Second Invited Response to CPSO Policy Department on Complementary Medicine Policy Review 2010/2011

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1. Flaws in the revised policy

The recently revised draft policy for complementary and alternative medicine has been published, and those who were invited to comment on the first draft are now invited to do so again; I am one of them. Thank you for this opportunity.

At first reading, I was happy to see that this revised draft repeatedly includes the language from both Section 5.1 of the *Medicine Act* and the relevant phrases from the 1991 *Brett* decision. The former, known as the Kwinter Amendment, incorporated into Ontario health legislation international medical law taken from the Helsinki Accord, which Canada signed on August 1 of 1975. That Section 5.1 states:

> *"A member shall not be found guilty of professional misconduct or of incompetence under section 51 and 52 of the Health Professions Procedural Code solely on the basis that the member practices 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".*

The *Brett* decision, delivered in an Ontario court, established that health professionals must be free to associate with minority peer groups who employ new or different techniques and treatments, and that health professionals must be able to do so without fear of being perceived as falling below the generally accepted standard of practice. The Decision concluded:

"If it be misconduct to use methods and techniques that are foreign to or disapproved of by the vast majority in the profession, the profession might never progress."

At the outset I would like to state that I find it less than helpful to contrast allopathic medicine with non-allopathic medicine. These terms suggest a schism, somewhat like Roman Catholic vs. Protestant. Given the tenor of the draft policy to which non-allopathic doctors are supposed to adhere, this distinction gives the impression of allopaths having a more reliable direct line to God.*

Throughout this revised draft of the CAM/non-allopathic policy the wording used in these two legal documents appear again and again, as indeed they ought to, seeing the CPSO's regulatory responsibilities flow from universally binding national and international law. During the past decade many more provincial and also Supreme Court legal decisions pertaining to medical practice have made their mark in Canada, but those two items cited above remain of key importance because they provided the basic foundation and set the tone for medical practice in Canada. What is profoundly disturbing is the fact that only some of the wording is provided, but the spirit of this draft policy and its requirements run completely contrary to those two binding legal items.

There are **two** serious flaws in this revised policy which require not just serious consideration for further revision, but are fundamentally unacceptable because they run counter to both law and science. This draft policy effectively would make the practice of medicine pretty much impossible and would stifle innovation in both – allopathic and non-allopathic clinical practice because it assumes that allopathic medicine functions according to the standard proposed for non-allopathic practitioners. Allopathic practice, in fact, is not at all constrained by that assumed standard; indeed, the most serious critique to this assumed standard can be shown to come from *allopathic* medicine (discussed in No. 2). This draft policy is in error on:

1. The unilateral and essentially arbitrary *reinterpretation* of what constitutes **informed consent** on the part of the patient seeking non-allopathic treatments, and

2. The prerequisite of a **Randomized Controlled Trial (RCT)** in order for the doctor to be able to offer non-allopathic treatments.

Nothing new can happen in diagnosis and therapy and no new discoveries about emerging diseases and previously unknown causes of well-known diseases, if exploration and individual observation are not protected. The new always appears through an individual observation. Of central importance is also the unique quality of the doctor-patient relationship which involves complexities of information and consent *not* as a one-time event with a signature on a piece of paper, but as an ongoing process while both doctor and patient evaluate and adjust treatment. It is disturbing that this revised draft

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* It is strange that the terms "allopathic"/"non-allopathic" are used as it was Hahnemann, the founder of homeopathy, who 200 years ago coined the term *allopathic* as a deliberately prejoritave term to describe the medicine of the day which was mostly limited to bleeding, leeching, cupping, emetics etc. in contrast to his own approach which was the first attempt to either strengthen or supporting the body's own defences, later recognized as the immune system.

appears to undertake a *reinterpretation of* **informed consent** as if the College - not the courts or the existing statutes - was in the privileged position to impose its own definition of how informed consent takes place and what it actually is. Since the College, as an administrative law body, is required to follow the laws of evidence as defined by the courts, the College is not at liberty to lead in creating such definitions and, therefore, cannot impose its own interpretation, even if this is intended to protect the public from harm; in fact, it could not even do so if all member-physicians agreed to such a redefinition. The establishment of such a revision would have to pass through the legislative route first before it can be implemented. Furthermore, since the point of informed consent is to minimize potential harm, it is important to remember that it is the courts which define if harm may have been done, and they do so on the basis of evidence as defined in law, not on the basis of opinion.

Finally, it needs emphasizing that this policy is not merely an academic discussion and an interesting practice guide, but it is created for the purpose of obtaining *obedience* from its physician members and, therefore, carries the very real threat of professional death, if informed consent is not obtained to the College's satisfaction.

A **patient** reading this document cannot help but come away with the impression that the College *imposes* what the patient may chose. The assurances by the College in this policy, and many other publically available statements, that this is not its intention are meaningless when this reinterpretation (limitation) of informed consent is made mandatory. The contradiction between stated intent and actual requirement is glaringly obvious when reading that randomized controlled trials (RCT) are the required prerequisite to even offering non-traditional treatment. Both patient and doctor are placed thereby in an insoluble bind. To equate scientifically based medical practice with RCTs is totally unacceptable for two reasons: such a requirement runs counter to existing statute and case law, and it is scientifically unsupported by the most rigorous standards in *allopathic* medicine. Here are some of the consequences of this requirement:

- It effectively **undermines the patient's autonomy**, that conscious "risk" a patient wishes to take voluntarily and for reasons that differ in individual cases; it is a risk choosing an allopathic treatment, and it is a risk choosing a non-allopathic one. No guarantees are associated with either. However, limiting patient powers of consent in this pre-determined fashion, creates an artificial double standard not applicable to allopathic treatments.

- This requirement effectively **annuls the intent of Section 5.1 i**n the *Medicine Act.* That section does *not r*equire any certainty about non-traditional treatments, it also does not assume any certainty about traditional/allopathic medicine, but merely requires that it not be more dangerous than the usual therapies (all of which carry often enormous risks, as most responsible doctors will agree). Section 5.1 does not require RCT to establish that it is no more risky than generally employed treatments. If Section 5.1 requires, in the opinion of the College and based on transparently provided evidence, an additional caveat, then the public consultation process available through legislative process is available to deal with such a suggestion. Of course, that would mean that the College

would have to provide legally acceptable evidence proving that RCT is the universally accepted standard in allopathic medicine and constitutes the gold standard for clinical application. That is not the case.

- This requirement also ignores and clearly **bypasses *Brett*** *w*hich specifically addresses the need to protect the minority opinion and experience; *Brett* explicitly protects the new, the not-yet-established, as being absolutely necessary for medicine to remain alive and well. Randomized controlled studies do not, as a rule, *start* something new, but test something partly or generally known and tried already. Anybody initiating a randomized controlled study could not even get started, or hope to receive funding, unless a huge amount of information, which has already been used in clinical practice, can be shown to exist, so that it is clear that compelling baseline information is available already from which such a randomized study can begin its inquiry. *Brett* is concerned with protecting that starting point. Progress in medicine is not possible without *Brett,* and even *Brett* itself rests on many very important legal decisions handed down in the UK prior to 1991. The concepts presented in *Brett* are entrenched in common law as well as internationally, hence the wording of the *Helsinki Accord*. Indeed, it is deeply puzzling and disturbing that such blatant disregard for both *Brett* and *Helsinki* are in evidence in this draft policy.

- *Brett* is further undermined by the fact that RCT is by definition a large research event involving a lot of patients, often more than one institution, and big money. ***Brett*, by contrast, explicitly protects the single doctor's intuition and insightful observation** gained from interaction with the individual patient and the professional need to discuss and study such observations with colleagues facing similar patients; it also protects the possibility of discovery of new diseases and new understanding of their causes – all situations that don't happen suddenly on a large scale, but most often are observed by a doctor here or there whose observations are later recognized as being generally important and valid. If RCT had been the prerequisite for handwashing, doctors might still not wash them. The fact is, that by the time a randomized trial is undertaken, the treatment it is intended to clarify, is published for the profession and available all over the world.

- **The importance of RCTs is affirmed as if they constitute a guarantee for safety and efficacy**. A serious misunderstanding arises thereby because randomized trials are discussed within the context of safety and efficacy. Such trials do not necessarily establish safety and efficacy; basic biochemistry and toxicology are a lot better at that! Anyone who has ever attended a conference devoted to drug design sponsored by the big drug companies will know that the chief concern discussed concerning old drugs as well as new ones hoping to get to market, is their universally acknowledged liver and central-nervous-system toxicity. Under the best of circumstances, RCTs tend to be very good on providing *statistical* information about safety and efficacy. The very fact that statistical

information is at the core of any RCT means that the exception, the biochemical individuality which later may prove to be very valuable for new insights – that this exception which non-allopathic doctors tend to face (or are attuned to noticing) is not considered. RCTs focus on drug therapy, but some non-allopathic medicine tries to deal with the often intolerable side effects of such drug therapy (however appropriate statistically) in those patients who remain ill. Indeed, if the RCT approach had been a requirement, the accidental discovery of penicillin would not have taken off: it was an accident after all interpreted by a prepared mind. True, such trials did not exist when Alexander Fleming made this discovery. But are we to assume that no more Alexander Flemings will appear? That no more accidental discoveries can be made? That the application of the unexpected will never be necessary again? That only statistics apply to clinical reality? Neither allopathic nor non-allopathic medicine is going to benefit from the imposition of such an inappropriate requirement for clinical practice.

- Most importantly, the RCT requirement <u>in terms of</u> safety and efficacy leads to the question **why the College believes that the onus is on the doctor to prove safety**. This is standing common law on its head. When a doctor treats a patient with something new and non-traditional, he/she certainly is legally required to do so using the best available evidence and must inform the patient of everything pertinent. However, the test of treatment cannot be exclusively determined by the availability of an RCT, but must focus on *patient outcome*. The obligation to follow a cookbook's recipe does not guarantee a good cake is baked. Every baker knows that lots of adjustments, imposed by local conditions, are often needed and that those will not be found in the recipe but arise from experience. This issue is of central significance to patient choice and their power of consent being respected, as well as to innovation in medicine. I have witnessed personally <u>many</u> discipline cases at the CPSO during which doctors were prosecuted <u>not</u> because a patient was harmed, placed in danger, neglected, or even complained, but instead because of the College's insistence of a *potential* lack of safety which was alleged in such trials, but never proven by the prosecution. In some of these discipline cases the prosecuting CPSO even explicitly agreed that the patients thus treated improved, but still penalized the doctor for supposedly having fallen below the standard of practice because of a *potential* issue of safety. To use the baking analogy again: it is as if the College agreed that the cake was fine, but the way the doctor cracked those eggs might have landed them on the floor instead of in the dough, so the cake then would have been no good. By that absurd reasoning *every* doctor in Ontario ought to be going through a Section 75 investigation for exposing patients to potential harm! The ignored fact is that the College, being the prosecuting administrative law body, *carries the burden of proof of harm* – and it is not the defense that must prove safety or lack of harm. Aside from the common law requirement that onus of proof rests with the prosecution, another reason this is so stems from the fact that

at the heart of administrative law in particular is its obligation to protect constitutional rights and observe the rules of evidence. Furthermore, the law requires that the evidence tendered by the defense (i.e. the results of the treatment, the patient information available in the chart) must be treated exactly the same way as if it was a court of law. Hence, this draft policy must make it very clear that it is not the non-allopathic doctor, but the College that must prove the case, if safety or harm are suspected in a non-allopathic practice.

2. Comparing the first draft with the second

In July of last year I provided my first invited response to the CPSO's current CAM Policy Review and to it I appended 71 citations from the current mainstream medical literature and case law. Despite that compelling evidence, this draft policy continues to ignore that about 80% of all currently accepted allopathic practices are not based on RCTs and that for especially surgical interventions there are no such studies at all. This 80% statistic of lack of scientific rigor underpinning allopathic medicine derives from the research of the US government and was affirmed by prosecution witnesses in CPSO discipline investigations of CAM doctors. It is also acknowledged in the current edition of the AMA and CMA's *Users' Guide to the Medical Literature* (more below on it). One especially interesting example of this lack of RCT rigor concerns vaccine safety: currently, the US Centers for Disease Control are in the process of commencing the first ever (!) safety trials on commonly used vaccines. They have been *presumed* to be safe for almost two centuries. No risk/benefit ratio has ever been seriously considered, even though adverse events have been faithfully recorded by the US government; in Canada no adverse events from vaccines are recorded, despite the repeated request from the Canadian Medical Association to initiate such a data base.)

The many citations on the current credibility crisis in allopathic medicine which I originally provided were all from the mainstream allopathic community. The *Wall Street Journal* reported on August 10 this year that the retractions of medical publications because of fraud and error has increased 15 fold in one decade with more than 300 of these having occurred last year. The Mayo Clinic announced this year (cited in the same report) that an entire decade of research into cancer therapy based on large randomized trials must be dismissed as based on fraud and error; this prompted the editor-in-chief of the *Lancet* to observe, that these fraudulent studies "are a scar on the moral body of science". The media and the standard medical publications constantly report on research and publication fraud, lack of safety in standard medicine, soaring conflicts of interest, and the resultant harm to patients. All of that information – no exceptions that I know of – arises from allopathic medical practices.

Why then does this revised policy read as if the College is ever so anxious to protect patients from harm and exploitation assumed to be potentially lurking in non-allopathic medicine? Written as if no credibility storm is engulfing allopathic medicine, this draft policy clearly *assumes* that doctors using non-allopathic therapies often might be crooks. This is plainly insulting. Such assumptions are unworthy of a professional College and a mere footnote should have been provided referencing codes of ethics and relevant statutes that deal with fraud of any kind and apply to both allopathic and non-

allopathic doctors. The policy wording clearly insinuates that the science and clinical justification of non-allopathic practices are to be assumed guilty until proven innocent, must be suspected of scientific deficiency and, therefore, may easily lead to deception and exploitation of patients.

In addition to this troubling assumption, what also has remained in the revised policy is the need for fundamental legal fairness regarding relevant expertise. In a court of law this disregard for appropriate peer input would be unthinkable and lead to a mistrial. By what authority this working group believes they can just assert having studied some *unspecified* non-allopathic information and then tell non-allopaths how to do their work, is beyond comprehension. The term that springs to mind is bullying.

In an e-mail replying to my inquiry on this matter, the College confirmed that the working group responsible for this policy consists of doctors who do not practice CAM, and that this is just the way it is done. This is all the more astonishing when considering the original assurance provided in the 1997 *Walker Report* which stated that *"in the elucidation of standards in complementary and alternative medicine, members of the profession respected in the field of complementary medicine approaches should be included in a standing advisory panel"*. Dr. Walker also made explicit reference to the then newly formed OMA Section on Complementary Medicine - none of whose members were part of this current working group.

This fact that the policy is handed down by people who do not practice non-allopathic areas undermines the credibility of this policy totally. In fact this is absurd (dictionary definition: at variance with reason). How would the working group members like it if non-allopathic doctors formed a working group of telling allopaths what standards of practice they ought to meet? This would be most entertaining! I suspect allopaths would rightly invoke the need for obeying the principles of natural justice.

3. The disappearance of Section 26 (2) of Regulation 114/94

When this review process first began, common courtesy demanded that those of us whose input was requested would assume good will and the collegial absence of bias on the part of the CPSO. I personally did assume good will, but now I am seriously doubtful because most recent developments have shown that such an assumption is no longer possible. During the time that this policy was in its preparatory phase, the CPSO requested that the Ontario government eliminated Section 26 (2) of Regulation 114/94:

> "*The fact that a member uses or recommends a non-traditional treatment is not, by itself, determinative of deficient clinical ability*."

Given that the CPSO caused this section to be removed, it is clear that any medical activities or recommendations by a physician in Ontario deemed to be "non-traditional" by the College, can now be considered potentially "determinative of deficient clinical ability." This attitude is further emphasized by the requirements outlined in the proposed draft policy, which resolutely undermines both *Brett* and the *Medicine Act* discussed above. The removal of this section demonstrates blatant disregard for patient autonomy and choice, and a clearly affirmed lack of support for and interest in innovation in medical practice. Therefore, this policy serves an undeclared status quo, but nothing else

that I can see. Removing this section sends the message that neither *Brett* nor Section 5.1 of the *Medicine Act* carry any weight with the CPSO. In other words: Do something non-traditional, and you may lose your license, because anything non-traditional may be a sign of your clinical deficiency – if we, the CPSO, believe it to be so. Given this section's removal, the stated intentions of this policy ring hollow.

4. On the homework done by the policy's working group

In vol. 7(2) 2011 of the *MD Dialogue* on page 6, the assertion is made that the working group did "a lot of homework" for "about two years". It would be most interesting to know what it was that was being researched, especially because this research was conducted by people who do not practice CAM and, therefore, cannot be expected to know where to look for information. The learning curve would have been very steep, but in two years it should have been easily possible to gain some healthy respect for non-allopathic medicine. The absurd requirement for randomized clinical trials would not be in this policy if serious research had been conducted into especially the *results* of non-allopathic practices, namely patient outcome.

Since no sources are given and the working group's research is lacking completely in transparency, it is naturally not possible for a non-allopathic doctor to point out where the working group may have missed crucial sources or misinterpreted something. This approach recalls the instructions of former CPSO attorney Donald Posluns to mind; in trials of doctors using non-traditional methods (which they had learned by careful study with specialized medical organizations, namely their legally protected "*Brett* group") his instructions to the panel used to be: "*You have never heard of* … [fill in the professional medical group of choice, no matter how large, how supported by published research, and how internationally prestigious] … *so, therefore, you must find Dr. X guilty of falling below the standards of practice in Ontario*." [Emphasis was his.] Indeed, ignorance was ordered - possibly to enforce bliss; it certainly made it plain that total arbitrary control over standards of practice was to be seen as an Ontario-specific privilege.

This draft policy displays the same spirit: this policy carries the threat of disciplinary censure if not obeyed and is handed down to doctors pre-identified by the College as being outside the pale and, therefore, suspect. It states, in effect: We looked into this and here is what we think you will do from now on; don't bother asking questions, because we are in charge.

Without providing the source for especially those rather insulting assumptions about potential patient exploitation and scientific deficiencies, that homework must be deemed at best mysterious. Nothing is spelled out. Nothing is communicated other than an assertion of authority based on an undefined and unproven suspicion.

No self-respecting, thinking MD can accept this policy – especially in view of the fact that patient demand has dramatically risen for non-allopathic treatments. Sick people are not necessarily stupid (as this policy seems also to assume), which is exactly why they are flocking in droves to doctors who don't practice by rote, don't automatically prescribe by CPS, and don't pop their symptoms into a predetermined traditional slot.

Since none of this homework is transparently discussed or provided for critical review, one must conclude with two-time Nobel laureate Linus Pauling that the working group has demonstrated that they are "down on what they are not up on."

5. Regarding complaints about CAM practitioners

On page 7 of the same *MD Dialogue* issue the admission is made that "*The College does not receive many complaints about physicians who provide non-allopathic therapies*." That is encouraging and not at all surprising, especially because it is a fact proven by the American and Canadian medical associations, that the leading cause of death is currently associated with allopathic therapies, as I also stated in my first response where I provided extensive supportive mainstream sources and statistics. Would it not be reasonable to encourage the exploration of therapies **not** associated with such a horrific body count? Indeed, would it not be the first and foremost responsibility, indeed the moral mandate, of the CPSO to explore this well-publicized fact of so many patients harmed by drugs and surgical misadventures in allopathic medicine and inform the members of this fact? The paragraph on page 7 continues: "*During the years 2005-2010, there were only 31 investigations arising from complementary medicine cases*" and that many of these "*involved egregious physician conduct with patients often being harmed or exploited*."

As I have followed the CPSO's discipline cases for close to 2 decades, it would be most enlightening to know what these 31 investigations since 2005 were all about, as I am unaware of them. If these were cases of fraud, they would belong into the jurisdiction of criminal law regardless of whether an allopathic or CAM practice was involved. Nevertheless, if any of these 31 investigations arose from a *specific* CAM practice gone horribly wrong, why were they not discussed in the background information to this proposed policy? This would explain if there are objective reasons for the CPSO's concern about the safety and efficacy of CAM practices? If these 31 cases provide evidence of harm through CAM/non-allopathic treatments, the public and the profession are *entitled* to know the details!

Without the details, a statement justifying the CPSO's perceived need for insisting most particularly on "clinical excellence and ethical practice" in all CAM practices (implying they are missing), this unsupported factoid about 31 CAM-related investigations amounts to hearsay at best and gossip at worst. As the policy is to be helpful to physicians and patients, it strikes me as absolutely vital that the specifics of such alleged "harm" and "exploitation" be made public to all. This is especially important because the latest statistics from the US government's poison control centers show that for 27 years straight not a single medical misadventure or death could be attributed to the therapeutic use of vitamins, minerals, and nutritional supplements. After all, it is the use of these in sometimes therapeutic doses, often given intravenously and specifically for chronic conditions or detoxification, that are a core element of many CAM practices.

6. CPSO's QUESTION 1: ***Does the draft policy address all the important issues related to physician conduct? If not, what did we miss?***

Throughout the draft policy, the assumption of harm and lack of scientific rigor in all matters of CAM/non-allopathic practices is assumed. The policy even goes so far as to warn that "*Physicians should be aware that patients might equate the [professional] affiliation with [a non-allopathic clinic] with a professional endorsement of efficacy and safety*." The doctor is expected to make sure that the patient doesn't get the wild idea that

non-allopathic is safe and effective, regardless of the published facts about the lack of safety of *allopathic* medicine and despite the extra training a doctor may have taken in non-allopathic methods - unless, perhaps a supportive RCT can be produced, even though such are rare even in supporting allopathic treatments the doctor also may offer. It creates the absurd situation in which a doctor is basically compelled to tell patients that his/her non-allopathic treatments are probably just bogus – just to make sure the patient doesn't get odd ideas which the College does not share (for unspecified reasons) . Offering bogus treatments is, of course, a clear lapse from the accepted standard of practice – and so the vicious circle spins around.

"What did we miss?

Given that medicine is principally supposed to be a science and non-allopathic doctors are exhorted in this draft policy to be super-scientific, it is astonishing that what is missing is – well! The science! Not a word of acknowledgement can be found in this draft policy about even the possibility of some scientific evidence existing for non-allopathic medicine. Given that the policy clearly insists that non-allopathic practitioners must abide by allopathic standards (as mis-interpreted by the authors of this policy), it is frankly amazing that there is no reference, directly or indirectly, to that master guide of *allopathic* medicine, namely the current 2008 edition of the ***Users' Guides to the Medical Literature – A Manual for Evidence-Based Clinical Practice*** published by the American and Canadian medical associations and edited by McMaster University's Gordon Guyatt (a member of the CPSO who coined the term "evidence-based medicine") and JAMA's Drummond Rennie. The editors and the long list of contributors are among the world's most luminous *allopathic* medical lights. Importantly, many of whom are especially well-known to their peers worldwide and to the mainstream media as well for exposing the wave of fraud in current medical research and for their commitment to restoring the ethical and scientific credibility of medicine. Drummond Rennie states that the purpose of this *Guide* is to

> *"... free the clinician from practicing medicine by rote ..... to put a stop to clinicians being ambushed by drug company representatives ... to end [doctors'] dependence on out-of-date authority*."

This latest edition of the EBM Guide explicitly incorporates guidance in the form of 7 totally new chapters on just RCTs and their shortcomings - hence, the draft policy appears to be an exercise in confirmation bias since allopathic medicine does not support reliance on RCTs as the gold standard for clinical practice. [*] Chapter 2 presents the fundamentals of RCTs and stresses that a well-conducted RCT may be the best possible information under ideal circumstances, but that it is far more helpful to the clinician to understand EBM as

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[*] A press release of August 25, 2011, from the University of California at Los Angeles (erivero@mednet.ucla,edu) reports that the *Journal of General Internal Medicine* just pulished a review of RCTs undertaken by researchers from the *Lancet*, JAMA, the *New England Journal of Medicine*, the BMJ, the *Annals of Internal Medicine*, and the *Archives of Internal Medicine* in which they revealed the sever shortcomings of RCTs with respect to misleading and c onfusing results; their research was focused on highest-impact RCTs published between June 2008 and Sept 30, 2010.

"any empirical observation [that] constitutes potential evidence, whether systematically collected or not. Thus, the unsystematic observations of the individual clinician constitute one source of evidence; physiological experiments constitute another source. Unsystematic observations can lead to profound insights, and wise clinicians develop a healthy respect for the insights of their senior colleagues in issues of clinical observation, diagnosis, and relations with patients and colleagues."

The authors of Chapter 2 then encourage the reader to move to those chapters devoted entirely to the evaluation of RCTs. Of significance to non-allopathic medicine is their observation (p.11) that

"*Unfortunately, n-of-1 RCTs are restricted to chronic conditions with treatments that act and cease to act quickly and are subject to considerable logistic challenges. We must, therefore, usually rely on studies of other patients to make inferences regarding the patient before us. The requirement that clinicians generalize from results in other people to their patients inevitably weakens inferences about treatment impact and introduces complex issues of how trial results apply to individual patients."* (Emphasis mine.)

About the hierarchy, which has RCTs at the top if they are well-designed, verified, and not contaminated by fraud, the authors observe (p.12):

"[physicians] should look for the highest quality available evidence, [but] … any claim that there is no evidence for the effect of a particular treatment is a non sequitur. The evidence may be extremely weak – it may be the unsystematic observation of a single clinician … but there is always evidence."

Chapter 9.2, the first of those 7 new chapters, is co-authored by Dr. Gordon Guyatt of McMaster University and Dr. John P.A. Ioannidis of the University of Ioannina School of Medicine in Greece and Tufts University School of Medicine in Boston. The latter is significant for this discussion because he recently appeared on CBC radio's "The Current" and observed in the interview with Anna-Maria Tremonti that currently all medical research is contaminated by fraud and that extreme caution is required in evaluating any of it. I refer the reader to the excellent article about Dr. Ioannidis published in *Atlantic Monthly* November 2010 entitled "Lies, Damned Lies, and Medical Science".

So here we have one of the great lights among *allopathic* doctors, a leader in medical research and analysis, writing for the American Medical Association's guide to EBM for the expressed purpose of sounding the alarm about RCTs: "Clinician beware!" he writes on page 115. Conceding that "ideally" RCTs would be the best source of information, he observes that this is impossible because realistically for

"clinicians [to] adopt interventions even though randomized trials have never been performed to test their effect on patient-important outcomes … even for medical

interventions randomized evidence is usually absent when it comes to interventions that need to be applied for specialized decisions, after some major first decision has been made. For these interventions their adoption and continued use in clinical practice has been based on various combinations of basic science, preclinical, and observational evidence."

Starting on page 303, the authors give an entire section dedicated to identifying fraud and bias in published research. One thing is certain: these acknowledged opinion leaders do not suffer from illusions about allopathic medicine and take great pains to be transparent; they do not suggest the reader just believe them because they are great guys.

Given the working group spent 2 years on research, it is odd that something as important as this manual on EBM was either not consulted or, if it was, did not inform the proposed draft policy. Setting the standard for *non*-allopathic doctors as RCT is not supported by the leaders of EBM for allopathic medicine, so why should it so exclusively be forced onto so-called *non*-allopathic doctors where it cannot possibly be any more useful than allopathic medicine has decided it is?

Just providing the *generic* details of those 31 cases mentioned in the *MD Dialogue* would have gone a long way towards fulfilling the need for transparency that is so evident in the *Users' Guide* which cites so many examples of studies and/or inferences gone wrong. Is it not the CPSO's mandate to guide the profession and protect the public? The assumption of non-allopathic medicine being not trustworthy, and the requirement of so extreme a standard (that exceeds what allopathic medicine deems appropriate and is not even endorsed as the gold standard) needs to be proven in order to be justifiable.

Of course, this criticism requires that I, too, provide at least some proof as to why RCTs are not appropriate as a standard for allopathic or non-allopathic medicine. The most infamous example comes from HRT (hormone replacement therapy). The use of synthetic horse-derived hormone therapy was backed by many prestigious studies conducted over many years, and millions of women were prescribed these carcinogenic drugs for decades, even though the average hormone dosage exceeded natural levels by 200 times; yet, despite the fact that so many cancers are estrogen-dependent, it was believed that HRT was protective against cancer, heart attack, stroke, osteoporosis and more. All those randomized controlled studies were undone finally by a series of honest RCTs which showed that none of this was the case, and that synthetic HRT was very bad news indeed because it *increased* the risks of all those conditions it was supposed to have been protective against. (See discussion of HRT in *Users' Guide* p. 70 ff).

There is no need to discuss in any detail the RCTs that supposedly established the safety and efficacy of the NSAIDS; the Vioxx scandal revealed just how fraudulent such studies can be. The controlled studies on SSRIs, and especially Prozac and Paxil, were totally fraudulent and temporarily fooled even those experts without whose approval these drugs would not have made it through FDA hurdles. See *Let Them Eat Prozac* by Dr. David Healy. To develop a healthy skepticism about controlled trials of any sort, all one needs to do is go through Health Canada's list of approved drugs and see what happened to them over time. Today almost all drugs have "black box warnings" (FDA) or "advisories" (Health Canada).

The most basic flaw in RCTs is in their methodology which is not immune to bias, fraud, plain errors of interpretation, and inappropriate assumptions. University of

Toronto's Dr. Ross Upshur writes, citing 2001 research by Saver and Kalafut:

> *"evidence of the optimal combination of agents to treat Alzheimer's disease would require 127 randomized trials, 63,500 patients and 286 years".* As for trials for the treatment of stroke, one would need at least 31 RCTs and require an enrollment of 186,000 patients all of which would last 155 years. The conclusion was that "*there are marked limitations to the ability of clinical trials to interrogate varied treatment combinations to determine the most effective treatment strategy ... [and] there is no guarantee or necessity that such studies are available at the time a clinical decision must be made."*

It follows that a CAM practitioner may <u>never, ever</u> be able to provide the sort of proof of safety the College demands. Upshur critiqued the EBM principles successfully because the following criticism he offered a decade ago was explicitly acknowledged as correct and referenced by its originator, Dr. Gordon Guyatt in this current 2008 *Users' Guide*. That original critique by Upshur stated:

"*… if the process of EBM …. becomes more oriented to directing practitioners to use pre-appraised and secondary evidence resources …. then authority has once more supplanted critical rationality as the base of medicine."*

The current *Users' Guide* makes the point over and over again that reliance on "out-of-date authority" is exactly what evidence-based medicine must never become. That is, however, precisely what this CPSO draft policy does and clearly intends to force upon non-allopathic practitioners.

Some branches of non-allopathic medicine are based on thousands of published trials; I refer the reader to the 2010 nine pound textbook on nutritional medicine with its 150,000 citations published last year by Dr. Alan Gaby (it weighs the same as the current edition of *Harrison's Principles of Internal Medicine*). Clinical trials of non-toxic therapies (e.g. essential nutrients, bio-identical hormones, various mind-body techniques, etc) are by definition safe. However, trials upon which allopathic medicine relies are as a rule conducted to find out if a synthetic substance of *assumed toxicity* or a physically invasive technique can be used with some <u>statistically</u> relevant efficacy to control symptoms of a narrowly specified nature –for as long as the patient's liver holds out, if a drug is involved. The drugs currently listed in the *Compendium of Pharmaceuticals and Specialties* (CPS) all medical practitioners are virtually <u>all toxic</u>; hundreds of pages are devoted to explaining just how toxic they can be even under the best of circumstances. That is not to say that they are not effective under appropriate circumstances and when the patient's history and bio-individuality has been properly and measurably assessed; however, reliance on the CPS and only the CPS is

The peer-reviewed literature in some *non*-allopathic medicine is replete with rigorous studies showing efficacy in symptom control without toxic side-effects, overall improvement, and outright cures through the use of non-toxic substances. I faithfully read those journals monthly. Is it possible that the working group did not consult the leading CAM journals ? That they didn't consult them is suggested in the erroneous assertion that CAM/non-allopathic studies/trials are usually "privately funded"; in fact, they are almost always university-based and/or come from the US National Institutes of Health and their

European government-funded counterparts. In any case, what does "privately funded" mean? The transnational pharmaceutical companies are all private and trade their products on the stock-market. The vast majority of our currently available synthetic drugs had their research, RCTs and all, funded by their manufacturers – a fact hardly indicative of transparency and independence.

Every physician wants to know if exploring new ways of treating patients and new disease complexes (which being new are by definition non-traditional) will be met with punishment or support by the CPSO. The details provided in the 2001 *Glasnost Report* and the fact that a decade later it was the CPSO which caused the removal of Section 26 (2) of regulation 114/94 cited above, signal clearly that doctors exploring new methods and putting patient outcome first, better be on guard or seek membership in one of the other colleges regulated under the RHPA. The original 1997 version of this CAM policy, was even then out of touch with medical and social reality; this new version may be outright dangerous to professional survival, and by extension to public health.

If safety and efficacy are really the main concerns of this policy, how can it naively assume that allopathic medicine is generally safe and effective? Radio, television, the newspapers tells us otherwise almost daily. I refer the reader to the endnotes and to the exhaustive source list provided in my first response.

What grates on the nerves with this policy is the arrogance in evidence through the very distinction made between allopathic and non-allopathic. (Dictionary definition:*" an attitude of superiority manifested in presumptuous claims or assumptions*.")

CPSO's QUESTION 2: ***Is the revised draft policy clearly written?***

It makes it clear that any Ontario physician contemplating the use of non-allopathic practices is in very real danger of winding up in a Kafkaesque world of prosecution without even the legal recourse he/she once had when Section 26 (2) of Regulation 114/94, mentioned above, still existed. Insistence on relying on unsubstantiated external authority, as opposed to real clinical experience, also comes through loud and clear. Medical students reading this policy, which is at variance with what they learn in university, might take flight from Ontario or wisely join one of the other colleges under the RHPA. Worst of all, the onus of proof of safety defined through an unattainable and misrepresented standard makes it clear that maybe becoming a doctor was a really bad idea. Read through the eyes of an educated patient with experience in non-allopathic therapies, the policy is frightening because the same old fossilized attitude to currently evolving understanding of illness is maintained with unmistakable firmness.

What also comes through very clearly is a total lack of understanding of what exactly non-allopathic medicine is, otherwise physicians would not be expected to always first "*err* on the side of caution" (emphasis mine). The insistence, that every Ontario doctor must offer allopathic treatment first, is what patients don't want to hear any longer. I understand the CPSO derives its mandate from serving "the public interest"; this policy serves something else, but not the public interest when doctors' clinical decisions are straightjacketed in this manner and patients are presumed to be ignorant.

CPSO's QUESTION 3: ***If physicians recommend non-allopathic therapies, do you think their recommendations should be based on scientific evidence?***

First of all, given that Section 26 (2) is now history, thanks to the CPSO, recommending non-allopathic treatment could get an Ontario doctor into conflict with the CPSO, so that part of the question requires no further response.

The second part of that question belongs in the category of the sort that is used to manipulate a pre-determined outcome for the questioner. It is like: "When did you stop beating your wife?" It does not permit you to explain that you didn't beat your wife and that maybe you don't even have a wife. In other words: does the College seriously entertain the possibility that a person with an MD, whose intelligence must be presumed to be rather good for just that reason alone, would answer "No!" to that part of the question? This question is painfully biased and displays an alarming level of ignorance about both – allopathic and non-allopathic medicine.

7. My recommendations

1. Scrap this policy. The entire exercise is pointless and not helpful in the least. It is not a policy – it is a bludgeon. There is no such thing as allopathic and non-allopathic medicine – and the term "complementary and alternative medicine" was originally invented by the pharmaceutical companies as an intended pejorative description. This artificial distinction is historically absurd, because the current so-called allopathic medicine is merely less than 150 hundred years old at best – taking Semmelweiss and Pasteur as the logical starting points for modern Western medicine. It is also *currently* absurd because a regulatory authority, such as the CPSO, is supposed to act in the public interest which means respecting medical science in evidence worldwide and demonstrate that it does not simply favor the sort of medical practice that is known to be the lifeblood of Big Business.

Given that homeopathy, naturopathy, and traditional Chinese medicine are all under the RHPA with their own colleges, they certainly have proven to be helpful to contemporary patients. Given that fact, the insistence that a CPSO member-physician may only use such therapies if these medical traditions are proven to meet an illusory standard is presumptuous.

Finally, since so much of non-allopathic medicine arose directly out of university-based research and at institutions, such as the CAM Division at the US National Institutes of Health, it is vital to recognize that these new areas will prove to be useful in clinical settings through **evolution**, and must not be choked off by biased **pre-emptive regulation**.

2. The only determinative factor, allopathic and non-allopathic, should be evidence – but not arbitrarily defined, but as defined in law. In medicine that means that evidence always has something to do with patient outcome. This is especially relevant when something new is tried for which research begins on a larger scale after the pioneering effort shows promising results and potential for measurement.

3. The single most important action the CPSO must take, if its credibility as a regulatory authority is to survive, is to explicitly and in the clearest language drop the double standard contained in this policy; it is not only scientifically and legally insupportable, it hinders doctors from widening their scope of practice. The CPSO is supposed to encourage widening of the scope of practice, not assume automatically that something suspect has occurred. The attitude displayed by the CPSO in this policy, to be imposed on non-allopathic practices, will make it impossible to practice medicine effectively in Ontario, and Ontarians will also have their fundamental rights ignored.

8. Imagining what this policy would do in the real world: A Cautionary Tale

Imagine a 50-year old female lawyer who in her pre-puberty years was repeatedly exposed to DDT from her father's pesticide business (DDT was outlawed in North America in 1978.). I am imagining her as a lawyer and will call her Anne McDonald; lawyers are professionally conditioned to "see red" more easily than most people. Those "gender bender" pesticides caused serious harm to Anne's endocrine system, made it impossible for her to conceive, and eventually necessitated a total hysterectomy in her late 20's, an intervention known to cause serious deficiencies in estrogen, testosterone, and progesterone. Anne also has a family history of breast cancer: her mother, one sister, and both the maternal and paternal grandmothers died of breast cancer. Her father, the pesticide merchant, died of brain cancer.

Following that total hysterectomy some 20 years ago, hormone replacement therapy (HRT) was initiated, specifically Premarin, which was the treatment of choice for natural menopause problems as well as surgically induced menopause. Problems with breast tenderness, frequent pain in the legs, unexplained weight gain, and persisting mild depression, unrelated to life circumstances, were becoming intolerable when Anne McDonald learned from the mainstream media that those protective claims made for decades for HRT drugs had been shown conclusively to be false, based on errors and fraudulent data manipulation. None of the protective claims held up, not even the one that seemed to remain unchallenged at first, namely less hip fractures in HRT users. That claim was base on just 6 patients out of 10,739 women and is, therefore, statistically meaningless. Indeed, all those conditions HRT was supposed to prevent were found to be *increased* by its use.

Anne's Google search confirmed that these damning studies were legistimate and that her symptoms were probably due to the years on Premarin. As her search also led her to the revelations of fraud concerning anti-depressants, such as Prozac, she was relieved to learn that her decision to refuse SSRIs for her persistent mild depression was now obviously attributable on sound caution. Anne McDonald was shocked to learn that HRT and SSRIs both carried an increased risk of cancer. Having a busy law practice, she had not seen her GP much, but had heeded his suggestion to reduce the dosage of her HRT pills to the lowest level.

Then one day in 2010 she went for an eye examination to get new reading glasses and read an article in a magazine about "natural" hormones which were described as non-toxic, approved by the FDA and Health Canada, and not associated with cancer etc. So she made an appointment with her GP, Dr. John Goodenough.

"Is it true," Anne asked, "that HRT and SSRIs are based on scientific fraud?"

"Well, doctors began to notice starting back in the 1990s that their HRT-treated patients seemed not to do as well as they should have and became sick with cancer when they were supposedly being protected against it by HRT. They also noticed that antidepressant users were increasingly getting cancer, and now we know that SSRIs also increase the risk of suicide." Dr. Goodenough pointed to a stack of issues of JAMA the CMAJ. He leaned over and fished out a copy of the *Lancet* from 1997. "They suspected and increased risk of breast cancer from HRT ever since this article here was published. That's 14 years ago now."

"So with my family history of breast cancer, can it possibly be a good idea to continue with Premarin at all?"

"No. You are absolutely right. Given what we know about these drugs, it is not in your best interest to continue," replied Dr. Goodenough and starts leafing through Anne's chart. "We already reduced the dose to the lowest available, but you still complain of breast tenderness and you haven't lost any weight in spite of going to Weight Watchers, and I understand you still have problems staying asleep."

"So what do I do?" asked Anne. "I can't just do nothing! I don't have any ovaries, so there goes estrogen and testosterone production, and without a uterus I am not going to get any progesterone! My Google search basically confirms that I am about to join my foremothers! What about *natural* hormones? I read about it in a magazine at my eye doctor's office. Can we try those now?"

"Oh dear!" Dr Goodenough sighs.

"Well? Do you know anything about this?"

"Oh yes," replied Dr. Goodenough. "Natural HRT is made from plants, the active ingredient is 200 times less powerful than the horse urine-derived HRT drug, that means its as safe as it can get and most unlikely to triggering cancer, the stuff is bio-identical which means the body's receptor sites recognize it as self rather than non-self and, therefore, the immune system is not triggered into alarm, no significant adverse events have so far been reported, some excellent outcome studies and observational ones have been published by universities in the US and Europe, and yes – natural HRT is FDA and Health Canada approved."

"OK, so we will try this." Anne relaxed visibly.

"I am not sure, " said Dr. Goodenough.

"Why?"

"Well, you see the College of Physicians and Surgeons of Ontario, which regulates medicine in this province, just brought out this new policy for alternative medicine – what they call non-allopathic. If I prescribe natural hormones to you, with your full consent even, they could take me into discipline and I could be in danger of losing my license."

"For prescribing a Health Canada-approved drug that is known *not* to be toxic?" Anne asks, incredulous.

"That's not the point, I am afraid. This new policy explicitly states that I cannot recommend or prescribe a so-called alternative or non-allopathic therapy, unless I can prove to you that a randomized controlled study has been done proving that natural hormones are no more toxic than synthetic HRT. The problem is that I can't tell you that such a study exists."

"But, but, but … you just said that there was good research on natural hormones

and you agreed that the research shows that the conventional HRT is a drug from hell, so what's this all about?"

"There are a lot of good studies involving large numbers of women. One just came out this year by Ruiz and his team in Texas. They proved the benefits – well, there is no down side to bioidenticals at all, in fact. That's all published."

"OK, what's the bullshit here, John?" Anne asked.

Dr. Goodenough looks visibly pained. The moment of truth has come and there is no escape. "The problem is," he explains "that because everybody now knows that conventional HRT is potentially dangerous, no ethics committee would approve a randomized controlled study comparing it to natural hormone therapy. Thousands of women would have to be recruited to take only the toxic HRT so the results from those patients could be compared to those women taking natural HRT. We cannot knowingly give potentially harmful drugs to patients – unless one outright lies to them, which has happened in enough studies to give me sleepless nights occasionally because you no longer know what the hell to rely on."

He reaches up to a shelf full of books and retrieves a book with the ominous title *White Coat Black Hat* by Carl Elliott, published in 2010. He hands it to Anne as he sits down and continues: "No woman in her right mind would agree to participate in such a study. Even the legions of so-called professional trial subjects on whom most drug trials rely and who undertake toxicity studies for pay, would balk at this. When they enter a drug trial the toxicity of some potential new drug is not yet known – but if recruited for this type of test of bioidenticals, they would know the risks they run. The cat is out of the bag. So, this means, that as things stand now, we might never, ever have a randomized controlled study proving that natural hormones **are** safe, even though we have incontestable proof that synthetic HRT **is** harmful to an unacceptably large number of patients. Now, according to this new CPSO Policy, which they have the power to enforce, unless I can show you such a never-never-land study, I cannot prescribe you a safe alternative without risking discipline."

"What idiot came up with this?" Anne McDonald asks.

Dr. Goodenough shrugs. "I know of doctors who did lose their licenses because of recommending or prescribing natural hormones and even just warning patients against synthetic HRT. One license was suspended when a doctor warned of excessive refined sugar intake for diabetics, because the Sugar Institute of Canada complained to the CPSO! The diabetics probably already knew this, of course. Another license was endangered by a long investigation because the doctor used non-steroidal treatment for asthma in children to prevent stunted growth – a known danger of those puffers. Yet another one got into trouble and lost her license essentially for testing anemic people for parasites – dogs get better treatment for worms, I suppose. Another one was put through a trial for almost two decades for treating people for pesticide poisoning. Right now two of my colleagues are under investigation for using bioidentical hormones because they supposedly should have done certain physical exams – which do not apply when using bioidenticals or when the patient has had a total hysterectomy. So, there you have it."

"This is nuts! And where do I go from here? Do naturopaths have the right to prescribe natural hormones? I don't want you to get into trouble." Anne McDonald the lawyer is beginning to feel itchy and combative.

"No, naturopaths do not have the right to prescribe – yet. They may sometime in

the future, as they do for certain things in British Columbia already. We can't hold our breath for that."

Dr. Goodenough is beginning to sweat. He remembers his mother's death from cancer, and then there are all those files in his office storage room - all those people he once saw and could not prevent from joining that vast majority – the dead.

"Funnily enough" he observes, starting to think out loud, "we have 5 compounding pharmacies in Toronto which specialize in making natural hormones, thyroid extract, and various natural treatments for asthma, and many more therapies that don't have the risk of awful side effects. There are many such licensed pharmacies throughout North America. You can also try the internet, of course, and you could go across the border. You can also go - "

" – to court," Anne McDonald interrupts Dr. Goodenough's free associations. "I don't mind telling you, John, that I am mightily pissed off. It's okay to prescribe toxic drugs, but you get into trouble if you prescribe something that isn't toxic because of some crazy standard the nontoxic stuff is supposed to meet. What makes these guys tick? Are they in bed with the pharmaceutical industry?"

"Who isn't! And if so, what do you want to do about it?"

"Well, John, this has been an education. I am going back to the office and assign staff to researching the *Charter*, the *Regulated Health Professions Act*, all the rest of the laws involved with negligence, harm, informed consent, etc., and I am going to have a look at what the heck the College derives its powers from and what those powers really are - and I'll check out all relevant case law. Maybe you better check my blood pressure as well, I am so mad I could spit." Anne McDonald rises and grabs her bag in preparation for her departure.

"Anne, sit down, will you," D. Goodenough says in a soft voice. She sits. He looks at the carpet between his shoes and sighs long and deep. "Anne, I am a doctor, and I will be damned but I will not be a drug company whore or a drug pusher. I am giving you a prescription for bio-identical. And my advice is that you stop right now - cold turkey - taking that crap Big Pharma duped us all into for so long. I also want to do a battery of tests, and come to think of it, we better check out your thyroid; those drugs and that DDT from back then are really bad for thyroid function. it. Let's start with taking blood, OK?" He rises to go into the next room where blood samples are taken.

"But – what about you? Aren't you scared?"

" [*expletive deleted*] … the College. Let's take your blood."

As Anne McDonald leaves his office, she says. "I am ready to battle."

Dr. Goodenough smiles: "Now go home and read that book by Carl Elliot. You might need some Gravol before you start reading, though." Anne McDonald goes to the door and Dr. Goodenough calls after her, "Anne, do NOT take Aspirin, but call me in the morning."

P.S. Even worse would be imagining a patient who suffered greatly from conventional HRT, required treatment for blood clots and suffered a heart attack, was taken off synthetic HRT and placed on bio-identical hormones - only to be told a couple of years later (December 2011), after feeling a lot better and no longer suffering from the side effects of synthetic HRT, that her doctor can no longer prescribe the bioidenticals for the same reasons given in the first scenario above.

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Manitoulin Island, August 2011