Invited Response to CPSO Policy Department on Complementary Medicine Policy Review 2010

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<u>Contents:</u> Becoming A Medical Journalist The Crisis in Medicine The CPSO's CM Policy Review Policy Formulation and Recent Legal Decisions Suggestions for This Policy Review Sources Cited

Becoming A Medical Journalist

In journalism, we are taught to follow the five W's and the one H: Who, What, Where, When, Why and How. Then comes the most important question: "Is it true?" which guides investigative reporting. I am a free-lance journalist and my area of interest is medical politics. My response to the current review of the CPSO's Policy on Complementary Medicine (CM) follows an invitation for comment from the CPSO's Policy department dated May 26, 2010.

Fifteen years ago, when I began writing about medicine, I naively assumed that *alternative* medicine was something that probably consisted of therapies and remedies that were often very ancient and had not been, or not yet been, subjected to modern scientific scrutiny for their efficacy and safety, and that some would be found to be still relevant being supported by centuries of empirical, clinical observation. Today, many of these have their own regulatory bodies. *Complementary* medicine I assumed to be comprised of generally helpful non-controversial therapies, such as good nutrition, massage, exercise, meditation, etc which were assisting mainstream high-tech surgery and pharmaceutical treatments arising from international scientific research. Today, these and related therapies are frequently under attack despite their demonstrated safety and efficacy.

Having grown up in India and worked for a decade in orphanages in Asia and South America, usually following wars or natural disasters, and having also adopted and raised five physically handicapped children, I had a deep respect for what modern medicine – surgery and drugs – can do to restore health. I was an uncritical admirer of modern medicine due to considerable experience with its excellence especially in emergency and tropical medicine. I also observed what it could do to save the lives of starved, mutilated, dehydrated children suffering from all types of tropical diseases; the restorative surgery I witnessed with polio victims suffering from the limb wastage, repair of birth defects such

as cleft palate, heart valve defects, scoliosis of the spine, or ritual mutilation was close to miraculous.

When I was diagnosed in 1996 with Myasthenia gravis (MG) – a serious neurological disorder – and told it was "incurable" and idiopathic, my critical faculties suddenly awoke. I had entered the domain of <u>chronic</u> illness, which is a very different experience. I now know that this is where money, power and ego dominate the scene, as for example Jeffrey Robinsons's excellent book (26) describes, and that this is primarily due to the fact that pharmaceutical drugs began to be publicly traded in the late 1970's. This area of modern medicine has made sickness into Big Business. This is also an area where CAM is the most successful in both treatment and prevention and, thus, runs counter to the sickness industry's interests. I don't believe this statement is controversial – the proof for this development is provided by conventional medical research, is published in the leading medical journals, and is the subject of congressional hearings, government investigations everywhere, patient- and therapy-protective amendments to existing legislation, and legal actions involving thousands of plaintiffs and tens of thousands of documented deaths and injury cases.

I was unwilling to accept my own diagnosis of MG as incurable and simply refused to believe that a cause could not be identified. I also refused the mutilating surgery automatically suggested as part of a one-size-fits-all protocol because it "might" prove to be useful (i.e. a thymectomy). I was also unwilling to take the only drug therapy offered, namely prednisone for life. Being trained in paleoanthropology and evolutionary biology, I knew that the thymus is important throughout life and that prednisone is generally harmful, especially when taken for years, because the body's cellular receptors for steroids eventually no longer cooperate.

The ignorance of the diagnosing professor of neurology pertaining to the life-long need for the presence of a healthy thymus, and the way in which my concern about long-term steroid treatment was shrugged off was alarming. What in the CPSO's Practice Guide is referred to as "...*the balance of knowledge and information favours the physician*" came into doubt. As the discussion quickly revealed, we weren't reading the same science journals. When I asked if it might not be possible to find a cause and a cure, the doctor laughed at me –and that is when I walked out. With my physician husband we began research on autoimmune diseases in the University of Toronto's medical science libraries.

Alternative medicine, as I found out, was not necessarily from China, India or other ancient traditions, but comprises *anything* that conventional medicine does not generally do and rarely includes in teaching programs – at least in North America, for in Germany and Austria, for example, every medical school includes most CAM modalities. Being preoccupied with regaining my health did not, at first, allow me time to look into Traditional Chinese Medicine & Acupuncture (TCMA), Ayurvedic medicine, Naturopathy, and Homeopathy. (Many years later, though, acupuncture saved my right kidney from a chronic infection that could not be treated with antibiotics.)

Chance provided a conversation with the then chief toxicologist of the WHO, Professor Boyd Haley, who informed me that MG is often caused by exposure to mercury and guided me to the relevant literature published in journals like FASEB. As I began to study toxicology and the nutritional deficiencies caused by environmental poisons, which interfere with all repair and metabolic mechanisms in the body, I learned a lot about chronic disease causation. Solid research showed that MG could also be caused by CNS toxins; my immune system had been slowly poisoned over two decades' exposure to DDT in India and a mouth full of equally neurotoxic mercury ("silver") amalgam tooth fillings. I also learned that DDT and mercury are synergistic, i.e. they increase each other's toxic effects when combined. All this was verified by tests originally developed by the WHO in the early 1970's and by Johns Hopkins Medical School and Sweden's Karolinska Institute in the following decades; the tests are readily available from various government-licensed laboratories in North America.¹

Following (alternative) detoxification protocols and (complementary) nutritional support regimes developed and/or taught by the American Academy for Environmental Medicine, the American Academy for the Advancement of Medicine, and the WHO, I rapidly regained my health and began writing about what I was learning. My first major article on mercury and MG was published in *The Medical Post* (see 10).

My research convinced me that the central difference between current CAM and most of conventional medicine is this: the former views diseases as symptoms of a cause that needs to be found, if at all possible; conventional medicine in addressing especially chronic disease is no longer cause-oriented, but labels diseases according to the characteristic patterned groupings of associated symptoms and treats those with drugs that control them more or less.

CAM also often offers treatment of symptoms with non-drug regimes, such as chronic pain management through acupuncture when drug tolerance can be a huge problem for the patient. Depending on how vulnerable to political influence regulatory bodies are, CAM may be tolerated in conjunction with conventional medicine, or CAM may be vigorously resisted. As long as CAM remains within the domain of "healthy lifestyle choices" (e.g. not smoking, recovering from alcoholism, exercising, eating plenty of fruits and vegetables, and employing relaxation programs or yoga) CAM tends to be supported also by conventional medicine; it poses no threat to medicine as business. However, as soon as especially medical doctors start using CAM to treat chronic diseases with CAM methods, and no longer use drugs or drug-based disease prevention therapies – that's when the politics of medicine becomes apparent, and the result is extremely ugly (41). The arms industry is less depressing because its stated aim is to kill people.

If a practicing physician becomes frustrated with the conventional approach (seeing the same patients with the same slowly intensifying symptoms over and over again can get one down) and happens to attend a few medical conferences offering (usually CMEaccredited) information on what happens when one searches for causes and avoids synthetic drugs as much as possible, job satisfaction will increase dramatically when the doctor then puts what was learned into practice. (The annual polls conducted in Canada on conventional physicians' job satisfaction have become worse with every passing year.) By

¹ I took part in a nationally organized class action against Health Canada initiated in 1996 for suppressing Environment Canada's 1970's research results on the toxicity of mercury amalgam dental fillings. Within a year, Health Canada advised all dentists to dispose of old silver fillings in accordance with rules governing toxic waste, thereby alerting discerning patients that their own mouths were toxic waste dumps; appropriate changes in teaching dental students followed shortly in all Canadian dental schools. Now more than 50% of dentists in North American no longer use these neurotoxic fillings; the liability threat has become too great due to the supporting research proving the connection between chronic illnesses and toxic dental products.

contrast, at one conference attended by almost 400 doctors from North America and the UK, representing many types of medical specialization (some university-based), the keynote speaker asked how many had turned to CAM out of sheer frustration with seeing their patients always drugged and never getting well. All hands went up.

My own involvement with conventional neurology ended completely when that neurologist, on whom I had walked out, confidently asserted that obviously I did not really have Myasthenia Gravis, because the "true" MG is incurable (a remission is the most one can hope for) and because MG has no known origin. It is this sort of sophistry that drives patients in droves to alternative medicine (42, 43, 44).

I faced a steep learning curve as I began to read, attend medical conferences in the US and Europe, and interview researchers and doctors on both continents. I also attended conferences held by Big Pharma for its own researchers and marketing managers. Those were most interesting because I learned that the industry is not at all interested in patients but is focused on three *marketing problems* problems: 1. rapidly increasing non-compliance due to intolerable side effects and the resultant loss of income; 2. controlling the unavoidable hepatoxicity of virtually all their synthetic (patentable) products which cannot be properly metabolized; 3. the "pipeline problem" because new chemical combinations for potential drugs are finite – they have "hit the wall".

Now a 4th problem has emerged: the increasing number of court-ordered settlements in favor of drug-injured victims (or the families of dead victims) of these toxic drugs have now with alarming frequency have begun to reach the multi-billion dollar mark - amounts even huge corporations are finding to be harmful to their business plans (21, 41, 46, 53, 57, 68, 71 and *Globe & Mail* July 21, 2010, on the most recent settlements involving Paxil and Avenda). These legal actions now involve all classes of drugs available.

One invited speaker at such a Big Pharma conference was Dr. Michael Gordon, a then and still current CPSO council member, who caused quite the stir when he insisted that Big Pharma really did have to remember that the principles of medical ethics are: *"autonomy* [of the patient and the doctor], *beneficence, non-malfeasance and distributive justice."* He felt, Big Pharma had betrayed doctors and patients and exclaimed: "Just exactly how wrong can things go!" when referring to the case of Dr. Nancy Olivieri the report on whom had just been published by the University of Toronto Press (6). Many leaders in mainstream medicine, including about a dozen Nobel laureates, had become outraged when the drug company Apotex had forbidden her to alter the consent forms for trial participants, thus preventing patient from knowing about the extreme toxicity and high risk of death (+ 40%) from liver failure caused by the drug for which she was conducting world-wide trials. (The following year, the European Union outlawed this drug; it is still available in North America and sold in Asia.)

Attending an international conference of medical regulators hosted on one occasion by the CPSO in Toronto, I listened to the concerns of medical regulators from about a dozen countries: all expressed the fear of losing their privilege of self-regulation because their policies, and the results of those policies, are perceived by the public to cause more and more harm and make protection of the public a sham. It was somewhat amusing also that my appearance caused great consternation. I was told, that although the conference was a public event every two years and held in different countries, they never had had a journalist turn up for any of them! They did not, as a result provide a syllabus copy, but quickly copied one for me.

Starting in 1998, when the Lazarou and Pomeranz study was published (53) I learned that the body count in medicine is caused by conventional medicine, not by CAM practices; we still don't have any deaths reported from nutritional supplements taken in maintenance or therapeutic doses (34, 40). By contrast, the Journal of the American Medical Association (JAMA) observed in 1998, that medical errors resulting in deaths was then equivalent to three jumbo jets crashing every two days, or about 700, 000 recorded deaths from iatrogenic causes annually, i.e. from properly prescribed and correctly taken pharmaceutical drugs. In addition, some 2 million Americans were estimated to suffer drugrelated injuries every year. JAMA also suggested that most probably only 1 in 20 adverse reactions were reported, likely due to fear of legal action. Pharmaceutical prescription drugs were pegged then as the fourth leading cause of death, which since then has been upgraded by research out of Johns Hopkins University to the leading cause of death (37, 42, 53, 57, 72). (While Canada does not gather its own statistics, but extrapolates from US stats, the drugs involved are FDA approved and, as we do not do our own drug safety testing in Canada, are accepted by Health Canada automatically (8).)

What is especially interesting is the fact that the pharmaceutical industry is fully aware of the reasons their products are toxic: their own publications and textbooks dwell exhaustively on the toxic effects of their products on the liver and CNS. Indeed, *Harrison's Principles of Internal Medicine* has for years been and still is <u>the</u> single best place to get reliable information on drug toxicity in its pharmacology section (for an analysis of the various editions of *Harrisons'* by me see 11, p. 284 ff). The American Association of Pharmacists has even taken the important pro-active step of publishing a constantly updated guide (a short one for patients available on amazon.com, a large and exhaustively referenced version is connected to its own website for doctors): *The Nutritional Cost of Pharmaceutical Drugs* (22). Every available drug is listed, the nutrients it depletes, the damage associated with each specific depletion, and how to supplement with nutrients/supplements so the damage is minimized or even avoided when only short-term drug therapy is involved.

In the aviation and transportation sectors this kind of carnage would be unthinkable and not tolerated by governments. Conservative MP Terence Young (Oakville) wrote a book on this deadly aspect of modern medicine last year (32). He is in the process of drafting a federal bill that would require Health Canada to observe the same stringent safety rules for drugs as government regulation requires from the aviation and transportation industry.

From my perspective, the worst part of all this is that those very drugs which are responsible for this carnage are the <u>first-line</u> therapies required according to prevailing standards of practice, unless or until they are removed from the market by the FDA and then by Health Canada. This has important implications for the current CPSO policy on

² There are websites by Quackwatch and its affiliated organizations that assert enormous harm is being done by CAM. Careful study of the cited "sources" invariably leads into dead ends because neither the legal sources cited as proof nor the medical research referenced are verifiable, or when found have been totally misrepresented; the legal cases were eventually dismissed or won by the CAM side of the argument, etc. Quackwatch has been barred from providing expert witnesses in more than 30 US States due to this pattern of misrepresentation and unverifiability of assertions made. For my own experience with Quackwatch see 10 p. 218 ff.

Complementary Medicine. The lack of dead and maimed patients associated with its treatments ought to be of supreme interest in the formulation of a policy explicitly aimed at "serving the public interest."

In my research, alternative medicine turned out, in most cases, to be based on firstrate basic-science research conducted by physicians and arising from university-based nutritional science, toxicology, bio-chemistry, genetics, the physics of biology, epidemiology, environmental studies, brain research, and evolutionary biology (my field of training). I was completely unprepared for this discovery as I began to read stellar journals such as *Nature, Science, Toxicology*, FASEB, *American Journal of Clinical Nutrition, Proceedings of the American Academy of Sciences, Medical Hypothesis*, the *Journal of Biological Chemistry*, the reports from various institutions like the National Institutes of Health, the FDA and EPA, the Santa Fe Institute for Complexity Studies, and their counterparts in the European Union as well as various German medical journals, as I am fluent in that language.

Even more astonishing was the discovery that the "Big Five" (*Lancet*, JAMA, BMJ, NEJM, CMAJ) often publish much of that basic science for <u>clinical</u> application. One of the worst shocks for me was the realization that pharmacology is <u>not</u> part of a doctor's mandatory training. Only in the past year or so has the Royal College made pharmacology mandatory – but, of course, this is for *specialists* only. I am still amazed that so many doctors are clueless about the toxicity of the drugs they prescribe, so much so that it is virtually routine to simply increase the dose or add more drugs of the same class if at first the minimum dose does not appear to work (in contradiction to pharmacological information provided in *Harrison's*). Hence, the body count caused by antidepressants which are now known to <u>increase</u> the rate of suicide and are associated with cancer, diabetes, birth defects, tardive dyskinesia and infertility (15, 14, 19); and ADHD drugs have increased the sudden cardiac death incidence in children by some 500% (3 and related website for updates).

Time and again I am met by alarmed surprise when talking to doctors and mentioning the fact that almost all classes of drugs listed in the CPS (*Compendium of Pharmaceuticals and Specialties*) are toxic and that the most frequently prescribed drugs are based on some form of outright fraud - discovered only after the so-called "post-market experience" gets published (3, 7, 18, 19, 34, 48, 40, 52, 55, 56, 63, 66).

Unfortunately, I have some personal experience in this area as well. While some of our handicapped adopted children fared exceedingly well through high-tech corrective surgery for polio and heart disease, for example, we also have one adopted daughter who lives in a long-term care facility and is confined to a wheel-chair; she depends on a feeding tube and a catheter; she is almost deaf. Suffering from bouts of depression and nightmares caused by emotional and physical abuse sustained in the early 1970's in a series of Ontario foster homes (closed by the government after the abuse was proven) before being adopted by us, she was later prescribed a cocktail of drugs which caused esophageal and partial limb paralysis, diabetes, thyroid impairment, and damage to the auditory nerve. All those drugs now have Health Canada warnings listed in the CPS which detail exactly those adverse reactions – a really quite intolerable euphemism. When no longer living at home, she trusted her doctors.

THE CRISIS IN MEDICINE

The current credibility crisis is due to the all-pervading conflict of interest in medical research and clinical application of that research. The two classic analyses of this development come from the editors of the *New England Journal of Medicine*, Marcia Angell and Jerome Kassirer (1, 18). The latter concluded: "The profession is under siege by big business, and I do not perceive a vigorous effort to rescue it."

In 2002, the *Annals of Internal Medicine* (vol. 136, no. 3) published simultaneously with the Big Five medical journals the "Physicians Charter" (recently updated and available on <u>www.professionalism.org</u>), which states that doctors must get back to the basic values of the Hippocratic oath of 2,500 years ago. While this is a paraphrasing of the long list provided, every item mentioned is taken from this document: don't exploit your patients sexually or abuse them financially, don't hurt them, let them freely chose among available treatments, meet their needs even if they are black, of different ethnic backgrounds, poor, developmentally delayed, gay or lesbian, already dying, old and frail and befuddled, or don't have any money. Above all, don't betray their confidence for profit and don't lie in your research because somebody offers to pay you for those lies.

At about the same time, German research had revealed that about half of what is published in medical journals is factually compromised and unreliable, and the *Globe & Mail* published statistics showing that more than 80% of our doctors are financially involved with the pharmaceutical industry. (10, 11,12) This Charter was prepared by an international team of medical ethicists and states at the outset: "We share the view that medicine's commitment to the patient is being challenged by external forces of change [which] tempt physicians to forsake their traditional commitment to the primacy of patients' interests."

The chief characteristic of corruption in modern medicine is the abandonment of patients' interests <u>and</u> increasing denial of their autonomy. The patient is sacrificed to "manageable risk" in the interest of maintaining profits, as observed by Dr. Michelle Brill-Edwards, the top drug regulator at Health Canada in the 1980's and early '90's; she famously described the attitude of the pharmaceutical industry to patients and drug safety as "road-kill on the highway to profit."

When physicians become part of that corruption – through ignorance, or fear of censure, or by active participation in profit sharing with Big Pharma - the patient can only turn to CAM, either by going to naturopaths, homeopaths, TCMA practitioners etc., who now have their own regulatory colleges – or by seeking out a physician trained in the appropriate CAM modality since doctors are permitted to perform acts most non-MD CAM practitioners are not allowed to do. Indeed, the advice from Marcia Angell, the former editor of the *New England Journal of Medicine*, is to fire your doctor if he or she is in any way financially connected to Big Pharma with regard to a drug prescribed to you (1).

Last year, on April 1, 2009, the editors of the Big Five published an article in the *Journal of the American Medical Association* entitled "Professional Medical Associations and Their Relationship With Industry: A Proposal for Controlling Conflicts of Interest". The accompanying editorial was entitled "Reassessment of Clinical Guidelines – Go Gently Into That Good Night." This call for radical reform, unprecedented in the history of medicine, was authored by the editors of the Big Five and some additional journals. Over the past millennia one worried about superstitions and charlatans, now we must be

concerned about the integrity of professionals with a string of important letters behind their names. The authors state:

"...too many guidelines have become marketing and opinion-based pieces, delivering directive rather than assistive statements...In one study of 44 guidelines, 87% of the guideline authors had some form of industry tie...guidelines are not patient-specific enough to be useful and rarely allow for individualization of care. Most guidelines have a onesize-fits-all mentality ... If all that can be produced are biased, minimally applicable consensus statements, perhaps guidelines should be avoided completely. Unless there is evidence of appropriate changes in the guideline process, clinicians and policy makers must reject calls for adherence to guidelines. Physicians would be better off making clinical decisions based on valid primary data."

Apparently, guideline committees are almost always stacked with Big Pharma representatives, as the JAMA authors, Angell, Kassirer and others describe. Indeed, entire diseases have been <u>invented</u> by the industry for which many of these guidelines are written, which then are enforced by the regulatory bodies. University of British Columbia's professor of Public Policy, Alan Cassels chronicles how the following symptoms were reinvented as diseases by Big Pharma (with only the *British Medical Journal* objecting occasionally to this development): high cholesterol, depression, menopause, attention deficit disorder, high blood pressure, premenstrual dysphoric disorder, osteoporosis, irritable bowel syndrome, female sexual dysfunction (7 see also 15, 23, 25, 26, 28, 30, 45, 56, 63). None of them are diseases in the proper meaning of the term. They are all symptoms that may be associated with all sorts of true disease conditions and, as such, should not be treated in isolation.

To ensure entry into the market for a drug, the clinical trials have time and again been most carefully doctored to the point where even top experts were fooled: Dr. David Healy, a leading UK pharmacologist and psychiatrist was himself duped into approving Prozac: Eli Lilly had permitted mostly participants unlikely to show side effects, and when serious ones began to be reported anyway, such participants were removed from the trials. Worst of all, the suicides which began to happen in the trials often early on, were simply hidden from the investigators in nebulous jargon which Dr. Healy finally unmasked when he got hold of the raw data. He found these difficult to obtain, but succeeded at last because the FDA is bound by US federal legislation to make such data available, but does not necessary volunteer them. His determined search finally caused the whistle to be blown, not just on Prozac, but on all SSRIs in his now famous book *Let Them Eat Prozac*.

All SSRIs are now black-boxed by the FDA and have Health Canada warnings, but they and their chemically identical second-generation "me-too" versions are still being prescribed, even though it is now known that the entire "serotonin hypothesis", allegedly underpinning depression, has no biological merit whatever (7, 14, 15, 19, 30, 52). However, having re-invented these symptoms as discrete diseases, long-term drug therapy protocols followed, immense money has been made on a lot of injured or dead people, and the regulatory system supports them in their standards-of-practice recommendations (4) instead of questioning them.

This year, the journal *Trials* (55) analyzed the data on 90 drugs and the 900 clinical trials on which their approval was based and found that between 40% and 60% (depending on the drug) of the really important findings had been completely omitted or even simply

changed to suit the drug's manufacturer, because most of those results were poor and did not justify approving them. This article is worth a very careful reading because it provides the proof that the vast structure of conventional medicine is based largely on fraud. Almost simultaneously the news appeared showing the 21 trials/studies on which the blockbuster drugs Vioxx (Wyeth) and Celebrex (Pfizer) were approved for use, were in fact bogus, and the researcher who had conducted them has been sentenced to jail time (66; for prevalence of such fraud see 45, in cancer see 51 and statistical manipulations see 56 and the same in cancer see 9, 48).

The ethical questions such findings raise have begun to be addressed by a joint letter (50) from the Institute of Medicine and Johns Hopkins University to the FDA, dated July 9, 2010, asking the FDA to eliminate the fraudulent practices prevalent in trials which endanger their participants (52, 72).

As for the credibility of medical journals (28 and 63), the editor in chief of the *British Medical Journal*, Richard Smith wrote a book on his two-decade long experience with how medical journals are co-opted by business interests and often tricked into publishing research based on hundreds of non-existent patients. Speaking at the University of Toronto in 2008, Dr. Smith was asked if one could trust *any* leading medical journals. He laughed out loud and exclaimed: "No!" Asked how patients should protect themselves from doctors acting in good faith on this mostly fraudulent research, he replied: "Patients have to understand that they are actually in a bogus contract with the doctor. The patient thinks that the doctor can fix his problem. That is a very powerful fantasy! Patients need to invest time and energy in researching their health problem and be smarter than the doctor. Nowadays that is possible!" He recommended the internet-based open-access medical journals; they are free of advertising and Big Pharma interference, e.g. *PLoS* and *Open Medicine*.

It is only fair to add that Big Pharma frequently goes so far in duping doctors, that it is very difficult for anybody to tell facts from fraud, such as the production of completely phony journals – a fact discovered a decade ago by the University of Toronto's Dr. Allen Detsky (26) and more recently reported from the Vioxx trial in Australia; there the court discovered that the *Australasian Journal of Bone and Joint Medicine* was totally bogus and that it brazenly used the names of genuine researchers as the alleged authors, without their knowledge, in reported studies that were pure invention.

Dr. Shiv Chopra (8), the Health Canada whistleblower who in 1999 prevented bovine growth hormone, a human carcinogen, from entering Canada's food supply, often jokes that the regulatory approvals process, dominated by Big Pharma interests, is based on what used to be called "tobacco science" when that industry was trying to "prove" the safety of cigarettes. That turned out to be literally true in Europe: this year, *PLoS Medicine* published the evidence showing that the European Union's current process of evaluating policy options in health care emphasizes business interests over public health due to the direct guidance its regulators accepted from the world's second largest tobacco corporation (64).

This very short description of the credibility crisis in medicine leads to the problem of what a doctor can honestly tell a patient. According to the current CPSO Policy on Complementary Medicine physicians are expected to *"ensure that their patients are told the degree to which tests, treatments or remedies have been evaluated, and the degree of certainty and predictability that exists about their efficacy and safety."* An informed doctor who regularly reads the Big Five and some of the highlypublicized books I just cited above, all mainstream publications penned by mainstream medical authorities, has no other option but to tell those patients who have not yet defected to outright Alternative Medicine, i.e. Naturopaths, Homeopaths and TCMA, the following:

"I am sorry to have to tell you that most of standard medical practice, and most of the generally used patented drugs, are based on fraud and have an appalling safety profile; safety; they also are rarely effective and carry the risk of injury or even death. I cannot, in conscience suggest them. The safest remedies and interventions are currently in complementary and alternative medicine, where so far no dead bodies have been reported from the therapeutic use of high-dose vitamins, minerals and supplements. We even know now that some 50 metabolic problems leading to many diseases can *only* be treated with nutritional supplements (33), and that the DNA repair system responds to high-dose vitamin treatment and prevents cancer from developing (59). There is no drug in existence that can do that. Some large population studies have shown us the same results (70, 71). At the very minimum, those won't kill or injure you, and a healthy lifestyle is perhaps the best revenge on the whole system (5); if you cut out toxic substances and follow the current recommendations of the US President's Cancer Panel, i.e. eat only organic food and filter your water to avoid chlorine, fluoride, and pharmaceutical drug residues, you are highly unlikely to develop cancer (40, 42, 44, 46, 47, 58, 59, 60, 67, 71). If you and I work like a team, because you may know what I need to know and you may need tests only I can order, I will help you as best I can with those tests that monitor the reduction of toxic waste in your body. We need no longer bother with the PSA for prostate cancer and mammography for breast cancer, because even the cancer societies no longer believe they are useful (38, 51, 58). Working together we will also save Medicare a hell of a lot of money" (39).

In 2006 Frederic Calon of Lavalle University wrote in the Canadian Medical Association Journal (CMAJ) an article entitled "Nonpatentable drugs and the cost of our ignorance" (39) outlining the financial fallout caused by this credibility crisis in medicine and how the use of safe, non-patentable remedies is financially the most credible course of action.

THE CPSO'S COMPLEMENTARY MEDICINE POLICY REVIEW

The myth that conventional medicine is generally safe and effective has become totally and absolutely unsustainable. Therefore, the tone of the CPSO's new Policy must be drastically changed: it can no longer sound as if venturing forth into CM territory is potentially dangerous and requires supervision and protection from those who know what is real medicine. This Policy has since its inception in 1997 not been particularly helpful to doctors or patients. Starting in the late 1980's, doctors, who added emerging complementary medicine knowledge into their practices, were frequently investigated and disciplined for their efforts, regardless of proof of patients' improvement or cure. Their extravagant display in often vast additional training did not, apparently, meet the "standards of practice" (13, 17, 69), and in any case, patient outcome became irrelevant in those proceedings. Patient choice was repeatedly considered a function of patient ignorance.

These types of CPSO-driven investigations (detailed in 13 up to 2001; for some subsequent cases see 12) are exemplified by the then CPSO prosecution lawyer, Donald Posluns' whose standard instructions delivered to discipline panels examining such doctors was: "The outcome of treatment is not a useful concept ... only the standard of practice is to be evaluated. You set the standards in Ontario, you have never heard of ...[insert professional organization's name where the doctor being investigated was trained] and its treatment modalities, therefore you have to find [him] guilty." I heard these instructions myself on several occasions and read them in the transcripts of investigations I did not attend.

Not only is it incomprehensible that a medical regulatory body's legal counsel is allowed to assert that new knowledge and new treatment modalities may not even be considered as possibly valid and useful, but positive patient outcome – the whole point of medicine – is thus dismissed as well. The panel was forcefully instructed to <u>stay</u> as ignorant as possible in order to ensure prevailing standards of practice are obeyed, and never mind the patients, or the public interest in fact.

Especially mystifying is the bald assertion that "you set the standards of practice in Ontario". The Regulated Health Professions Act, Schedule 2, Section 3, very clearly explains what a regulatory college is expected to do, namely to ensure the quality of medicine by promoting advancement of knowledge, staying abreast of new developments, ensuring member doctors increase their knowledge in "changing environments" and are aware of "emerging issues". The section immediately following explains why: namely "to protect the public interest.

A regulatory college does <u>not</u> have the mandate under the law to <u>retard</u> knowledge or just pretend it does not exist. This, however, is the recorded attitude. ³ Furthermore, doctors are not permitted to use modalities or drugs that have not already been approved by Health Canada and have become listed as prescription drugs or been delisted to be sold as OCDs. If the same scrutiny of an Ontario doctor's use of treatments were routinely employed in CPSO investigations, for example, whenever a new anti-depressant or cholesterol-lowering drug comes on the market by Health Canada approval, a lot of lives would be saved every year in Ontario. Health Canada approval of complementary medicine practices and remedies is ignored if the CPSO happens not to approve of a given practice or remedy. The demonstrated bias of CPSO-driven investigations is in favor of

³ MPP Monte Kwinter observed in the key-note address at a conference on complementary medicine at the University of Toronto some years ago, that "unfortunately the attitude at the CPSO is that if it ain't invented in Ontario, it ain't invented. (10)

pharmaceutical drugs; the record also shows that complementary medical practices, regardless of the excellence of their underlying research, and despite the integrity of the publishing journal, are treated with extreme prejudice. The 1997 Policy did nothing to change that, indeed even the approving discussion of some of these practices in the then current edition of *Harrison's Principles of Internal Medicine* have been found to be dismissed in some disciplinary investigations (13).

It is now becoming increasingly frequent, that doctor using complementary medicine in their practices are subjected to exhausting analyses of their consent forms whenever it would be patently absurd to attack the complementary medical practice itself on account of its Health Canada and/or international acceptance or unassailable university-based research quality. It is difficult to dismiss the impression that the CPSO's approach has adopted yet another questionable course of action: if the doctor cannot be shown to be deficient in training, and if the treatment or drug employed cannot be shown to lack Health Canada approval, no injured or dead patient can be found, and if the methods involved are based on a medical peer group - then the assumption that the patient's intelligence is resorted to, and an attempt is made to make it appear that it is the patient's safety that is the CPSO's chief consideration.

The universally acknowledged basis of science is what Karl Popper enunciated in 1934 in *The Logic of Scientific Discovery* in which he argued that a scientific hypothesis must constantly be tested by attempts to <u>falsify it</u> (24, 20). To rest on the illusion of absolute certainty is dogma, not science – nor is this approach in accord with the intent of the RHPA. Time and again, CAM doctors' disciplinary investigations have been conducted as if CPSO standards of practice are infallible. Such an attitude in medical regulation is nothing less than disgraceful and causes the whole medical enterprise to become disreputable.

That illusive "standard", which is to be protected by rigorous maintenance of ignorance, has never been made clear to anybody; many lawyers demanded such information during investigations of this type - always without success. Like a mirage, that standard has shifted depending on the outcome the discipline department appeared to be aiming for in a given case. Indeed, given that it is obvious that any medical standard must be based on published research and clinical results, it is utterly astounding how so many disciplinary investigation of complementary medicine doctors simply ignored the scientific publications made available by the defense as legal evidence. The legally required examination of evidence remained just as elusive as the standards of practice.

Given this disregard for patient choice and treatment outcome, one hesitates to want to even know what those standards might be, should they ever be found. In several such disciplinary investigations I attended, hundreds of patient testimonials were submitted by the defense - in addition to the supportive science and the proof of appropriate training obtained by the physician being investigated. Those testimonials were heart-breaking to read and proof that curative medicine – as opposed to symptom control - sometimes does exist. This will be discussed below in more detail in connection with the Truehope case.

Criminal lawyer Michael Code, then of Sack Goldblatt Mitchell and now an Ontario judge, commented in his exhaustive legal analysis of many such disciplinary hearings: "The proceedings against [such doctors] would, therefore, appear to involve the *Alice in Wonderland* proposition that doctors are to be disciplined on the basis of some pure scientific principle that has no regard for actual harm and no regard for the satisfaction or

dissatisfaction of the patients. That the CPSO would spend ten long years, from 1988-1999, pursuing this kind of [issue at] enormous expense through endless disciplinary processes, would seem, at a minimum, to show inappropriate judgment and overzealousness." During a press conference in the Media Studio of Queen's Park, on May 10, 2000, Code added: "That's [the CPSO's] analytical methodology - that the actual satisfaction of the patients, whether the treatment actually seems to help, is of no value in establishing scientific principles."

Unfortunately, this determination to uphold elusive and essentially arbitrary standards of practice, unrelated to patient outcome and patient choice, has not changed in the past ten years. The investigations continue as before to be set in motion by the report provided by an investigator chosen by the CPSO - generally a person either ignorant of the complementary medical practice involved or outright hostile to it. The accused doctor has also no opportunity to set matters right, to correct blatant factual errors in such investigator report. That report, factually true or not, is the basis on which the decision is made to proceed with a disciplinary investigation on the astounding assertion that the investigation will bring out the facts eventually. No murder trial commences in this fashion.

Currently, some such cases are still unresolved, new ones have been initiated, and, interestingly, many involve doctors using complementary practices unsupported by patient complaints or evidence of harm. This stands in clear contrast to the relatively straightforward problems of sexual and other types of interpersonal abuse or surgical misadventures, which CPSO disciplinary investigations handle usually appropriately.

What <u>should</u> be happening – <u>especially</u> with doctors utilizing CAM practices – is collegial inquiry into the scientific basis the doctor is acting upon, whether these modalities are supported by active peer groups and research projects, whether this peer group publishes regularly, provides training programs, perhaps even in CME-accredited conferences - and <u>above all</u>, there ought to be a keen interest shown by the CPSO in how those patients are doing who chose to be treated in these ways.

Instead, I find that the assumed superiority of conventional medicine is so engrained, that even for this current review of the CPSO's CM Policy, neither the Ontario Medical Association's Complementary Medical Section nor the Ontario Society of Physicians for Complementary Medicine were asked to provide representatives to take part in the deliberations of the policy's Working Group. That group's views and decisions will affect all those doctors who use complementary medicine. Given the record so far of CPSO-driven disciplinary investigations of doctors using such practices, the danger continues to be the chance of being handed "a professional death sentence", as lawyer Morris manning so aptly once observed.

Given that the crisis in current medicine is due to **fraud** and **toxicity** and the **conflicts of interest** arising from widespread fraudulent research in <u>conventional</u> medicine, it is of vital significance that complementary medicine is demonstrably not burdened by those problems. Complementary medicine is undoubtedly not perfect – but when the physician using such methods is properly trained in the area concerned, the results at the minimum tend to show that nobody gets killed or maimed and lives are not made miserable by the known side effects of drugs.

This current review of the CPSO's CM Policy cannot hope to be useful (cf. Question No 1) if it doesn't address what has been ignored (Question No 2), and, therefore, an improvement of this CAM Policy (Question No 3) cannot be achieved unless the

existing and all-pervading problem of fraud and toxicity pervading conventional medicine is acknowledged.

Patient demand for CAM did not arise due to some unexpected tide of superstition and irrationality in society. This new interest in CAM was borne of experience. The 5th century B.C. tragedian Aeschylos who observed in the *Orestia*: "... humanity only learns through suffering." Nobody – patient or doctor - turns to CAM except through the experience of painful disappointment.

POLICY FORMULATION AND CASE LAW

There are two legal decisions in Canada that should inform the deliberations of this review of the CAM Policy. The first is the 1991 Ontario court ruling *Brett et al vs. Board of Directors of Physiotherapy* in which Justice O'Leary stated:

"...If it be misconduct to use methods and techniques that are foreign to or disapproved by the vast majority in the profession, the profession might never progress. In the case of medicine, for example, acupuncture would probably not have become a method of treatment in Ontario... the member cannot be found guilty of professional misconduct if there exists a responsible and competent body of professional opinion that supports that conduct or judgment ...It is not sufficient for a conviction that the disciplinary panel prefer the opinion of the vast majority over that of the smaller though equally competent and responsible body of opinion that supports the member in his conduct or judgment."

In the year 2000, the so-called Kwinter Bill became part of Ontario's Medicine Act (Section 5.1). MPP Monte Kwinter was determined to have the wording on medical practice from the international Helsinki Accord on human rights become part of Ontario's health care legislation. It was created by the International Medical Association and accepted by the WHO as a universal guide. The Ontario's Medicine Act now states that a physician

"... cannot 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 [he/she] practices a therapy that is non-traditional or that departs from the prevailing medical practice, unless there is evidence that the therapy poses greater risk to a patient's health than the traditional or prevailing practice."

When the Complementary Medicine Policy was created by the CPSO in 1997, the CPSO asserted that member physicians are "not only responsible to their patients but also the their College". That patient care is supposed to be virtually equal in weight to the doctor's allegiance to his professional organization is a crass assertion of systemic conflict of interest that runs counter to fundamental principles of ethics. This makes no sense and is thoroughly objectionable. A regulatory college is not a private club with its own rules that members are expected to obey or else are asked to leave. The College exists for the purpose of protecting the <u>public</u> interest, and nothing else, as made clear from the wording and intent of the RHPA.

The second important legal case that ought to inform this review is the ruling in the **Truehope** case handed down by Justice Meagher on July 28, 2006 in the Provincial Court of Alberta. (The entire judgment and other relevant documents are reproduced in 11, available online for free downloading.) This case speaks especially to the issue as to whom a doctor is responsible above all else.

Health Canada had abruptly stopped the use of a vitamin and mineral CAM therapy for extreme bipolar disorder patients registered in a large, formal trial conducted jointly by the University of Alberta in Calgary and Harvard University in the US. The efficacy of the treatment had begun to be established clinically and the results were beginning to be published in the appropriate journals.

At that point Health Canada, which had approved the trials originally, stopped it on a technicality. This caused extreme distress in all trial participants and caused several suicides, as had been predicted by the responsible bipolar experts (doctors and psychiatric psychologists) when Health Canada announced its intervention. When the suicides began to happen, these doctors informed Health Canada that they would <u>not</u> obey the government's order, and they did indeed proceed to treat these patients with the forbidden therapy and continued the trial. The case went to court and Health Canada lost on the basis of the "defense of necessity" which is supported by several Supreme Court rulings. This defense may be invoked when a person's judgment is motivated by "instinctive action" and the desire to save somebody's life in an emergency, even if doing so runs counter to established norms and involves breaking a law.

What is especially important in this case is the fact that the <u>evidence</u>, on the basis of which the case was won for Truehope's patients, was <u>patient testimony</u> – the very thing dismissed in CPSO trials of CM-using physicians. The evidence admitted by the court as being <u>most</u> important was what the patients reported they had experienced as helpful; this evidence took even precedence over the scientific information provided, although that did completely supported patient testimony.

This "defense of necessity" was judged appropriate also because the patient testimony detailed the horrific side effects they had suffered from the conventional standard-of-care drug therapy which had caused them to enter this trial. It follows, that doctors, who inform themselves about the current problems pertaining to drug safety and efficacy and then decide to utilize complementary medical remedies instead, are entering the same legal territory dealt with in the Truehope case. Not only is the physician's responsibility to the patient paramount, but a doctor's disobedience to any other authority, that may attempt to interfere in the doctor-patient relationship, is now legally supported in a specific case as well as by previous Supreme Court decisions as cited in the Truehope judgment.

I recall a personal experience where the patient's need was nearly sacrificed to regulatory policy: having I learned that silver/mercury amalgam fillings provided one of the causes of my MG, I offered my dentist the relevant research articles on the toxicity of silver amalgams published in FASEB, requesting that my fillings be removed. The response was: "I can't do that because I might lose my license." This was true: the position of the College of Dentists in the mid-1990's was that silver amalgams should not be removed simply because the patient asked to have them taken out. I found a dentist who had no hesitation in acting ethically and on the basis of good science, and he took them out. When the last filling was removed, the total toxic body burden was reduced at the source

such that I was once again able to drive a car and finally also to read again – the blurred double vision caused by the constant release of methyl-mercury vapor rising into my brain from the fillings had been stopped and my eyes were functional again.

Within the CPSO's recent history there are unfortunately a many similar instances, and some of them precipitated disciplinary action for alleged transgressions such as: not referring a patient with Multiple Chemical Sensitivity symptoms to a psychiatrist (because MCS was supposedly evidence of craziness, not of verifiable toxicity); continuing to treat chronic pain patients contrary to CPSO guidelines because treatment was effective and in accord with the international decision to treat pain as the Fifth Vital Sign; weaning patients off antidepressants because the physician had learned from conventional journals that SSRIs are known to be potentially carcinogenic and, therefore, used Truehope-type protocols instead; replacing steroid therapy in Crohn's disease patients with the Gottschall Diet; treating patients with Chronic Lyme Disease in contravention of the CPSO's allegiance to the position of the Infectious Disease Society of America, which asserts contrary to world-wide published evidence that there is no such thing as a chronic form of Lyme disease. There are many more such examples.

The CPSO's CM Policy came into being in 1997 after the Walker Report and a great deal of publicity surrounding the then ongoing prosecution of Dr. Jozef Krop which covered in total 14 years; his failure to meet the standard of practice was diagnosing and treating Multiple Chemical Sensitivity, a new and emerging condition supported by enormous published research conducted also in Canada and at the University of Toronto. This diagnosis the CPSO's disciplinary panel asserted was based "only on his beliefs" and had "no scientific validity".

Ironically, the day this assertion was made (June 19, 1999) was also the same day on which Johns Hopkins University, arguably the most prestigious medical school in North America, published the now internationally accepted criteria for the diagnosis of MCS; Dr. Krop was a signatory (10, 13).

Those criteria had been developed in the US and in conjunction with governmentfunded research from the University of Toronto. Eventually, the science underlying those "beliefs" became the basis of Ontario's current anti-pesticide legislation. Recently, federal and provincial politicians were tested for those toxic chemicals Dr. Krop was identifying a decade earlier in his patients as causes of disease. *Slow Death by Rubber Duck – How the Toxic Chemistry of Everyday Life Affects our Health*, a report on a project undertaken by Environmental Defense and the Ivey Foundation (29), references that science (2,16), which in the Krop trial was put forward as evidence (dismissed as beliefs), along with excellent patient outcomes obtained from detoxification protocols used in CM. Those infamous "beliefs" have become important to public health.

This sort of embarrassment, now part of medical history (the Krop case is taught in some law schools in the US as an example of the abuse of administrative law), ought to be instructive to the formulation of a useful CM Policy. Its purpose ought to be the prevention of further bloopers of this kind because they undermine the credibility of medical regulation, endanger self-regulation as a privilege, and betray the public trust.

SUGGESTIONS FOR THIS POLICY REVIEW

"Does the Policy provide useful guidance?" "Are there any issues <u>not</u> included in the current policy that should be addressed. If so, what are they?" "How could the policy be improved?"

These were the questions posed by the Policy Department for this CM review process.

Useful guidance to the public and the CM physician would require that the *credibility crisis* in medicine is acknowledged, that fundamental principles of *natural justice* are explicitly observed with regard to physician behavior and CPSO disciplinary investigations, the treatment of scientific and legal evidence, and that *patient choice* must be recognized as inviolate.

The credibility crisis in current medicine is unfortunately reflected on the smaller, local, scale in the fact that the CPSO Working Group, responsible for this policy review, did not, as a matter of basic fairness and collegiality, put members of the Ontario Medical Association's CAM Section and the Ontario Society of Physicians for Complementary Medicine in this group. Apparently, an informal discussion with some of this OMA section's members took place at the CPSO some time ago - after the CAM doctors asked for it. That is neither enough nor appropriate. This policy review appears thus to be a top-down, father-knows-best sort of exercise in which the CPSO's Working Group deliberates and evaluates in terms of conventional medicine (seeing the group's members are not CM-practicing doctors themselves) and then hands down a policy to those wishing to work with CM modalities - rather like a somewhat cautiously indulgent patriarch gives guidance and warning to those straying from the road most traveled.

Due to this clear lack of collegiality this review is in danger of continuing in the same spirit enunciated in the 1997 Walker Report where it was stated that "*a fair review*" of a physician's conduct regarding CM "*can be independent of the particular expertise of the assessor*." This assertion was an affront to natural justice back then and remains so today. It must be explicitly reversed; it is undoubtedly vulnerable to constitutional attack.

My first – and most fundamental objection – to this current review is the fact that it is being conducted without members of the OMA's CM Section and the OSPCM being on the Working Group. If the CPSO wishes to convince the membership and the public that its intentions are honest and meant to serve the protection of the public interest, serve patients needs, and guide member physicians in a helpful manner during these turbulent times in medicine, this Policy review should be <u>immediately postponed</u> until 50% of this Working Group consists of CM doctors, practicing in Ontario and as selected by their boards. Otherwise this review process may become an offence to natural justice.

Next: any wording that insinuates that CM is less safe or effective than conventional medicine must be removed. There are no facts to support such a suggestion, and enormous published support for the exact opposite view is now the prevalent fact. Undoubtedly, conventional medicine will in good time dig itself out of its current morass of corruption and set itself right again – as has happened throughout the history of medicine many times. Meanwhile

CM practicing physicians must not be treated as poor country cousins with suspected dubious motives. Full collegiality is the minimum to be expected in regulatory attitudes to CM. That means, that a relevant and improved CM Policy must include active encouragement to <u>all</u> CPSO member physicians to be willing to acquaint themselves with CM modalities in order to be able to refer a patient accordingly and most likely also improve the safety and efficacy of their own practices.

The current CAM Policy has a somewhat vaguely but undoubtedly well-intentioned phrase to that effect already, i.e. that it should not be an offence to refer a patient to complementary medicine. However, it has no teeth. If full collegiality is to be seriously undertaken, then at the very least it should become absolutely understood that an investigation into a CM physicians practice under section 75 of the RHPA <u>must require the appointment of an assessor who knows what this doctor's practice is all about</u>. A true peer is a constitutional right, in terms of basic procedural fairness outlined in Canada's Criminal Code. The same must apply to all Quality Assurance activities, such as periodical peer reviews. Afore-quoted criminal law expert Michael Code also occasionally observed, "Doctors in this province have less procedural protection than an ordinary person accused of murder." Indeed, the assessor of a practice – conventional or complementary <u>must</u> have the relevant expertise for the given case.

Any investigation of a CM practice requires a <u>true peer</u> to be appointed for the purpose. Negotiating and establishing the credentials of a true peer acceptable to both the prosecution and the defense ought not to be difficult, seeing the Criminal Code already has plenty of provisions and supportive case law, as well as constitutional principles for guidance. The initial investigation must be uncontaminated by actual or perceived prejudice and bias and avoid ignorance about the modality in question to predetermined the trial's outcome (13, 10, 11). Such systemic unfairness is bad for medicine, bad for patients, and puts also the law in disrepute. Explicit support for the patient's freedom to chose between alternative therapies is needed in the revised CAM policy. Furthermore, it should be made clear that no conventional physician may deny such patient choice, but the doctor ought to be willing to explore and help to interpret information new to the physician and offered often by the patient. Time and again I encounter people who are told, when moving or having to find a new family doctor, that the new physician will not continue, for example, bio-identical sex or thyroid hormone therapy but insists (without explanation to justify this!) on pharmaceutical drugs instead (which the patient took great care to avoid, as the Truehope trial participants had done). Such narrow-mindedness could be legally challenged. CM generally uses bio-identical substances, and conventional doctors need to learn about patient individuality and preference. Patient choice is key to good medical practice and is a function of team-work. The current CM Policy states

"It should not be misconduct to refer a patient, honestly and without conflict of interest, to unconventional or complementary practitioners, when appropriate, and when there is no reason to believe that such a referral would expose the patient to harm."

This sentence appears to be a tip of the hat to the *Brett* decision and the Kwinter bill. Yet, in view of the current crisis in conventional medicine this phrase is sadly amusing. The "misconduct" and "conflict of interest" are not really found in the CM area of practice, but all but overwhelm conventional medicine; also, there is no explanation as to who is going to do the deciding that a referral to a CM physician (or non-MD practitioner of CAM) is "appropriate" or may not "expose the patient to harm". There is no need for this paternalistic phrase at all, if the new CM policy asserts the following principles:

Patient choice is affirmed because it is in accord with fundamental, constitutionally guaranteed human rights.

Collegial equality with non-CM member physicians is acknowledged, provided CM practitioners are trained in the modalities offered by an existing *Brett* group.

Full recognition of the established or emerging validity and assumed integrity of Complementary Medicine is declared.

Not changing the CM Policy as suggested above would require that the Working Group provide verifiable evidence that contradicts what has been detailed and referenced in this presentation.

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