Tuck's Paralegal Services o/b Trueman Tuck
Office: Bldg. 1, Suite 4, 6835 Highway 62 North, Belleville, Ontario, Canada K8N 4Z5
Mailing: P.O. Box 160, Foxboro, Ontario Canada K0K 2B0
Tel: 613-968-3007 Toll-free: 1- 888-611-5243
Fax: 613-968-3215 Fax-free: 1- 888-872-7035
www.tucksparalegalservices.ca www.theparalegallitigator.com
Trueman@tucksparalegalservices.ca

A full service, Ontario wide Paralegal Legal Services Firm getting results for our clients since 1995!

URGENT – PERSONAL ATTENTION OF HON DR. ERIC HOSKINS

Delivered by Courier
And emailed to: ehoskins.mpp.co@liberal.ola.org and all MPPs

February 2, 2015

Tel: (416) 656-0943

Page(s): 4 plus 6 Exhibits

Hon Dr. Eric Hoskins, MPP
Minister of Health and Long Term Care
803 St. Clair Ave West
Toronto, Ontario M6C 1B9

Dear Hon Dr. Eric Hoskins,

Re: Urgent request for further postponement of the proclamation of the amendments to *RHPA, Psychology Act* and *Psychotherapy Act for six months while the issues are discussed with all affected Health Practitioners and the affected public to allow resolution of the interpractice conflicts with the new amendments*

I have been retained by concerned self-employed non-pharmaceutical-based Health Care Professionals and consumers who depend on Traditional Natural Health Care approaches as their primary health care system.

My clients are concerned that their constitutionally guaranteed rights of *INFORMED FREEDOM OF CHOICE* both in health care treatments and self-employed trade and commerce careers are being violated by the above-noted undemocratic and against-public-interest legislative amendments.

If your government permits implementation of these three flawed amendments, it is my clients' position that your government will not only become responsible for causing harm to the health and well-being of Ontario citizens, but there will be increased deaths from pharmaceutical drugs/medicines as vulnerable individuals are denied access to safer natural remedies and treatment options.

You and your government need to be aware that these same medical/pharmaceutical cartel schemes were attempted in the UK and failed. Please see **Exhibit 1,** being a letter from Terence Watts, MCGI dated April 28, 2014, explaining how absurd it is to create a situation where hypnotherapists are regulated by psychotherapists. His statements are extremely relevant since he is a highly regarded psychotherapist and hypnotherapist worldwide.

Also, for your convenience, attached as **Exhibit 2,** is the Fraser Institute Study on these related regulatory issues dated September 2009, authored by Cynthia Ramsay.

There is serious misinformation being circulated relating to these three amendments. There are claims being made that you and your staff have assured non-pharmaceutical health care providers and select organizations that the three above-noted amendments will have no impact on the current trade and commerce activities of thousands of non-pharmaceutical regulated and unregulated self-employed health care professions in Ontario. This is obviously not the case since their treatments are now 'controlled acts'!

I have spent decades defending Dr. J. Krop and supporting M. Kwinter's 2000 legislative initiative designed to prevent harassment of medical doctors while encouraging full and equal access to both pharmaceutical and traditional natural health care approaches. The initiative also successfully dealt with pharmaceutical cartel restraint of trade and commerce across this country and internationally, including with Health Canada.

I was successful in convincing the Federal Minister of Health to intervene and to stop Health Canada staff from intercepting lawful import shipments of natural remedies in the past, but not in time to prevent needless deaths and disability. It is my belief that you and your staff could find yourselves in the same situation if you insist on forcing people to accept electroshock, chemical lobotomy and harmful diagnoses that cannot be supported by scientific fact, instead of continuing their current safe, freely-chosen and effective natural remedies and treatments.

Psychiatric treatments are already controlled under the *Psychiatry Act*. Further regulation of psychiatric treatments under a new 'controlled act of psychotherapy' is unnecessary. There is no justification for permitting the appropriation by psychologists of natural treatments and remedies and the subsequent pooling of these with dangerous psychiatric approaches, which then facilitates a false claim that a new controlled act is necessary to 'protect the public'.

I coauthored an award winning book called *Death by Modern Medicine* a number of years ago that proved, using medical records, that there was at least the equivalent of seven [7] jumbo jets per day full of passengers dying needlessly in North America as a direct result of the pharmaceutical health care system's mishandling of their activities [See **Exhibits 3 & 4**].

I have a very important legal, duty-of-care question for you. Have you personally undertaken your own legal due diligence review of the documentation pertaining to the specific social evil the three above-noted legislative amendments were purportedly designed to protect the public from? If so, could you please forward a copy to the undersigned immediately so that I may understand the pith and substance these legislative amendments were intended to address.

According to the Orthomolecular Association, Dietary Food Supplements are one area of Traditional Natural Remedies, as an example, that produces *zero deaths* in a year. **Exhibit 5** attached provides a comparison of the proportionate risk of death in Canada from all causes. Note that pharmaceutical products are over 20,000 times more likely to cause death than Dietary Food Supplements.

It is my understanding that you and your staff are well aware that the three above-noted amendments had not been properly circulated to the affected legal entities before the Omnibus Bill they were embedded in underwent a 3rd reading and Royal Assent. I further understand that this fact was raised by concerned MPPs at the time the legislation was being processed.

As Ontario citizens, my clients are extremely concerned that their wealthy and powerful competitors are permitted by their government to use this type of legislative sneak attack to interfere with the free market provision of health care services by self-employed professionals in Ontario.

Attached is my letter dated January 23, 2015 requesting that the Hon. Naqvi, Government House Leader immediately intervene and NOT ALLOW the above-noted three competitor-created amendments given Royal Assent in Omnibus Bills 171 and 179 in 2007 and 2009, respectively, to be proclaimed into Ontario law [See **Exhibit 6**].

Please see details of my client's' concerns at the website http://www.stoppsychotherapytakeover.ca. Please also note that at the website http://tinyurl.com/qxwczo2 there are already over 6,600 signed petitions supporting our request that these three ill-conceived competitor-created legislative amendments not be implemented into law.

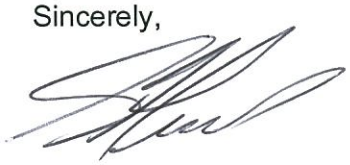
We have only been retained recently and are conducting a thorough investigation into the origins of these three legislative amendments and what potential Provincial and Federal Statutes may be applicable for criminal and/or civil interventions should the postponement that we have requested be refused or ignored.

Could you please advise whether business impact studies were conducted?

We are also immediately filing a Freedom of Information Request.

As we collect the information and determine the consensus of the affected regulated and unregulated health care professionals we will provide your office with a detailed brief and proposal.

Sincerely,



Trueman Tuck
Lobbyist, Regulatory Consultant
& Paralegal Litigator

Copy to All MPPs by e-mail and cover by fax

Exhibit	Document Description
1	Letter from Terence Watts, MCGI dated April 28, 2014
2	Fraser Institute Study authored by Cynthia Ramsay, dated September 2009
3	*Death by Modern Medicine* Outline
4	Jumbo Jet Study Results
5	Orthomolecular Association Article titled "No Deaths from ANY Dietary Supplement" by Andrew W. Saul; Editor dated January 16, 2015
6	Letter to The Hon. Naqvi, Government House Leader from T. Tuck dated January 23, 2015

Exhibit 1

Terence Watts

Fellow of the Royal Society of Medicine
Member of the City & Guilds Institute

Hypnotherapist
Psychotherapist

April 28, 2014

To whom it may concern,

Hypnotherapy and Psychotherapy

As a therapist with more than twenty-five years experience, and whose expertise was considered sufficient that the Secretary of State of the UK Government allowed the use of the term 'Institute' for my school of Hypnotherapy, I feel I am sufficiently qualified to comment on the difference between these two disciplines.

Although there are *some* similarities in *some* of the therapeutic work that may be conducted, to consider that they are one and the same thing is absurd. I use both methodologies, since there are some people who do not receive hypnotherapy very well, or who are anxious about it. I have listed here just a few of the specific qualities of each which illuminate the differences:

- Hypnotherapy deals directly with the subconscious mind while psychotherapy deals primarily with the conscious mind, a process which is is usually slower. This is contributory to the fact that Hypnotherapy will often find a faster relief from symptoms than psychotherapy.
- Hypnotherapy works beneath the 'Conscious Critical Faculty', reducing involuntary resistance; psychotherapy, because it works with primarily with the conscious mind, cannot even get beneath the conscious critical faculty. This one of the reasons why psychotherapy is usually a slower therapy.
- Hypnotherapy is an effective tool for all forms of regression therapy, used to discover and eliminate the cause of deep seated issues. This is not to say that psychotherapy cannot be used for this style of work, only that it can take many more sessions and even then will usually leave 'pockets' of unexplored emotional process, rendering the possibility of a resurgence of symptoms.
- Psychotherapy is perhaps the best therapeutic endeavour where a client is 'hypnophobic' or is one of the few individuals who are unable to enter into a useful working state of hypnosis.
- Psychotherapy works well for conscious processes such as OCD; it is largely unsuccessful when working with situations where subconscious forces are at play. (Smoking cessation and compulsive gambling are good examples.)
- The use of 'Clean' (i.e. non-leading) language during any form of investigative therapy is vital if the risk of innocent people being accused of misdeed is to be avoided. Many psychotherapists are not trained in this concept; *all* regression-centred hypnotherapists are.

/cont.

15 Clarence Road Southend on Sea
Essex SS1 1AN UK
Tel: 01702 345715 FAX: 01702 434432
Email: tw@terencewatts.com
www.hypnosense.com

Hypnotherapy and Psychotherapy (cont.)

- There are many situations which can be effectively resolved with just one session of hypnotherapy, including: *examination and test fears; driving fears; nail biting; public speaking; career stress* and more. Psychotherapy usually needs several sessions to achieve the required result.
- It is not unusual for a client to be uncertain as to the reason for their malaise and they present with no more information than that 'things just aren't right, somehow.' Because it works beneath the level of the conscious and rational mind, hypnoanalysis excels at resolving such a situation, while attempting to use any form of psychotherapy (working with the conscious mind) would be a laborious and potentially fruitless task.

I could continue but feel that I have by now clearly illustrated the differences between the two disciplines. I have concentrated on the advantages of hypnotherapy here because it would seem that it is being proposed by some that there is no special case for this methodology and that it is simply psychotherapy by another name. It is a fact that there are situations in which psychotherapy would be favoured but this only further proves the 'separateness' of each.

Now, there is a school of thought that appears to confuse the act of psychotherapy with other, more diverse, acts of working with the mind. It is fair to say that all psychotherapeutic endeavour acts upon the mind, just as all elephants are grey. But just as all things that are grey are not elephants, all work with the mind is not psychotherapy. A priest works with the mind but does not provide psychotherapy and indeed would probably be poorly qualified to do so. The work of a professional artist, actor or musician has an often profound effect upon the mind, maybe even a healing or soothing effect, yet those individuals can hardly be described as psychotherapists. So it is important not to confuse the act of psychotherapy with the processes conducted by the media, clergy, advertisers - and even the parent comforting a child who has, say, just fallen from a bicycle. The difference can be further illustrated by the indisputable fact that most psychotherapists might be affronted to be described as a salesperson... yet the latter's occupation relies on making a shift - often a diametric shift - in the mental attitude of another. In short, the act of psychotherapy creates a shift in thought process but it is not fair to say that a shift in thought process is always the result of the act of psychotherapy.

Yours faithfully,

Terence Watts, MCGI
Fellow of the Royal Society of Medicine
Member of the City & Guild Institute of London, UK
Freeman of the City of London

EXHIBIT 2

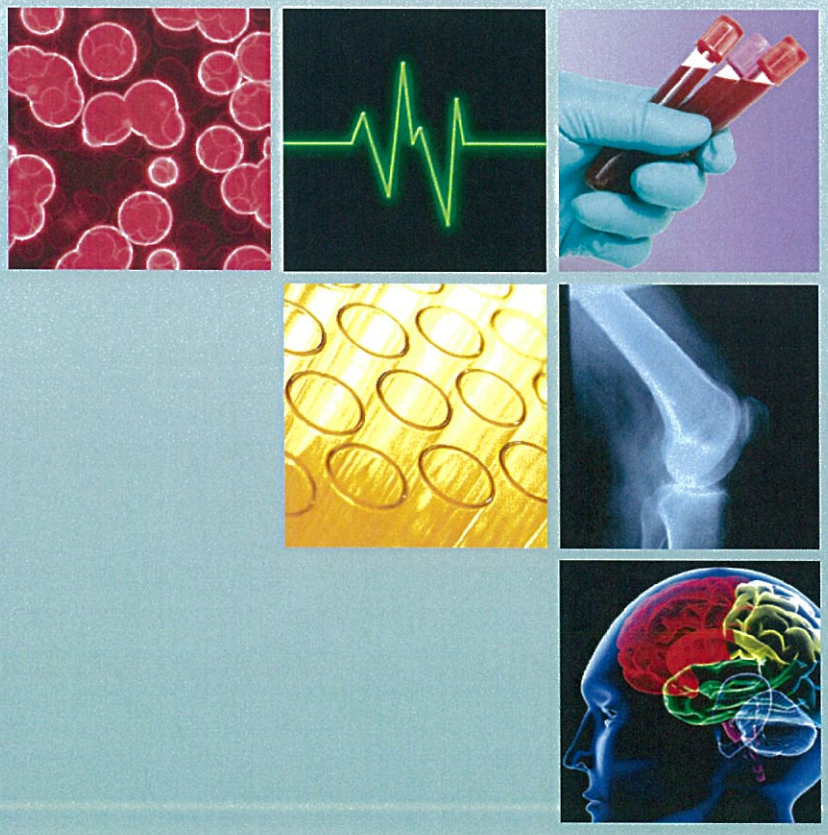
Studies in
Health Care Policy

35 YEARS 1974-2009
FRASER INSTITUTE

September 2009

Unnatural Regulation: Complementary and Alternative Medicine Policy in Canada

by Cynthia Ramsay



Studies in
Health Care Policy

September 2009

Unnatural Regulation: Complementary and Alternative Medicine Policy in Canada

by Cynthia Ramsay

Contents

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

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

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).

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

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

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 the 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).

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).

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, A01.040 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 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

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

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%

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
Completed PLAs	4,405	35%
• Licensed	1,780	14%
• Refused	1,676	13%
• Withdrawn	949	8%
Outstanding (remaining backlog	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).

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

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).

EXHIBIT 3

Matrix Vérité Publishing

"Publishing the Truth for the Truth Seekers"
P.O. Box 160, Foxboro, Ont. Canada K0K 2B0
Cdn. Office: 6835 Hwy. 62 North, Belleville, ON Canada K8N 4Z5
Email: trueman@tucksparalegalservices.ca
Website: www.matrixveritepublishing.com

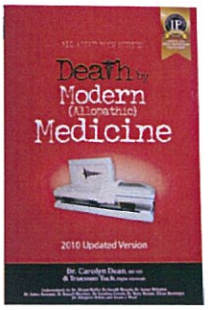
DEATH BY MODERN MEDICINE

by Dr. Carolyn Dean, MD ND and Trueman Tuck

INDEPENDENT PUBLISHER IP AWARD WINNER 2006

WINNER OF THE OUTSTANDING HEALTH BOOK OF THE YEAR AWARD 2006

Presented by the Independent Publishers



"Death by Modern Medicine" proves that the number one cause of death in North America is being lied about and deliberately concealed by our massive maze of sole and aggregate government corporations and the allopathic investment industry private corporations.

The evidence contained in the book proves that in North America, the equivalent of approximately 7 jumbo jets per day, full of passengers are crashing (over 2000 people per day) and in many cases needlessly dying! This is equivalent to approximately the same total deaths that occurred from the 9-11 incident reoccurring every 10 days or so, for a full year!

"Death by Modern Medicine" goes beyond the statistics of deaths due to drugs to how the medical monopoly that created the system in the first place is allowed to control health care. A tale of propaganda, health care bureaucracy, the business of cancer, our own personal addiction to sugar and drugs and the denial we all harbor to help us cope with the overwhelming burden, are all woven into the pages of this 300 page soft-covered book.

Dr. Carolyn Dean MD ND

Trueman Tuck
Paralegal Regulatory,
Crisis Manager & Lobbyist
www.tucksparalegalservices.ca

Sugg. Retail Price - $29.99
Wholesale Price - $19.95 + S&H ($15.00)
(Minimum $200 purchase to access wholesale prices)

Retail: www.tucksdiscountvitamins.com
Wholesale: www.curesnaturally.com

Wholesale Case Discount
1 Case Lot of 30 - 10% off* - $17.96 each
* Shipping & Handling $30.00 per case

Phone: 1-800-246-5589 or 613-968-2187
Fax: 1-888-872-7035 or 613-968-3215

Please reserve _____ books
Name _____
Address _____
_____
Telephone: _____
Email: _____

Total _____
Card # _____
Expiry Date _____
Signature _____

VISA MasterCard AMERICAN EXPRESS

Fax your order directly to:
1-888-872-7035

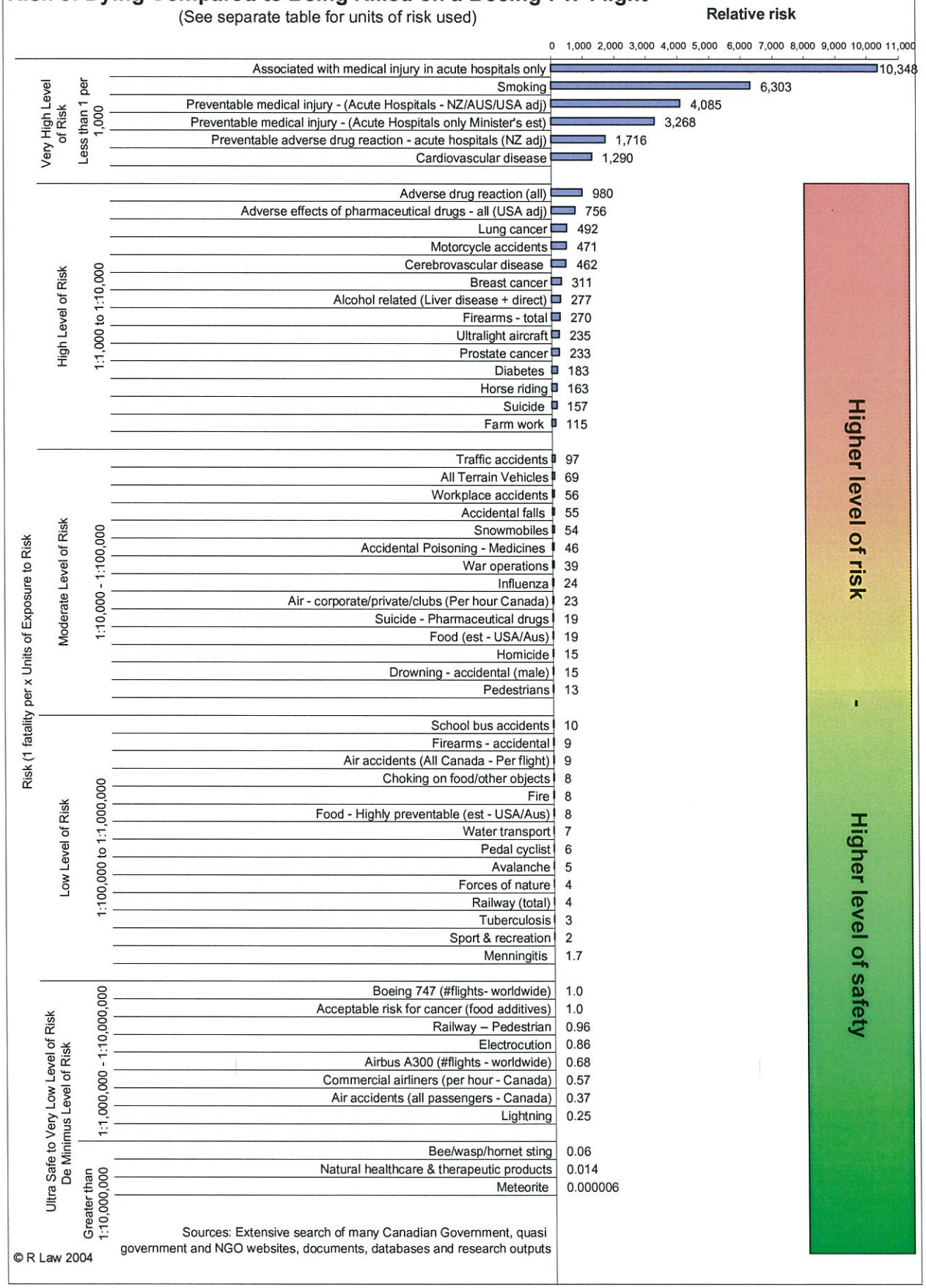
For Media Interviews call Tucks Paralegal Services at 613-968-3007

* Shipping charges for Canada only. Actual shipping charges billed for all exports.

EXHIBIT 4

Risk of Dying Compared to Being Killed on a Boeing 747 Flight

(See separate table for units of risk used)



Sources: Extensive search of many Canadian Government, quasi government and NGO websites, documents, databases and research outputs

EXHIBIT 5

FOFI FRIENDS OF FREEDOM INTERNATIONAL
founded in 1995 to globally preserve, protect and enhance our unalienable human being rights, freedoms and liberties
Freedom Line: 613-968-5599 Fax 613-968-3215 myrights@friendsoffreedominternational.org

No Deaths from ANY Dietary Food Supplement/Traditional Natural Remedy

Category :	**Topic :**
Tuck's Citizen-Rulers/Freeman-on-the-Land communications	Tuck's Citizen/Rulers communications
Date Posted :	**Source Date :**
Jan 19, 2015	Nov 30, 1999
Source Author	**Source Description**
Andrew W. Saul, Editor	Orthomolecular Medicine News Service
Source URL	

FOR IMMEDIATE RELEASE
Orthomolecular Medicine News Service, January 16, 2015

No Deaths from ANY Dietary Supplement

Zero Fatalities from Minerals, Vitamins, Amino Acids, Herbs, Homeopathic Remedies

by Andrew W. Saul, Editor

(OMNS Jan 16, 2015) There was not even one death caused by ***any*** dietary supplement in 2013, according to the most recent information collected by the U.S. National Poison Data System. The new 251-page annual report of the American Association of Poison Control Centers, published in the journal *Clinical Toxicology* (1), shows ***no deaths whatsoever*** from any dietary supplement.

Additionally, there were zero deaths from any amino acid or herbal product. This means no deaths at all from blue cohosh, echinacea, ginkgo biloba, ginseng, kava kava, St. John's wort, valerian, yohimbe, Asian medicines, ayurvedic medicines, or any other botanical. There were zero deaths from creatine, blue-green algae, glucosamine, chondroitin, melatonin, or any homeopathic remedy.

Furthermore, there were zero deaths from any dietary mineral supplement. This means there were no fatalities from calcium, magnesium, chromium, zinc, colloidal silver, selenium, iron, or multimineral supplements. Reported in the "Electrolyte and Mineral" category were two fatalities from the medical use of "Sodium and sodium salts." These are not dietary supplements.

The U.S. National Poison Data System is "the only comprehensive, near real-time, poisoning surveillance database in the United States. In 2013, poison professionals at the nation's 55 poison centers managed about 2.2 million human poison exposures, with children younger than 6 accounting for about half of all poison exposure cases."

No man, woman or child died from any nutritional supplement. Period.

If nutritional supplements are allegedly so "dangerous," as the FDA, the news media, and even some physicians still claim, then ***where are the bodies***?

The Friends of Freedom International
C/O Tuck's Freedom Centre
6835 Highway 62 North, Building 1, Unit 4
Belleville, Ontario, Canada
K8N 4Z5
Phone: (613) 968-5599
Toll Free: 1-800-258-1556
Toll Free Fax: 1-888-872-7035
Fax: (613) 968-3215

Mailing Address
P.O. Box 160
Foxboro, Ontario
Canada K0K 2B0

Contact Us
Phone 1-800-258-1556
Phone 613-968-5599
Fax 613-968-3215
Toll Free Fax: 1-888-872-7035
Email myrights@friendsoffreedominternational.org

Exhibit 6

Tuck's Paralegal Services o/b Trueman Tuck
Office: Bldg. 1, Suite 4, 6835 Highway 62 North, Belleville, Ontario, Canada K8N 4Z5
Mailing: P.O. Box 160, Foxboro, Ontario Canada K0K 2B0
Tel: 613-968-3007 Toll-free: 1- 888-611-5243
Fax: 613-968-3215 Fax-free: 1- 888-872-7035
www.tucksparalegalservices.ca www.theparalegallitigator.com
Trueman@tucksparalegalservices.ca

A full service, Ontario wide Paralegal Legal Services Firm getting results for our clients since 1995!

URGENT – PERSONAL ATTENTION OF HON YASIR NAQVI

FAXED Jan 26/15 T. Trueman Court only.

Delivered by Courier
And emailed to: ynaqvi.mpp.co@liberal.ola.org
And cover only by fax to: (613) 722-6703

January 26, 2015

Tel: (613) 722-6414

Page(s): 21

FILE COPY

Hon Yasir Naqvi, MPP
Government House Leader
Office of the Government House Leader
Room 223, Main Legislative Building, Queen's Park
Toronto, Ontario M7A 1A2

Dear Hon Naqvi:

Re: Urgent request for further postponement of proclamation of the amendments to *RHPA, Psychology Act* and *Psychotherapy Act for six months while the issues are discussed with all affected Health Practitioners and the affected public to allow resolution of the interpractice conflicts with new amendments*

I act on behalf of a number of concerned non-pharmaceutical Health Care practitioners and consumers who depend on non-pharmaceutical health care approaches as their primary health care approach.

Please see the website http://www.stoppsychotherapytakeover.ca and perhaps you can note the over 6,600 petition signatures at http://tinyurl.com/qxwczo2

I understand that in 2009, your government's Omnibus Bill 171 was given Royal Assent. This Bill affected many *Acts,* but as can be seen from the MPP discussion comments at the time, there was no public consultation or time allowed to research and review the three legislative amendments affecting the *Registered Health Professions Act*, the *Psychology Act* and the *Psychotherapy Act.*

These amendments make unlawful the existing practices of some ten thousand non-pharmaceutical Health Care professionals in Ontario and could be considered to be unlawful constraints of trade and commerce activities and a violation of the *An Act concerning Monopolies, and Dispensation with penal laws, etc. R.S.O. 1897, Chapter 323* [See **Exhibit 1**]. As you are likely aware, it is a violation of several Provincial and Federal Acts to conspire to restrict trade and commerce activities of your competitors.

The Amendments awaiting proclamation are;

[1] *Registered Health Professions Act, 1991, Section 27(2)*;

[2] *Psychology Act, 1991, Section 4*, and;

[3] *Psychotherapy Act, 2007, Section 3 & 4.*

We understand that at least the *Psychotherapy Act* amendments have been set down for proclamation in March 2015.

We request that your government decline to set down any of these three ill-founded, against-public-interest, and likely unlawful amendments for proclamation for six months in order to provide my clients and their organization the opportunity to continue canvassing the some 14 Million Ontarians and ten thousand affected Ontario Health Care practitioners for their input into appropriate amendments that would ensure Ontario citizens continue to have access to competent and effective treatments by existing holistic, traditional, spiritual and energy practitioners of their personal choice.

We note that this same effort at monopoly failed in Britain some years ago, because the public refused to accept violations and impositions on their rights to decide for themselves what to eat, drink, think and how to act and react. People around the world insist on their right to define for themselves what is 'normal'.

These same types of issues arose a number of years ago in Ontario in regards to non-allopathic regulated and non-regulated Health Care approaches being used by Medical Doctors in combination with pharmaceutical based approaches. Monte Kwinter's amendment in 2000 attempted to resolve this issue with the following amendment to the *Medicines Act,* 1991 which states, to quote;

"Non-traditional practice

5.1 A member shall not be found guilty of professional misconduct or of incompetence under section 51 or 52 of the Health Professions Procedural Code solely on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient's health than the traditional or prevailing practice. 2000, c. 28, s. 1."

We are canvassing thousands of affected regulated and unregulated non-pharmaceutical based Health Care Professionals in order to develop a detailed brief with legislative reform amendment proposals that would effectively address the protection of public mental health choices without violating the constitutionally protected rights of both patients and non-pharmaceutical-based health care practitioners.

Another critical factor that needs to be taken into consideration is that, as you are aware, all Ontario Citizens have a constitutionally protected right of *Informed Freedom of Choice in Health Care.* I can provide a sworn affidavit from one affected practitioner who has practiced clinical hypnotherapy since 2008 after training in advanced medical and dental hypnotherapy at the government regulated Pacific Institute of Advanced Hypnotherapy in British Columbia. This affidavit will provide evidence that this practitioner who had no interest in psychotherapy and holds no masters degree is regularly referred psychiatric patients to her practice by psychiatrists

and medical doctors in Eastern Ontario, including from the Royal Ottawa Hospital and successfully provide assistance that would become unlawful under these three proposed amendments.

Also attached is a letter written to the Minister of Health and Long Term care from Carole Baker who had been subjected to endless psychiatric and psychotherapeutic treatments for 17 years to no avail [See **Exhibit 2**]. Her conditions were worsening and her physical issues due to medication side-effects were causing serious medical concerns. After 30 days of the above referenced practitioner's natural hypnotherapy treatment, Ms. Baker started full recovery resulting in a return to work, to full family life, and freedom from brain-damaging pharmaceutical drugs.

This is but one example of many documented successes of non-pharmaceutical Health Care approaches that we will be bringing to the attention of all MPPs in order to help them fully understand the importance of appropriately amending legislation to create a level playing field for all styles of Health Care that are competent, effective, and well established over many decades and in some cases centuries and thousands of years. The availability of options must be a cornerstone of any initiative to rein in the escalating Health Care costs in Ontario.

Together these three amendments as currently worded and once proclaimed, would unjustifiably end free-choice in health care treatments for a wide range of human health challenges for 14 Million Ontarians, forcing them to go to the USA or to other provinces for their preferred treatments. An estimated 10,000 traditional non-pharmaceutical drug-based holistic and spiritual care practitioners would have their currently lawful trade and commerce health care practices that studies show save the health care system $10-14 Billion annually made illegal, depriving them of their livelihoods.

The constitutional rights and freedoms of every Ontarian are violated by these amendments, something that is inconsistent with the Canadian view that everyone is an individual and every individual has inalienable rights to choose their own food, beverages and health care.

The essence of Monte Kwinter's Bill was to ensure access by Ontario citizens to the most effective and least harmful Health Care treatments and Practitioners, without bias or discrimination and interference of drug-influenced conventional professions. We believe that this well established guiding principle needs to be adhered to in these matters as well.

The marketplace speaks more loudly and more accurately than any claims made by lobby groups. The public chooses to pay out-of-pocket for their traditional, holistic, energy and spiritual treatments and the amount they spend is doubling every ten years. This is important especially since statistics show that any claims that the public needs to be 'protected' from non-medical, non-pharmaceutical, non-psychotherapy practitioners is categorically false.

Our legislative initiative could, with our developing suggested amendment, create a health care situation similar to that found in British Columbia, which is a more equally accessible Holistic Health Care approach that respects the wide range of cultural Health Care approaches from all countries around the world.

We are certain you would agree with us that any legislation affecting the constitutional rights and freedoms of 14 Million Ontarians that was passed without proper public consultation in 2007 should not be proclaimed until all concerns have been fully and properly addressed.

There is a real danger of the pharmaceutical-based health care practitioners scheming to restrict the trade and commerce activities of their major non-pharmaceutical competitors. This was revealed a number of years ago in the US conflicts between the allopathic pharmaceutical-based Medical Doctors and the Chiropractors in the Chiropractic Antitrust Suit, *Wilk, et al vs. the AMA, et al.*

Those of us who depend on non-pharmaceutical Health Care approaches as our primary sources of wellness in Canada and the USA have not forgotten that organized pharmaceutical medicine has spent many decades and millions of dollars trying to discredit and destroy non-pharmaceutical health care competitors such as chiropractic and herbalists.

Today the vestiges of this suppression are still found on fringe websites that ignore the body of peer-reviewed research supporting chiropractic care and most non-pharmaceutical health care approaches. Suppression is still found in the efforts of conventional mental health professions to distract the public from facts such as those provided by the Barrio studies of 1969-70 which showed that hypnotherapy was far more cost effective and efficient than psychiatry and psychotherapy by a huge margin [See **Exhibit 3**].

Our research to date indicates that in anticipation of these three amendments being passed into law, a new APA Dictionary of Clinical Psychology (1st edition, 2013) has been created. It has appropriated hundreds of natural human interactions and treatment approaches that have been around for centuries and listed them as 'psychotherapeutic approaches'. This Dictionary will then be used to facilitate the complete takeover of all treatment and counseling in Ontario by pharmaceutical-based psychologists within their scopes of practice, because treatments such as dietary supplementation, Transcendental Meditation, dance therapy, exercise therapy, coping skills training, motivational therapy and so on are suddenly 'psychotherapeutic techniques' and therefore a 'controlled act' under the *RHPA.*

There needs to be a careful balance between a specific lawful scope of practice activity within one modality of the practice of medicine and a prohibited act that is restricted due to actual risks of harm. Example – we can all agree that it takes special training to inject anything into a human body, to do electroshock or a lobotomy. Thus injections, electroshock, and lobotomy being prohibited acts, unless the specific health professional is properly trained and regulated, makes Public Health Protection sense.

On the other hand, what is occurring with these three amendments are cleverly and solely self-serving to pharmaceutical-based Health Care professionals and are not dealing with a *validly* prohibited act that has any connection to Public Health and Safety issues. In fact, what is being attempted in these amendments will do exactly the opposite. They would create a situation where far safer and publically-preferred treatment approaches would be unilaterally banned (after dilution and systematic elimination of techniques), thereby forcing Ontario consumers to change to more dangerous treatment approaches. One can only imagine the endless suffering that will be experienced by those, such as Carole Baker, who have already tried conventional treatments to no avail.

One Ontario-regulated Health Practitioner lobby group should not be enabled to unilaterally lobby for new legislative amendments such as these, where the new proposed legislative amendments will result in eliminating existing competitors in their previously safe, effective, and lawful trade and commerce activities. One can see that if the entire Jury is manned by foxes, every chicken will be mentally ill, incompetent and without voice.

We hope that you and your colleagues can see the positive benefits of postponing these proclamations as requested and working with our client. Ontarians would then be spared costly court-challenges and the unnecessary distress involved in protecting their health from risk associated with loss of freedoms and choices.

We implore you to use your power to give us the opportunity to seek input from the 10,000 plus practitioners negatively impacted by these three proposed amendments and the millions of Canadians and particularly Ontarians who rely on non-psychotherapeutic approaches in order to develop more objective and comprehensive legislative modernization reform proposals.

We do not want to create bad legislation in Ontario that might be used as precedent to introduce similar bad legislation in other provinces of Canada.

It is important to note that traditional, holistic, spiritual and energy-based non-drug therapies are the number one primary health care approach across the world, used by 80% of the world's population.

Given the escalating public health care costs and financial pressures on your government, delaying the proclamation of these ill-advised changes and working with our organization to create more constitutionally-acceptable legislative amendments in Ontario will be a win-win for your government and 14 Million Ontario citizens who spend billions on natural treatments. The amendments that we ask to be postponed are:

(a) Registered Health Professions Act, 1991, Section 27(2)

Note: On a day to be named by proclamation of the Lieutenant Governor, subsection (2) is amended by the Statutes of Ontario, 2007, chapter 10, Schedule R, subsection 19 (1) by adding the following paragraph:

14. Treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning.

See: 2007, c. 10, Sched. R, ss. 19 (1), 20 (2).

(b) Psychology Act, 1991, Section 4:

Note: On a day to be named by proclamation of the Lieutenant Governor, section 4 is repealed by the Statutes of Ontario, 2007, chapter 10, Schedule R, section 18 and the following substituted:

Authorized acts

4. In the course of engaging in the practice of psychology, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

1. To communicate a diagnosis identifying, as the cause of a person's symptoms, a neuropsychological disorder or psychologically based psychotic, neurotic or personality disorder.

2. To treat, by means of psychotherapy technique delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning. 2007, c. 10, Sched. R, s. 18.

See: 2007, c. 10, Sched. R, ss. 18, 20 (2).

(c) Psychotherapy Act, 2007:
Note: Sections 3 to 11 come into force on a day to be named by proclamation of the Lieutenant Governor. See: 2007, c. 10, Sched. R, s. 20 (2).
Scope of practice
3. The practice of psychotherapy is the assessment and treatment of cognitive, emotional or behavioural disturbances by psychotherapeutic means, delivered through a therapeutic relationship based primarily on verbal or non-verbal communication. 2007, c. 10, Sched. R, s. 3.
Authorized Act
4. In the course of engaging in the practice of psychotherapy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to treat, by means of psychotherapy technique delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning. 2007, c. 10, Sched. R, s. 4.

Please acknowledge receipt in writing of this communication and advise me on or before January 29, 2015 of the status of the referenced amendments. Please feel free to contact me at 613-968-3007, or by email at Trueman@tucksparalegalservices.ca.

Thank you for your anticipated consideration and attention to this very important matter. We look forward to your confirmation that your government will not further support these three harmful legislative amendments as currently drafted by exercising your prerogative to refrain from proclaiming them into law and that your government will work with us to develop revised amendments that will far better serve the real needs of citizens of Ontario.

Sincerely,

Trueman Tuck
Lobbyist, Regulatory Consultant
& Paralegal Litigator

cc: Hon. Dr. Eric Hoskins, Minister of Health and Long-Term Care by courier, fax & e-mail
All Ontario MPPs by e-mail

Exhibit	Document Description
1	*An Act concerning Monopolies, and Dispensation with penal laws, etc. R.S.O. 1897, Chapter 323.*
2	Letter from Carole Baker to the Minister of Health and Long Term Care dated January 12, 2015
3	Barrio studies of 1969-70

Transmission Report

Date/Time	01-26-2015	13:06:51	Transmit Header Text	
Local ID 1	6139683215		Local Name 1	tucks professional services

This document : Confirmed
(reduced sample and details below)
Document size : 8.5"x11"

Tuck's Paralegal Services o/b Trueman Tuck
Office: Bldg. 1, Suite 4, 6635 Highway 62 North, Belleville, Ontario, Canada K8N 4Z5
Mailing: P.O. Box 160, Foxboro, Ontario Canada K0K 2B0
Tel: 613-968-3007 Toll-free: 1-888-611-5243
Fax: 613-968-3215 Fax-free: 1-888-672-7035
www.tuckspara legalservices.ca www.theparalegalalligator.com
Trueman@tuckspara legalservices.ca

A full service, Ontario wide Paralegal Legal Services Firm getting results for our clients since 1995!

URGENT – PERSONAL ATTENTION OF HON YASIR NAQVI

Delivered by Courier
And emailed to: ynaqvi.mpp.co@liberal.ola.org
And cover only by fax to: (613) 722-6703

January 26, 2015 Tel: (613) 722-6414

Page(s): 21

Hon Yasir Naqvi, MPP
Government House Leader
Office of the Government House Leader
Room 223, Main Legislative Building, Queen's Park
Toronto, Ontario M7A 1A2

Dear Hon Naqvi:

Re: Urgent request for further postponement of proclamation of the amendments to *RHPA, Psychology Act* and *Psychotherapy Act* for six months while the issues are discussed with all affected Health Practitioners and the affected public to allow resolution of the interpractice conflicts with new amendments

I act on behalf of a number of concerned non-pharmaceutical Health Care practitioners and consumers who depend on non-pharmaceutical health care approaches as their primary health care approach.

Please see the website http://www.stoppsychotherapytakeover.ca and perhaps you can note the over 6,600 petition signatures at http://tinyurl.com/qxwczo2

I understand that in 2009, your government's Omnibus Bill 171 was given Royal Assent. This Bill affected many *Acts*, but as can be seen from the MPP discussion comments at the time, there was no public consultation or time allowed to research and review the three legislative amendments affecting the *Registered Health Professions Act*, the *Psychology Act* and the *Psychotherapy Act*.

These amendments make unlawful the existing practices of some ten thousand non-pharmaceutical Health Care professionals in Ontario and could be considered to be unlawful constraints of trade and commerce activities and a violation of the *An Act concerning Monopolies, and Dispensation with penal laws, etc. R.S.O. 1897, Chapter 323* [See **Exhibit 1**]. As you are likely aware, it is a violation of several Provincial and Federal Acts to conspire to restrict trade and commerce activities of your competitors.

Total Pages Scanned : 6 Total Pages Confirmed : 6

No.	Job	Remote Station	Start Time	Duration	Pages	Line	Mode	Job Type	Results
001	203	6137226703	13:03:35 01-26-2015	00:02:22	6/6	1	EC	HS	CP19200

Abbreviations:

HS: Host send	PL: Polled local	MP: Mailbox print	CP: Completed	TS: Terminated by system
HR: Host receive	PR: Polled remote	RP: Report	FA: Fail	G3: Group 3
WS: Waiting send	MS: Mailbox save	FF: Fax Forward	TU: Terminated by user	EC: Error Correct