no evidence to support the notion that such a danger to the public existed. Among his findings were that consumer complaints about interior designers to state regulatory boards were extremely rare, and that nearly all the complaints filed were about whether designers were properly licensed and not about the quality of service. He also found no statistically significant differences in the average number of complaints against design companies in highly regulated states, less regulated states, and states with no regulation. Theoretically, stricter control over who practices a profession should result in higher-quality practitioners, which should result in fewer complaints. But of the 52 lawsuits involving interior designers that have been filed since 1907, Carpenter found that most dealt with breach of contract issues, while very few addressed safety or code violations.

The relevance of Carpenter’s findings for health professions is manifold. His results indicate that the demand for regulation came exclusively from certain industry leaders and associations, through lobbying, hearing testimonies, sample legislation, letter-writing campaigns, incrementalism, persistent legislative attempts, and other forms of persuasion. Carpenter also noted that titling laws (which ensure exclusive use of a professional title) represented a first step toward full occupational licensure.

An earlier analysis by Elizabeth Graddy (1991) looked at the circumstances in which governments may be more inclined to consider licensing a profession. The study examined six health occupations—dietician, nurse-midwife, occupational therapist, physician assistant, psychologist, and social worker—and found that although organized interest groups did influence how those occupations were regulated, the public interest also played an important role (Graddy, 1991: 25). The study also found that interest groups seek to obtain the regulations they want by giving political support to legislators, and that licensing an unregulated occupation and licensing a certified occupation are both less likely when professional competitors are well organized (Graddy, 1991: 42). Graddy’s study determined that the stronger

the majority party in the legislature and the lower the turnover in its upper house (i.e., the more stable the political market), the more likely licensure is to be adopted, in contrast to certification or no regulation at all. Graddy also found that states with more legislative staff support are more likely to select licensure, and that licensure is preferred over certification or the absence of regulation when the potential risks to consumers are high (Graddy, 1991: 43).

The 1991 study recommended that regulators weigh, for each individual occupation, what consumers might gain from having more information about qualifications and procedures, against the higher prices they may have to pay, the reduction in access to care, and the restrictions on innovation that might result from various forms of regulation (Graddy, 1991: 45).

However, most governments seem to believe that bigger is better with regard to regulation, and that costs are somehow reduced as a statutory regulatory body increases in size. That was the rationale behind the United Kingdom's move to bring practitioners of acupuncture, herbal medicine, traditional Chinese medicine, and other traditional medicines under the umbrella of the multi-professional Health Professions Council (United Kingdom, Department of Health, 2008: 10). In the United Kingdom, the main concerns with regulating complementary medicine practitioners were "the need to minimize the number of titles that are protected, in order to ensure that these titles can be clearly communicated to the public, and are readily understood and seen as credible." But the UK government also recognized that "it is also important that existing, commonly used and recognized titles should be protected in order to ensure that individuals do not use these titles as a means of avoiding regulation" (United Kingdom, Department of Health, 2008: 15). The government steering group that examined these issues recommended that the titles of acupuncturist, herbalist, and traditional Chinese medicine practitioner be protected.

What is interesting about the road to licensure is that, once it starts, there is usually a sense of urgency. In the United Kingdom, the government recognized that "acupuncture has been used in the Orient to restore, promote and maintain good health for over 2,500 years" (United Kingdom, Department of Health, 2008: 30). It also noted that it had been working with practitioners of acupuncture, herbal medicine, traditional Chinese medicine, and other traditional medicine systems for more than a decade in some cases. Yet the steering group that examined these issues was "of the view that there is an urgent need to proceed without delay with the statutory regulation" of these professions (United Kingdom, Department of Health, 2008: 20).

While acknowledging that "acupuncture is a complex intervention and lack of a suitable placebo control has hindered efforts to evaluate efficacy," the steering committee may have felt an urgency to proceed with statutory regulation because of recent randomized control trials—the gold standard for credibility in Western medicine. As the committee's report notes, those trials

established the benefits of acupuncture for knee arthrosis, arthritis of the hip, neck pain and migraine headaches. To this can be added evidence of efficacy in treating more acute conditions such as post-operative pain, nausea and vomiting, anxiety disorders, dysmenorrhoea and pain control after oral surgery. Recent studies have also provided evidence of cost-effectiveness for treating conditions such as low-back pain, headache, knee pain, hip arthritis and neck pain. (United Kingdom, Department of Health, 2008: 30–31)

The committee also noted that because of a positive study on the effect of acupuncture on lower back pain, the German health authorities decided to include acupuncture in routine reimbursement through social health insurance funds for the treatment of lower back pain (United Kingdom, Department of Health, 2008: 30–31).

There seems to be a domino effect with regulation, not only within a country, but also across countries. For example, the effect begins with a question such as, “Why does a country like Germany license acupuncturists, given the relative safety of the procedure as it has been practiced for centuries?” Then, in a matter of years, the question becomes, “Why don’t other countries/jurisdictions cover it, as there is so much potential for harm without regulation?” Indeed, recent research provides evidence that such an effect does exist: initial findings show that the adoption of one or more therapies by a given hospital influences the adoption of other alternative therapies by other hospitals (Park, 2008).

Such a pattern can be seen in Canada, where many legislative and regulatory changes affecting health professionals across the country occurred, or began to occur, between 1995 and 2004 (CIHI, 2006: 10). For example, until 1994, unregulated personnel had practiced midwifery in Canada for years (CIHI, 2006: 121). But that year Ontario became the first province to pass legislation making registration with a provincial or territorial licensing authority a condition of practice as a midwife. Since that time, four more provinces and one territory have introduced mandatory registration or licensure for midwives.

The fact that various countries, states, and provinces in the developed world, with relatively similar health care systems and standards, regulate different professions differently should give us reason to question the validity of the safety and quality arguments for licensure. The fact that “grandfathering” clauses are the norm in the transition from an unregulated to a licensed profession also undermines the safety argument. Empirical work in the 1990s suggests that political influence and funding of licensing initiatives by the professions seeking licensure are the most important factors in determining whether an occupation will become licensed (Kleiner, 2000: 199).

To use another Canadian example, the Chinese Medicine and Acupuncture Association of Canada (CMAAC) is a nonprofit, charitable

organization. On its website, it clearly states that “from its inception in 1983, its mandate has been to lobby for regulation of TCM [traditional Chinese medicine] and acupuncture for the best interests of the public and to protect the high repute of TCM community.” It gives a detailed history of such lobbying efforts from 1996 to 2007, when the College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario was established by the Traditional Chinese Medicine Act of 2006.

One of the association’s arguments for licensure was that there was a need for all practitioners to meet minimum standards, especially medical doctors. “The failure to regulate the profession of TCM will perpetuate the myth that acupuncture is best delivered by a regulated health professional whose membership in the regulated health profession per se does not guarantee adequate training in acupuncture,” the website notes. “Many TCM practitioners voiced their concern over the lack of recognition of their TCM profession and the need for the implementation of regulations.”

Titles were also an “important issue” for the association, “as currently unregulated professionals require a title to lend credibility to the profession and to enable the consumer to differentiate between the varying types of acupuncture that are available, such as anatomical/adjunct acupuncture, and TCM treatment in combination with acupuncture” (CMAAC, 2009b).

For his part, then Ontario health minister George Smitherman is quoted on the CMAAC website as saying, during the discussions leading up to the profession’s regulation, “We owe it to the people of Ontario to ensure they are protected.” His comment that “if passed, this legislation will help give Ontarians confidence in the quality and safety of these treatments” makes Smitherman sound more like a promoter than a watchdog.

Of course, on numerous occasions the CMAAC has stressed safety concerns and the desire to protect the best interests of Ontarians, while also arguing that the practice of traditional Chinese medicine and acupuncture “has always been open to criticism, mainly due to the lack of a regulatory body” (CMAAC, 2009b). Once safety was assured, it was argued, health care costs and waiting lists for conventional care would decrease as more people chose—and were made more healthy by—TCM and acupuncture.

As with the acupuncture licensing process in the United Kingdom, there was a grandfathering of current practitioners in Ontario, and the profession was brought under the purview of the Regulated Health Professions Act of 1991 (RHPA), which regulates several other health occupations, including medical doctors, chiropractors, psychologists, and others. Ontario’s RHPA allows more than one group of practitioners to provide some of the same services. The act also includes the scopes of practice for each of the professions, describing what they (and the other licensed professionals) can do. It restricts the performance of certain tasks to members of specified professions, and it features a clause to prevent health professionals from acting outside

their scope of practice and unlicensed health care providers from treating or advising people about their health or identifying themselves as qualified to practice that profession (Gilmour et al., 2002: 155). Not every profession included in the act is allowed to do all of the controlled acts, and some can do none. There are some exemptions from the prohibition on performing controlled acts—for example, in the case of aboriginal healers and midwives providing traditional services, and those who treat a person by prayer or spiritual means (Gilmour et al., 2002: 155).

The BC government also has a Health Professions Act, to which it added chiropractic, optometry (with its newly created College of Optometrists of BC), and three other professions earlier this year. When the announcement was made in March, Dr. Patrick Bickert, chair of the board of the College of Chiropractors of BC, said,

The movement of the chiropractic profession under the Health Professions Act recognizes the public's desire for more accountability and transparency in BC's health professions, and we will continue to work hard to meet our mandate of ensuring public safety and holding our members to the highest standards of professionalism. (British Columbia, Ministry of Health Services, 2009)

According to the BC Ministry of Health Services, 18 professions, regulated by 17 professional colleges, are now covered under the province's Health Professions Act: chiropractors, dental hygienists, dental technicians, denturists, dieticians, licensed practical nurses, massage therapists, midwives, naturopathic physicians, occupational therapists, opticians, optometrists, physical therapists, psychologists, registered nurses (including nurse practitioners), registered psychiatric nurses, traditional Chinese medicine practitioners, and acupuncturists. All new members of a board of a health profession college are now required to sign an oath that they are guided by the public interest in their duties, and the 17 health profession colleges covered by the act are required to publicly post information about college disciplinary proceedings (British Columbia, Ministry of Health Services, 2009).

Once a profession has attained government licensure, its services will often be covered by a government health plan. That governments do not fund treatments from licensed providers only based on their efficacy or safety is evident in the fact that, in the past, when governments have needed to reduce their budgets, they have removed types of care from their list of insured services. For example, many provincial and territorial governments in Canada stopped funding, or “delisted,” health services like routine eye exams, physiotherapy, or chiropractic, in the mid-1980s and 1990s, but some of those services were later reinstated after public protest (CIHI, 2005: 23).



Gaining access to public funds for the treatments that practitioners of a certain health profession provide seems to be one of the main goals of licensure. This is one of the reasons why other groups competing for government money often will not support their peers' efforts to become licensed. In Australia, as in other countries, medical doctors have pointed out the seeming incongruence between the demand for health care systems to use more cost-effective and evidence-based medicine, while governments spend millions of dollars annually on treatments of questionable merit—meaning CAM treatments, even though there are many conventional medical treatments of dubious value (Westmore, 2004, Apr. 22).

Earlier this year, the head of the BC Medical Association (BCMA) “raised concerns about proposed regulatory changes that would allow BC naturopaths to prescribe drugs, order lab tests and identify themselves as doctors without a qualifier, such as ‘naturopathic,’ in the description” (Stueck, 2009, Jan. 28). “Our main concern is safety and science,” said the BCMA’s president in an interview, while the head of the BC Naturopathic Association stressed, “There’s no confusion with patients. Certainly patients know that our approaches in treatment and how we support the body are different than in allopathic [standard] medicine” (Stueck, 2009, Jan. 28).

But as one study has noted, “When physician groups insist that changes in scope of practice be contingent upon evidence of improved outcomes, politicians should remember that, at present, there is no basis for the claim that patient safety is assured under the current system (an artificial construct of past legislative action) or the claim that patients are at greater risk when state regulation is relaxed” (Svorny, 2008: 13).

## International efforts to regulate CAM professionals

As with NHPs, Canada is not alone in regulating CAM practitioners. Recent action to license CAM practitioners has taken place in Belgium (2003), Catalonia (2007), Denmark (2006), Ireland (2006-2007), the Netherlands (1993), Norway (2006), Portugal (2006), Sweden (2006), and the United Kingdom (1993, 2000, 2007) (Roberti di Sarsina, 2007).

The three most commonly used alternative therapies in Europe as of 2007 were homeopathy, acupuncture/traditional Chinese medicine, and herbal medicine (phytotherapy), and in almost all countries, doctors were allowed to practice any CAM therapy without any real training (Roberti di Sarsina, 2007).

Allowing a medical doctor with little knowledge of TCAM to be a provider of this type of care places the treatment into an allopathic context, rather than creating a more integrated system. For example, in some

countries, acupuncture is offered in clinical settings and no reference is made during the treatment to the theories of energy (*qi*) flow that underlie its use in traditional Chinese medicine (Bodeker et al., 2007: 11). Furthermore, efforts to increase the professionalization of CAM (i.e., through licensing) put pressure on CAM providers to align their practices more with the Western medical model (Welsh et al., 2004).



## The risks of natural health products and complementary medicine

The general argument for more regulation seems to be that, as use of NHPs and other self-care products has increased, so also has concern among consumers over the quality and efficacy of NHPs. The World Health Organization contends that while use of TM/CAM has been increasing, appreciation of its risks and how to avoid those risks has not kept up. For example, the WHO claims that it is not commonly understood that side effects following reactions between herbal medicines and chemical drugs can occur (WHO, 2002: 26–27).

However, there is little evidence to support such contentions. In general, Canadians may be risk averse and show a preference for wanting the government to protect them, but they do not associate many dangers with CAM. The polls cited earlier in this paper seem to suggest that there is even less concern among users of these products and treatments. Other survey data and studies indicate that Canadians are responsible users of self-care products such as NHPs. For example, more Canadians agreed (46%) than disagreed (24%) that many claims made by the manufacturers of natural health products are unproven, but few agreed (12%) that they were advised against using NHPs or that NHPs were harmful to use (14%) (Ipsos Reid, 2005a: 9).

Surveys show that unwanted side effects or reactions to NHPs are not common. Only 12% of NHP users surveyed in 2005 reported experiencing unwanted side effects or reactions to NHPs (Ipsos Reid, 2005a: 9). Further, in a 2006 survey, the participants who said that they had experienced an adverse drug reaction (ADR) most often experienced it as a result of taking a prescription drug (68%), while 6% said their ADR was the result of taking a nonprescription drug; 4% attributed their ADR to a natural health product, and 4% to an interaction between two or more different types of products (Decima Research, 2006: 37).

While other surveys have shown that patients are hesitant to disclose their use of NHPs and complementary therapies to physicians, 50% of respondents to the 2006 survey were likely to contact their physician if they experienced an ADR, 23% would stop taking the drug, 16% would go to the hospital, 14% would report the reaction to their pharmacist, and 4% would not do anything (Decima Research, 2006: 38).

According to the 2006 survey, 78% of Canadians believe consumers should have shared responsibility for drug safety. With respect to specific actions Canadians may take to ensure the safe use of drugs and health

products, respondents were most apt to read product labels and follow instructions for use (87% very likely, 10% somewhat likely), 89% were likely to report an adverse reaction or side effect that they or a family member experienced, and 68% were very likely to obtain information about potential adverse reactions and side effects from various sources (Decima Research, 2006: 22–23).

Though institutions such as the World Health Organization contend that there is a widespread perception among the public that herbal medicines are entirely safe because they are made from natural ingredients, this claim is not borne out by the facts. As most opinion polls show, the vast majority of consumers are well aware that there are potential dangers associated with all types of medication: prescription, over-the-counter, and natural/herbal.

A 2003 Gallup survey on NHPs found that 49% of NHP consumers would hesitate to take certain herbal NHPs because of insufficient safety information. The survey also showed that 58% of NHP users expressed concern about side effects and harmful interactions from taking herbal NHPs (Foster et al., 2006: 3).

Similarly, a 2008 study comparing Canadian and German attitudes found that, despite two different advertising regulatory regimes, both Canadians and Germans (76% and 75%, respectively) recalled a “warning, precaution, or advice” that consumers should follow for consumer health products. There was no doubt in the public’s mind that people with certain health conditions should not use specific nonprescription medicines; this view was held among 92% of Canadians and 85% of Germans. Furthermore, both Canadians and Germans agreed that it is important to read and follow label directions (98% and 91%, respectively) (NDMAC, 2009: 15–16).

That study found that both Canadians and Germans believe that nonprescription medicines have risks (84% and 71%, respectively), yet many believe that those medicines are completely safe (67% and 81%, respectively). To better understand this contradiction, a follow-up study of Canadian consumers was conducted a year later, and Canadian consumers explained that they considered nonprescription drugs safe even though they have risks because adverse reactions may occur with any medication or food, or if individuals have pre-existing health conditions (NDMAC, 2009: 15–16). And despite Germany’s stricter advertising guidelines, Germans less frequently declared that nonprescription medicines have risks and were more likely to view those products as safe.

In general, Canadians seem to be cautious and informed users of NHPs and other self-care products. This, in addition to the data provided below, indicate that, contrary to various assertions, there seems to be no urgent need for more government involvement in regulating NHPs to protect Canadians’ safety.

## Practitioners

The first national study of adverse events in hospitals in Canada was conducted in 2004. According to the Canadian Institute for Health Information (CIHI), 7.5% of adult medical or surgical patients admitted to acute care, non-specialty hospitals in 2000 had an adverse event, more than one-third of which were considered to be “highly preventable” (CIHI, 2007: 2–3). The study defined adverse events as “unintended injuries or complications resulting in death, disability, or prolonged hospital stay that arise from health care management” (Baker et al., 2004). While most patients recovered, about 21% died, though some deaths may have occurred because of an existing condition and not necessarily because of the adverse event. The CIHI notes that an extrapolation of these data across the country suggests that between 9,250 and 23,750 people per year experience a preventable adverse event in hospital and later die—more than the number of Canadians who die from breast cancer, motor vehicle and other transport accidents, and HIV combined (CIHI, 2007: 2–3).

In Canada, most doctors receive malpractice protection from the Canadian Medical Protective Association, which tracks the number of legal actions launched and the amounts paid out to successful complainants. In the 1990s, the association found an increase in the number of malpractice lawsuits, peaking in 1996 when 1,415 lawsuits were filed, but dropping to 1,083 in 2004. The association also found that an increasing proportion of lawsuits that go to trial have judgments in favor of doctors—82% in 2004, up from 73% in 1994—and that patients are making fewer complaints about doctors to regulatory bodies (Canadian Health Services Research Foundation, 2006).

A 1998 article in the *Journal of the Canadian Chiropractic Association* looked at a retrospective review of major disciplinary issues coming before provincial chiropractic regulatory boards, in which all provinces except British Columbia participated. A total of 99 complaints from 1991 to 1997 were reviewed, and the most frequently reported issues were alleged sexual misconduct, lack of professionalism, unskilled practice/excessive billing, advertising issues, and alleged fraud (Toth et al., 1998: 231–32).

Canadian data on malpractice or adverse events involving CAM practitioners are not readily available, but data from the United States illustrate the relative safety of such practices. Of course, all else being equal, one would expect to see more lawsuits against well-insured, highly compensated individuals relative to the number of lawsuits against less well-insured, lower paid individuals. In addition, Western medicine is used more often than CAM in most countries, including Canada and the United States. Thus, irrespective of the actual risks of different treatment modalities and practitioners, there would likely be more lawsuits against medical doctors and hospitals

than massage therapists and acupuncturists, for example. [20] In other words, CAM practitioners could pose a higher risk but be sued less often. That being said, an analysis of the National Practitioner Data Bank's (NPDB) malpractice figures for 1990 to 1996 in the United States found that claims against chiropractors, massage therapists, and acupuncturists occurred less frequently, and usually involved less severe injury than claims against medical doctors (WHO, 2002: 14–15).

The NPDB has maintained records of state licensure, clinical privileges, professional society membership, Drug Enforcement Agency actions taken against health care practitioners, and malpractice payments made for their benefit since September 1, 1990, in the United States. Of the medical malpractice reports made to the NPDB from 1990 to 2004, there were 191,804 regarding physicians, 4,388 regarding chiropractors, 445 regarding nurse midwives, 39 regarding acupuncturists, 10 regarding naturopaths, and five regarding homeopaths (Health Grades, Inc., 2009). This means that of the malpractice reports made to the NPDB about these six types of health practitioners during that period, chiropractors, nurse midwives, acupuncturists, naturopaths, and homeopaths together accounted for only 2% of the reports. By the end of 2006, the NPDB contained reports on 408,730 adverse actions and malpractice payments involving 237,835 individual practitioners (NPDB-HIPDB, 2007: 5). Of the 237,835 practitioners reported to the NPDB by 2006, 69.3% were physicians, 13.3% were dentists and dental residents, 9.2% were professional and para-professional nurses, and 2.8% were chiropractors (NPDB-HIPDB, 2007: 7).

That said, concerns do arise from time to time. In the United States, physicians were responsible for 79% of the medical malpractice payment reports in 2006, dentists for 10.3%, and all other health care practitioners for 10.7% (NPDB-HIPDB, 2007: 7). However, the number of physician malpractice payment reports decreased by 10.7% from 2005 to 2006, and the number of “other practitioners” malpractice payment reports increased by 11.8% (NPDB-HIPDB, 2007: 26).

In addition, in a worldwide literature search reported by the World Health Organization in 2002, 193 adverse events following acupuncture (including relatively minor events such as bruising and dizziness) were identified over a 15-year period (WHO, 2002: 14–15). A much more recent study found that of 39 parents having children with a brain injury who had used CAM (such as osteopathy, massage, aromatherapy, reflexology, and homeopathy) for their children, nine reported suspected adverse effects from the treatment (*eCAM*, 2007: 61).

As well, a 2002 study reported in the *Canadian Medical Association Journal* found that “among people younger than 45 years, the odds of

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20 Under the same reasoning, there would likely be more lawsuits against pharmaceutical manufacturers than producers of natural health products.

experiencing a vertebrobasilar [21] accident (VBA) was increased 5 times if they saw a chiropractor within the week before the event” (Ernst, 2002).

But surveys have shown that “many neurologists encounter cases of severe adverse reactions that occur at various times after cervical manipulation, whereas most practitioners of spinal manipulation are of the opinion that these events are extremely rare” (*eCAM*, 2007: 60). The Canadian Chiropractic Association’s (2009b) website, for example, has an extensive list of studies from 1991 to 2004, conducted by researchers in several different countries, that attest to the effectiveness and safety of chiropractic care for musculoskeletal complaints. The website also notes that millions of neck adjustments are performed annually in Canada without incident, and cites a 2007 study that looked at more than 19,000 chiropractic patients and tracked more than 50,000 neck adjustments and found no cases of serious adverse effects (Canadian Chiropractic Association, 2009a). The association claims that “long-term use of nonprescription pain relievers carries a far greater risk of serious complications than neck adjustment,” and that “recent research into the rare cases of stroke found that patients who visit a chiropractor are no more likely to experience a stroke than are patients who visit their family physician” (Canadian Chiropractic Association, 2009a).

Controversy over the effectiveness and safety of various health treatments illustrates why such concerns may be better handled through the tort system in Canada and not through licensure and strict regulation of entry. Some have argued that courts are best suited to encouraging the use of evidence-based medicine because they recognize “that evidence, and even facts, are disputable, that experts may disagree, and that there is a political element to interpreting evidence,” and they rely on “the robust criticism and testing of positions by opposing camps rather than ... on authority and eminence” (Rodwin, 2001: 444–45). Others have more broadly concluded that consumers would benefit if the education, credentialing, and scope of practice decisions for health care practitioners were left to the private sector and the courts (Svorny, 2008: 2).

## Natural health products

Internationally, no one has been able to make reliable estimates of the instances of illness caused by herbal medicines (MHRA, 2008: 4). The Committee on Identifying and Preventing Medication Errors in the United States could only find three peer-reviewed studies addressing incidence rates for medication errors arising from the use of over-the-counter (OTC) drugs. The committee could find no studies of medication error rates associated with CAM,

21 “Vertebrobasilar” means pertaining to or affecting the vertebral and basilar arteries.

although they did note that these medications have the potential for adverse interactions with prescription drugs (Aspden et al., 2007).

Even with respect to NHP-drug interactions, there are few published reports. One analysis of case reports that tried to establish causality of NHP-drug interactions found that 13% of the reports were well documented, but 69% had insufficient information and could not be evaluated. Of the interactions presented in such case reports, St. John's wort (54 cases, 78.7% of cases) was the most common NHP that interacted with pharmaceuticals; ginkgo (3.7%) and ginseng (2.8%) were the next most common. Warfarin (18 cases) and cyclosporine were the most common drugs that interacted with NHPs (Foster et al., 2006: 3). Table 5 shows several suspected drug interactions with St. John's wort, as well as the number of reports filed with the United Kingdom Committee on Safety of Medicines for each interaction involving St. John's wort—a total of 40 over a period of just under seven years.

The United Kingdom Medicines and Healthcare Products Regulatory Agency says that it receives about 70 suspected adverse drug reaction reports relating to herbal medicines each year, but that it believes that number to represent only a small portion of cases. This belief is based on the fact that when there was much publicity about St. John's wort interacting with other medicines, reporting doubled. The agency expects that with more publicity, as well as the recent extension of the UK's adverse reporting mechanism to patients, self-reporting will increase (MHRA, 2008: 5).

**Table 5: Reports of suspected interactions between St. John's wort and conventional medicines received by the United Kingdom Committee on Safety of Medicines, October 1996 to June 2002**

Compound or medicine	Reports	Comment
Warfarin	4	Increased international normalized ratio (2 reports); decreased INR (2 reports)
Selective serotonin reuptake inhibitors	4	Paroxetine (3 reports); Sertraline (1 report)
Theophylline	1	Reduced serum theophylline concentration
Indinavir, lamivudine, stavudine	1	HIV viral load increased
Tacrolimus	1	Medicine ineffective
Oral contraceptives	14	Intermenstrual bleeding (6 reports); unintended pregnancy (8 reports)
Others	15	Including: HRT (2 reports), atorvastatin (1 report), moclobemide (1 report), verapamil (1 report), enalapril (1 report), lithium (1 report), thyroxine (1 report)

Source: Medicines Control Agency, 2002: 6.



In the United Kingdom, there has been a “handful” of identified deaths associated with the use of herbal medicines and a small number of cases entailing very serious illness, such as kidney or liver failure requiring transplant and other cases involving extended hospitalization (MHRA, 2008: 5). However, most of the safety concerns that the UK Medicines and Healthcare Products Regulatory Agency (MHRA) reports are for herbal remedies containing dangerous or illicit ingredients and the deliberate addition of pharmaceuticals or toxic heavy metals to such products. Compared to adverse reactions, including death, from NHPs, the MHRA reports that “there are a much higher number of cases where MHRA recover from the market dangerous unlicensed products (typically sold in, or destined for, clinics) which pose a clear risk to public health.” A recent example of such a case was a seizure in May 2008 by the MHRA and the police of nearly 500 boxes containing bottles of an unlicensed “herbal” lotion containing steroids (MHRA, 2008: 5).

According to the 2007 annual report of the American Association of Poison Control Centers’ National Poison Data System (Bronstein et al., 2008), analgesics (over-the-counter and prescription) were the most frequently involved substance in human poisoning that year, followed by cosmetics/personal care products and cleaning substances. Table 6 shows that vitamins, with 66,189 cases, were less frequently involved in poisoning than food.

The poison control centers’ 2007 annual report also contains data on deaths by poisoning from various sources. Table 7 is a sampling of the report’s extensive Table 22B, which gives the medical outcomes—none, major, or death—of exposure to single-substance pharmaceuticals. There was one death reported from a dietary supplement and one from an unspecified type of vitamin, while there were nine deaths from cough and cold preparations or antihistamine/decongestant products.

Many years ago, the Uppsala Monitoring Centre of the World Health Organization carried out an analysis of suspected adverse reactions to herbal medicines reported over a period of 20 years. Of the 2,487 cases reported involving single-ingredient herbal products, 21 (0.8%) of the suspected adverse reactions were fatal (Medicines Control Agency, 2002: 24).

In a Swedish study published in 2008, subjective adverse drug reactions were reported by 6.4% of the total study sample: 10.2% of the 2,851 users of prescription drugs (approximately 290 people), 1% of the 2,862 users of OTC drugs (29 people), and 0.1% of the 1,352 users (more than one person) of herbal drugs (Isacson et al., 2008).

As a comparative measure, in 2005 alone, more than 2,000 Canadians died from accidental or intentional poisoning involving drugs (legal and illegal), 2,305 died from falls, 205 died from complications following medical and surgical care, and 122 died from exposure to the forces of nature (Statistics Canada, 2005). It has been estimated that at least 1.5 million preventable adverse medication events occur each year in the United States in hospitals,



**Table 6: Substances most frequently involved in human exposures (top 25) in the United States, 2007**

Substance	Number	Percent*
Analgesics	309,431	12.5
Cosmetics/personal care products	225,410	9.1
Cleaning substances (household)	216,228	8.7
Sedative/hypnotic/antipsychotics	154,602	6.2
Foreign bodies/toys/misc.	127,777	5.1
Topical preparations	111,634	4.5
Cold and cough preparations	111,222	4.5
Antidepressants	98,898	4.0
Pesticides	96,307	3.9
Cardiovascular drugs	86,122	3.5
Alcohols	82,432	3.3
Antihistamines	79,157	3.2
Food products/food poisoning	78,102	3.1
Bites and envenomations	77,325	3.1
Antimicrobials	67,445	2.7
Vitamins	66,189	2.7
Plants	60,514	2.4
Hormones and hormone antagonists	54,613	2.2
Gastrointestinal preparations	54,428	2.2
Hydrocarbons	48,497	2.0
Chemicals	48,400	2.0
Stimulants and street drugs	46,143	1.9
Anticonvulsants	43,080	1.7
Arts/crafts/office supplies	40,140	1.6
Fumes/gases/vapours	40,017	1.6

\*Note: Percentages are based on the total number of human exposures (2,482,041) rather than the total number of substances. Frequency of exposure may reflect availability of the substance.

Source: Bronstein et al., 2008: 944.

nursing homes, and outpatient settings, excluding errors of omission, such as the failure to prescribe necessary medications (Aspden et al., 2007: 5).

In 2006, a total of 38,396 persons died of drug-induced causes in the United States [22] (Heron et al., 2009: 26). In 2005, the US Food and Drug Administration (FDA) received 300,000 reports of serious adverse events

- 22 “Drug-induced causes” includes deaths from dependent and non-dependent use of legal and illegal drugs, and poisoning from medically prescribed and other drugs, but excludes

**Table 7: Demographic profile of single-substance pharmaceuticals exposure cases by generic category**

Substance implicated in the exposure	Number of single exposures	Medical outcome (a)		
		None	Major	Death
Cough and cold preparations and various types of antihistamine/decongestant products	85,159	21,156	164	9
Dietary supplements, herbals, homeopathic (includes amino acids, botanical products, cultural medicines, and hormonal products)	21,687	4,579	34	1 (b)
Vitamin A	550	91	0	0
Vitamin C	1,531	236	2	0
Vitamin E	740	154	0	0
Vitamin category as a whole (including multivitamins and vitamins A, B3, etc.)	58,622	11,496	17	1 (c)

Notes:

(a) Medical outcomes were also collected in categories labelled “minor” and “moderate.” As a result, the numbers listed here do not represent the total poison exposure experience.

(b) Multibotanical with ma huang.

(c) Vitamins – other.

Source: Bronstein et al., 2008: 1020–28.

and 140,000 reports of non-serious adverse events from drug manufacturers, as well as 25,000 reports concerning suspected adverse events associated with drug use directly from individuals (Congressional Budget Office, 2006). While reporting adverse events related to dietary supplements is not mandatory, the Food and Drug Administration’s Center for Food Safety and Applied Nutrition collects safety information that is submitted voluntarily by industry, health care providers, and consumers. In 2005, that program received almost 500 reports of suspected adverse events relating to dietary supplements (Congressional Budget Office, 2006).

Many conjectures have been made about why few adverse reactions to natural products are reported, including the lack of surveillance systems for monitoring NHP adverse reactions in many countries. The WHO, for example, contends that the fact that only 3% of the 771 cases of counterfeit drugs reported to the organization as of April 1997 involved herbal medicines could be the result of limited monitoring, rather than an indication that there are few adverse reactions to herbal products (WHO, 2002: 24). Other explanations for the lack of adverse reactions reported include the reluctance of patients to inform their physicians that they take NHPs, the

unintentional injuries, homicides, and other causes indirectly related to drug use, as well as newborn deaths due to a mother’s drug use (Heron et al., 2009: 26).

fact that physicians do not always recognize the connection between the adverse reaction and the NHP, a failure of physicians to write up the case, and uncertain causality (Foster et al., 2006: 4).

A 2007 survey of Canadian physicians, dentists, pharmacists, and naturopaths found that, overall, only three in 10 health professionals—63% of pharmacists, 43% of physicians, 7% of naturopaths, and 5% of dentists—had ever reported an adverse drug-NHP reaction (Environics Research Group, 2007: 6). This survey also revealed differences in opinions between naturopaths and their medical colleagues. For example, on the whole, 83% to 88% of health professionals considered prescription and nonprescription drugs to be generally or very safe, and 65% felt the same way about NHPs. However, 89% of naturopaths considered NHPs to be safe but were less sure about prescription (45%) and non-prescription drugs (67%) (Environics Research Group, 2007: 4). [23] Disagreement was also found between naturopaths and other health professionals on the subject of adverse reactions: over 80% of the health professionals surveyed considered the adverse reaction problem in Canada to be either somewhat serious (51%) or very serious (35%), but naturopaths (71%) were far more likely than other professionals (26% to 28%) to consider adverse reactions a very serious problem (Environics Research Group, 2007: 6).

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23 In part, this may relate to differing levels of knowledge of and experience with pharmaceuticals and NHPs among different types of practitioner.

# Recommendations

The Natural Health Products Regulations were put in place five years ago, but the Natural Health Products Directorate has yet to provide any evidence that the regulations have improved Canadians' access to safe, effective, and high-quality natural health products. In fact, tens of thousands of NHPs are now off the market, and more than \$90 million dollars—which could have gone towards any number of much-needed health care services, other tax-funded services, or reductions in taxation—has been spent creating the NHPD, drafting the NHP regulations, and beginning the regulatory process. It is likely that the Canadian economy has lost billions of dollars from the economic activity that rejected products and products awaiting licenses would have generated were they allowed to be sold in the country. Dozens of complementary and alternative medicine providers have become licensed in the last two decades, and yet there is no evidence of a discernible improvement in patient care outcomes. The increased number of licensed health professions has likely only secured health providers higher wages and reduced the availability of health care to Canadians.

Since the costs of regulating NHPs and CAM practitioners seem to far outweigh the benefits, this study has two recommendations: the Natural Health Products Directorate should be abolished and all current health practitioner licenses should be replaced with certification.

## 1. Abolish the Natural Health Products Directorate

The cost of the Natural Health Products Directorate has averaged more than \$9 million per year since it was created in 1999, and there is little positive to show for the expenditure. Even ignoring the substantial costs to the Canadian economy from business lost because of the NHPR, the amount spent on the NHPD cannot be justified in terms of lives saved or adverse reactions avoided. If the incidence of adverse reactions and death from NHPs in Canada is similar to that in the United States and the United Kingdom, then each year in Canada there are two to six deaths caused by NHPs and 39 to 55 adverse reactions. Based on the cost of the NHPD alone and assuming that the NHP regulations could result in zero deaths or adverse reactions, Canadians are annually spending more than \$1.5 million for each death or nearly \$166,073 for each adverse reaction avoided. Though this is an extremely rough calculation, the cost of the NHPD seems exorbitant relative to the risk posed to Canadians by natural health products.

### Estimating the cost per life saved by the NHPD

Averaging the total cost of the Natural Health Products Directorate (operating costs, salaries and wages, and transfers for research programs) since its inception in 1999 to fiscal year 2008-2009 yields an annual expenditure of approximately \$9,133,998 over 10 years.

If the ratio of drug deaths (38,396) to adverse drug reactions (465,000) in the United States is the same as the ratio of dietary supplement deaths to adverse reactions from supplements (500), this would mean that 41.29 or, rounding down to the last “full person,” 41 Americans died in 2005/2006 from using dietary supplements.

The United Kingdom reports 70 herbal medicine adverse reactions and a “handful” (between 3 and 10, for the sake of the argument) of deaths from herbal remedies annually.

According to data from the US Central Intelligence Agency, as of July 2009, Canada had about 55% of the population of the United Kingdom and 11% of the population of the United States. This means that, rounding to the nearest whole number, each year in Canada there are between 39 (using the UK figures) and 55 (using the US figures) adverse reactions to natural health products, and between two and six deaths (using the UK figures as the outer ranges because the American figures result in an estimate within them: five deaths per year).

The upper estimates of adverse reactions (55) and deaths (6) were used on page 57 to calculate the cost of the NHPD for each adverse reaction and for each death avoided if the directorate could eliminate either (not both).

Once the NHPD is abolished, independent groups could verify the safety and quality of NHPs and their manufacturers, distributors, and other parties in the process. One example of such a group is the Nonprescription Drug Manufacturers Association (NDMAC), which for decades has had a number of voluntary codes and guidelines for the industry, covering such issues as marketing practices, labelling, advertising, and poison control. Another example is the Canadian Standards Association (CSA), which works in Canada and internationally to develop standards for areas as diverse as business management, construction, and health care. In health care, for example, the CSA has set minimum requirements for safety in medical devices, buildings, technological systems, and the management of professional practices (CSA, 2009). Both the NDMAC and the CSA offer training and resources for members. In the United States, the American Botanical Council has a program that provides safety information on contraindications, pregnancy,

and lactation warnings, among other things, and information about adverse events in order to help consumers use herbal remedies responsibly. It also offers courses on herbs (Foster et al., 2006: 12–13).

Health Canada could still make known any safety risks it discovers and warn the public and care providers through professional journals, the media, its website, advertisements, and other means. As Laeeque and her colleagues (2006) argue, strict enforcement policies, such as inspections of industry premises, are expensive and time-consuming; publicly available lists of approved products or companies could improve the likelihood of compliance more effectively than increasing enforcement. Non-regulatory forces are often more effective and efficient at generating desired outcomes, as “private incentives and market forces are driven by societal pressure to act responsibly in order to maintain their ‘license to operate,’ while attracting and retaining key employees, maintaining customer relationships, and managing public reputation” (Certified General Accountants Association of Canada, 2006: 79).

## 2. Certify rather than license

All current health practitioner licenses should be replaced with certification, and various organizations should be given the opportunity to become certifying agencies. Any current debates about licensing more professions should be redirected towards certification.

Certifying practitioners of CAM would give consumers more choice when selecting a health care provider. Consumers could pay a higher fee for a practitioner with government-sanctioned skills (i.e., through a professional college) or a practitioner who is considered qualified in certain skills by an independent certifying organization or competing professional associations [24]; or they could pay a lower fee for a practitioner without such certification. Since it allows for more choice, certification should result in lower service fees than licensure, and there is evidence to support that contention. Competition among many providers will make it very difficult for any one provider or group of providers to achieve above-normal profits or economic “rent.” Further, provider quality would likely be more actively monitored and

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24 Currently, there are various pieces of legislation that concern health care practitioners, as well as specific practitioner colleges that regulate their members. There is no need to have just one college or certifying/accreditation body for each health profession. In the United States, for example, the Joint Commission is a private standard-setting and accrediting organization that relies on providers of health care services (hospitals, laboratories, disease-specific programs, etc.) to voluntarily subscribe to its service and pay the commission to assess and educate them on quality. In total, the commission accredited about 16,000 organizations and programs in 2008 (Wachter, 2009b).



standards more aggressively maintained because of competition between certifying organizations and professional associations. [25] This would encourage higher quality among providers than if registration was the only requirement to practice health care or if a monopoly licensing organization was created by the government.

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- 25 Svorny (2008) notes that brand names and reputation are used in many industries to assure quality, but that brand names have played a smaller role in health care, perhaps because of the prevalence of licensing boards. However, Svorny also notes that “brand name and reputation are growing as a basis for quality assurance in health care markets” and would likely play an even greater role in the absence of government licensing (2008: 11).

# Appendix A: Schedule 1 of the Natural Health Product Regulations

The following is taken directly from Schedule 1 to the Natural Health Product Regulations (Natural Health Products Regulations, Canada Gazette, 2001).

## SCHEDULE 1 (Subsection 1(1))

### INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2.	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3.	Any of the following vitamins: <ul style="list-style-type: none"> <li>biotin</li> <li>folate</li> <li>niacin</li> <li>pantothenic acid</li> <li>riboflavin</li> <li>thiamine</li> <li>vitamin A</li> <li>vitamin B6</li> <li>vitamin B12</li> <li>vitamin C</li> <li>vitamin D</li> <li>vitamin E</li> <li>vitamin K1</li> <li>vitamin K2</li> </ul>
4.	An amino acid
5.	An essential fatty acid
6.	A synthetic duplicate of a substance described in any of items 2 to 5.
7.	A mineral
8.	A probiotic

SCHEDULE 2  
(Subsection 1(1))

EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item Substances

1. A substance set out in Schedule C to the Act
2. A substance set out in Schedule D to the Act, except for the following:
  - (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and
  - (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3. A substance regulated under the Tobacco Act
4. A substance set out in any of Schedules I to V of the Controlled Drugs and Substances Act
5. A substance that is administered by puncturing the dermis
6. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

## Appendix B: Medicinal versus non-medicinal ingredients in Canada

According to the NHPD's *Evidence for Safety and Efficacy of Finished Natural Health Products Version 2.0 —December 2006*, certain ingredients may have both non-medicinal and medicinal properties, depending on dosage. For example, if peppermint oil is used as a flavouring agent within a specified concentration limit, then the NHPD will consider it a non-medicinal ingredient. However, if the concentration of peppermint oil exhibits pharmacological activity, it needs to be assessed as a medicinal ingredient and declared as such on the product license application and label.

The NHPD document also notes that herbs that do not have a recognized non-medicinal purpose are generally unacceptable as non-medicinal ingredients. One example given in the document is a product containing echinacea leaf powder as filler in an echinacea root capsule. While there may not be a safety concern, the leaf powder has pharmacological effects and, therefore, does not meet the definition of a non-medicinal ingredient.

The reason for this approach, the document explains, is that all NHPs in large amounts can have pharmacological effects and, for most of these products, a minimum dose—below which the ingredient could be treated as non-medicinal—has not been determined.

## Appendix C: Levels of evidence required in Canada <sup>[26]</sup>

According to the Natural Health Products Directorate's *Evidence for Safety and Efficacy of Finished Natural Health Products Version 2.0—December 2006*, health claims are assessed by the directorate based on the credibility, strength, and quality of evidence provided to support the claim. Different types of claims require different levels of evidence. The NHPD permits three types of claims: therapeutic, risk reduction, and structure-function.

Therapeutic claims relate to the diagnosis, treatment, and mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans. Risk reduction claims describe the relationship between using a medicinal ingredient and reducing the risk of developing a specific disease or abnormal physiological state. Structure-function claims describe the effect of a medicinal ingredient on a structure or physiological function in the human body, or a medicinal ingredient's support of an anatomical, physiological, or mental function.

Products are divided into two categories according to the claim: traditional use claims and non-traditional use claims. Traditional medicine includes practices based on the beliefs and experiences indigenous to different cultures that are used in the maintenance of health, as well as in the prevention, diagnosis, or treatment of illness. Products with traditional use claims are divided into two subcategories, according to the evidence provided: pharmacopoeial evidence for traditional use claims (which only require one reference) and other evidence for traditional use claims. Applicants who make a traditional use claim but do not meet the requirements of the first category must provide at least two independent and reputable references supporting the conditions of use.

In the case of oral traditions, the NHPD requires that an indigenous, ethnographic, professional, and/or scientific authority prepare a written account of relevant information from recognized authorities on traditional healing. Their evidence must support the traditional use of the product and how it is used (e.g., dose, duration of use, and risks). They must also show that the ingredient has been used in such a manner for more than 50 years.

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26 All of the information in Appendix C is taken directly from the Natural Health Products Directorate's *Evidence for Safety and Efficacy of Finished Natural Health Products Version 2.0—December 2006* document.

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