I Introduction

Healthcare pluralism in Canada, as well as in the United States, is on a continuous rise. Data from the United States show that in 2007 almost four in ten Americans used complementary and alternative healthcare. Expenditure on Complementary and Alternative Medicine (CAM) in the US amounted to about $34 billion in out-of-pocket spending in 2007, with $11.9 billion spent on visits to practitioners. The US data also indicate that, while about 27.4 percent of the adult population used CAM for health promotion, 17.4 percent used CAM for treating disease or illness.

A study by the Fraser Institute in Canada shows that 74 percent of Canadians use complementary and alternative health services, while 71 percent have used natural health products to combat chronic and debilitating medical conditions. The study found that 17 percent of Canadians have used natural health products simply for preventive healthcare purposes. According to a different study by Health Canada, 81 percent of Canadians are convinced that there will be an increase in the use of natural health products over the next ten years. In spite of the rising profile of medical pluralism in Canada, restrictive federal and provincial laws and policies place complementary and alternative health services and products out of the reach of many Canadians and impede the practice of complementary and alternative medicine by many Canadian health practitioners.

The traditional definition of medical negligence or medical malpractice, which renders a physician’s practice of CAM a standard case of deviation from acceptable practice standards, further inhibits the professional autonomy of physicians interested in practicing CAM or integrated medicine. However, recent legislative changes, such as amendments to the Medical Acts or health professions legislation of some Canadian provinces, attempt to ease the contentious relationship between the biomedical institution and CAM practice by recognizing — without actually exposing — the practice of CAM through the circuitous approach of modifying the grounds on which biomedical healthcare professionals may become liable for medical malpractice.

For example, amendments to Medical Acts in Alberta, Ontario, British Columbia and Manitoba provide that physicians will not be liable for unprofessional conduct solely on the basis of departing from the prevailing medical practice or practicing non-traditional therapies. These provisions in Canadian law are modeled after similar provisions in Acts regulating medical practice in several states in the United States (US), including Oklahoma, Texas, Washington, Oregon, New York, North Carolina, Massachusetts, Georgia, Colorado and Alaska. Today, while a good number of laws and legislative amendments, which are denoted as health freedom laws, in the US as well as Canada provide that physicians may become liable for unprofessional conduct for practicing a non-traditional therapy except where the chosen therapy poses a greater risk to the patient than the conventional therapy, Alaska's health freedom provision (and before the recent amendment following a key legal decision, North Carolina's) has a different proviso which makes physicians automatically liable for a non-consultation therapy where the patient is harmed. Washington's health freedom law incorporates both types of provisos, attaching liability to a physician's use of a non-traditional therapy only where it results in harm or creates unreasonable risk.

Denoting these provisos as the “harm principle”, this chapter explores the critical implications of the principle alongside the disparities between the two variants of the provisos and their impact on the practice of CAM and integrated medicine. The chapter contends that, in deviating from the traditional standards for a finding of liability for medical negligence or malpractice, the provisos draw a subtle hierarchy between CAM and biomedicine and further impede the practice of CAM. While outlining the impact of the provisos on the integration of CAM and biomedicine, the chapter outlines how the health freedom provisos reinforce the co-option model of CAM integration — a model involving the practice of validated CAM therapies by physicians, and fundamentally excludes non-biomedically trained CAM practitioners from hospital-centered CAM practice.

It is noteworthy that there seems to be a gradual trend in legislation towards the more nuanced provision that emphasizes the degree of risk of a CAM therapy comparative to standard or recognized treatment as the scrutiny for finding of professional liability — a trend that appears to have been spurred, at least in the case of North Carolina, by adverse judicial opinion. However, it remains important to deconstruct the inherent problems and limitations of the harm provisos in order to serve as a decision-making guide for future US and Canadian state and provincial legislatures that are yet to adopt a health freedom law.

The analysis and perspectives articulated in this chapter draw from law and ethics — from the analytical tools provided in the law of professional negligence and the ethical principles of non-maleficence and, inferentially, autonomy. These disciplines collectively illuminate the approach adopted and thesis herein espoused. Given the nature of the subject of complementary and alternative medicine — a subject imbued with the complexities that trail healthcare and health law studies — and its dependency on law for legitimacy, the analysis of the harm principle through legal and ethical lenses is fundamental to achieving the ultimate goal of validation and legitimization of CAM.

The discussion is set out in three sections. The following section defines and examines health freedom laws in Canada and the United States. Next, in the context of a general overview of malpractice in CAM practice, the “harm principle” is analyzed with some focus on the similarities and differences between the two versions of the harm principle adopted by US states and Canadian provinces. The section also examines the implications of the provisos within medical negligence law. Following the discussion of the harm principle, the section highlights the slippery-slope effect of the amendments towards the co-option model of medical integration, and evaluates the impact of the amendments on the growth and development of the field of CAM. The concluding section discusses possible legislative and interpretive reform of the harm principle with primary focus on the importance of minimum standards of acceptable medical practice as part of the evaluation of a healthcare professional's liability for the practice of CAM.

II Health freedom laws in Canada and the United States

Medical malpractice or medical negligence more generally occurs when a healthcare practitioner provides a treatment that deviates from acceptable standards of medical practice and the treatment causes harm to the patient. This universal definition under the law of torts of which negligence is one of several subjects implies that physicians practicing CAM — a constellation of practices which, in many respects, do not conform to the theories of biomedicine — deviate from the standards of biomedicale practice, stricto sensu. Health freedom laws in the context of physicians' liability for the practice of CAM are legislative attempts to extend the boundaries of physicians' scope of practice to accommodate (the increasing occurrence of) CAM practice by physicians without the automatic liability that traditionally attaches to such practice.

Generally, health freedom laws (or medical freedom laws as they are also called) are laws or legislative amendments that protect the freedom of patients to make decisions about the type of healthcare or health services they should receive and the autonomy of health professionals to provide those services. This omnibus definition recognizes the variation in the laws that have been labeled “health freedom laws”. Hence, it places within the taxonomy of “health freedom laws” or “medical freedom laws” legislative provisions and statutes that are passed with the objective of broadening patients’ access to complementary and alternative therapies — amendments that are directed at alleviating the risk of professional liability for physicians who practice CAM.

Laws crafted to overturn the specter of prosecution under which unlicensed CAM providers practice their profession are another example of health freedom laws. Thus, some health freedom laws, such as Minnesota’s Complementary and Alternative Health Care Freedom of Access Law (CAHFAL), signed into law by Governor Jesse Ventura in 2000, also aim to allow unlicensed CAM practitioners to practice as long as they do not carry out certain restricted procedures such as surgeries and x-rays or prescribe certain drugs, while guaranteeing reimbursement through third-party insurers to licensed providers. Such laws, as in the case of Minnesota’s CAHFAL, often have built-in protective mechanisms for the public, including provisions for full disclosure of practitioners’ practice and training as well as enforcement mechanisms to prevent fraud.
Interestingly, also labeled as "health freedom laws" are state statutes in the US that focus on undermining, through counter-legislative provisions, the validity of the United States' Patient Protection and Affordable Care Act (PPACA). The PPACA, which was signed into law by President Obama on March 23, 2010, was heralded by controversies, legal and otherwise, led by both political figures and the lay and in its wake by legal and constitutional challenges regarding the individual health insurance mandate provided by the law. Also the subject of challenge were the scope of congressional powers and the right of states over healthcare, amongst other issues. Besides several court challenges instituted by some states, there have also been new state laws promulgated to negate several key provisions of the Act, such as its mandatory healthcare insurance provision. This latter group of statutes, with the underlying objective of challenging the alleged restriction of rights under the PPACA, is beyond the focus of this chapter.

The underlying objective of health freedom laws coming within the first two categories outlined above is to provide broader freedom for health professionals and patients interested in non-mainstream therapies. Central to the discussion in this chapter are amendments specifically designed, at least apparently, to limit the risk of professional liability for physicians practicing CAM or other experimental therapies. A number of states in the US, including New York, North Carolina, Oklahoma, Texas, Washington, Oregon, Massachusetts, Georgia, Colorado and Alaska, have passed health freedom laws that redefine the threshold of liability for physicians interested in practicing CAM, though with different wordings, and therefore, as argued below, different legal effects. In some cases, as in the case of Minnesota's CAHFAL, a health freedom statute or proviso is the result of collective efforts through mobilizations by concerned practitioners or patron groups to challenge the status quo following high-profile litigations against CAM practitioners. It could arise from the sometimes-incessant disagreements between boards of medical examiners and associations or professional bodies representing alternative healthcare practitioners.

Health freedom laws provide that physicians will not face disciplinary action or be held liable for malpractice for merely using an unconventional or a non-traditional therapy. The caveat, as outlined in Alaska's health freedom law, is that the practitioner will be guilty of misconduct where the treatment administered results in harm. This is one of two dominant versions of the harm principle. The classification of the principles into two groups is primarily for convenience. In actuality, the "harm" and "risk" provisos come in a spectrum of types. Some other statutes have a more nuanced, and perhaps tolerant, version of the proviso. For example, the harm principle under Colorado's Medical Practice Act, which of course comes under the section on what constitutes "unprofessional conduct", is stipulated as follows:

"Unprofessional conduct" as used in this article means:

(3) (a) For purposes of this section, "alternative medicine" means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of such methods. A licensee who practices alternative medicine shall inform each patient in writing, during the initial patient contact, of such licensee's education, experience, and credentials related to the alternative medicine practiced by such licensee. The board shall not take disciplinary action against a licensee solely on the grounds that such licensee practices alternative medicine.

While Colorado's law does not expressly adopt either of the provisos verbatim, it does implicitly impose disciplinary actions by the board where a licensee practices an alternative therapy that is outweighed by the risks associated with the therapy.

Another interesting formulation of the proviso is to be found in Washington's health freedom provision. The Washington provision combines both forms of the principle into a rule that simpliciter attaches liability to either the occurrence of harm or to the use of a therapy that creates an unreasonable risk. According to the law, the administration of a "non-traditional treatment" is not by itself proof of malpractice, provided the treatment does not result in harm or create unreasonable risk to a patient. Thus, a physician would be liable for malpractice if an applied alternative therapy causes harm simpliciter.

Some other laws provide, equally tolerantly, that physicians will be liable for professional misconduct only where the non-traditional treatment poses a greater risk to the patient than the traditional or conventional treatment. The Medicine and Allied Occupations Act of North Carolina now has a health freedom amendment of the tolerant category. Section 90–14 of the law, which outlines the disciplinary powers of the North Carolina Medical Board, provides as follows:

The Board shall not revoke the license of or deny a license to a person, or discipline a license in any manner, solely because of that person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.

Prior to the amendment that gave rise to the above new provision — a move inspired by a judicial decision, a physician was guilty of professional misconduct based on "departure from, or failure to conform to, the standards of acceptable and prevailing medical practice ... irrespective of whether or not a patient was injured by the therapy." As evident in the case of Re Guess, the old rule could have a deterring effect on practitioners, as well as their patients, whose conduct did not otherwise constitute a breach of clinical standards.

Employing legislative language similar to that used in the "tolerant" version of the harm principle in the US, the relevant Acts regulating physician practice of the Canadian provinces of Ontario, British Columbia, Alberta and Manitoba stipulate that non-conventional practice by provincial physicians will not result in liability except to the extent that the therapy constitutes a higher risk alternative compared to the conventional treatment. According to section 5.1 of Ontario's Medicine Act,

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

In Alberta, section 5 of Schedule 21 of Alberta's Health Professions Act, provides:

The college must not act against a registrant or an applicant for registration solely on the basis that the person practises a therapy that departs from prevailing medical practice unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice.

In British Columbia's Health Professions Act, 1996 stipulates:

The college must not act against a registrant or an applicant for registration solely on the basis that the person practises a therapy that departs from prevailing medical practice unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice.

A similarly worded provision is contained in section 185 of Manitoba's proposed Regulated Health Professions Act. These provisions convey the same rule. Except to the extent that it is unclear whether the law conceives the traditional or prevailing therapy as biomedical, this version of the harm principle apparently aims to ensure that patients receive treatment that poses the least risk to the patient's health and safety. With the lack of clarity on whether the legislative intent is to allow "prevailing" or "traditional treatment" to be defined as either biomedical or CAM, it is debatable whether the phrases should be construed as such.
A more progressive interpretation is the non-discriminatory reading, that is “traditional” or “prevailing” treatment should be taken to mean treatment that is either biomedical or CAM. This construction of the phrases accommodates a future in which the biomedical community would accept specific validated CAM therapies as the standard therapies for particular conditions. In fact, there are early judicial and legislative signs indicating the likelihood of such a future when both law and medical norms would evolve to hold physicians to a higher standard of care requiring full disclosure of procedures or treatments which are currently described as non-conventional or fringe and hold physicians liable for failure to do so. The US case of Gemme v Goldberg22 illustrates this point. In that case, a physician who did not inform his patient that surgery was elective and that the patient could opt for an alternative treatment was held to have breached the informed consent rule. According to the court, the jury could have decided that the physician had breached the informed consent obligation by negating “to disclose a viable alternative that might have produced a less perfect result but may have represented a safer or less invasive procedure”23.

An important legislative pointer to the broader meaning of “prevailing” or “traditional” medical practice may be found in British Columbia’s Health Professions Act, 199624. As already observed, section 25A.4 of the Act provides that the “College” will not indict registrants or applicants “solely” on the ground that the registrant practices a therapy that “departs from prevailing medical practice” unless it can be demonstrated that the therapy poses a greater risk to patient health or safety than does prevailing medical practice.24 The Act includes in its definition of “college” the British Columbia College of Chiropractors, the College of Dental Surgeons of British Columbia, the College of Surgeons and Physicians of British Columbia, the College of Pharmacists of British Columbia, and any other college “continued under” section 15(1) of the Act.25 The inclusion of the College of Chiropractors in the definition may be taken to suggest that “prevailing medical practice” could refer to either CAM or biomedicine. Yet, it remains unclear whether statutorily unregulated CAM practices in British Columbia would be classified as “prevailing medical practice”. Canadian health freedom provisions would stand in contrast to some in the US if “prevailing medical practice” does not include unregulated CAM practices, considering that statutes denoted as health freedom laws in the US also include statutes or provisions authorizing unregulated CAM providers to practice within defined scopes and guidelines.

Although the harm principle may serve as a welcome legislative attenuation of the hitherto “strict liability”26 imposed on physicians who practiced outside their professional boundaries, the law insists on a number of safeguards for patients. Generally, physicians practicing within the area of CAM or integrated medicine must comply with the informed consent principle, providing patients complete information on the benefits and risks of the proposed treatment. Physicians are also required to conduct appropriate examination and testing, provide follow-up patient monitoring and keep medical records.27 In fact, the health freedom laws of some states, such as Texas and Louisiana, require physicians interested in administering a CAM therapy to conduct comprehensive examination, offer an appropriate diagnosis and treatment program, and carry out patient reviews, as well as comprehensive and accurate record keeping.28

Therefore, although physicians have some more latitude to practice CAM either as an individual therapy or as part of a broader biomedical regimen, they are required to continue to follow traditional clinical, ethical and legal guidelines. This point was made clear in Zinkuvich v College of Physicians and Surgeons of Ontario29 a case involving a physician who was indicted for violating professional standards of practice. The physician was alleged to have used methods of diagnosis and treatment with no scientific validity. Although the disciplinary committee of the College found him guilty of professional misconduct, the committee stipulated, while acknowledging the harm principle, that the use of an unconventional therapy was not of itself evidence of professional incompetence.30

III The harm principle

The provisions discussed above identify the occurrence of harm or presence of risk of harm greater than that associated with the prevailing regimen as the legal threshold for a finding of liability. This strict requirement of injury or of a greater risk of harm for a finding of liability for CAM practice is, as evident in the foregoing discussion, herein described as the “harm principle”. The legislative focus on the occurrence of harm is hardly surprising. As Beauchamp and Childress have noted, the doctrine of non-maleficence, which prohibits us from harming others, is in the realm of medical ethics a principle that “has been treated as effectively identical to the celebrated maxim Primum non nocere: Above all [or first] do no harm”.31 The Hippocratic Oath itself includes the principle of non-maleficence as well as the doctrine of beneficence: “I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them.”32 The ethical principle of non-maleficence binds physicians to a duty of assessing the likely risks of a therapy or medical procedure before using the therapy or carrying out the procedure. The obligations imposed by the principle include both the duty to avoid inflicting harm on others and the duty to avoid imposing risks of harm.33 Thus, the two primary versions of health freedom laws — the first basing liability strictly on the occurrence of harm and the second requiring that the alternative therapy does not pose a greater risk than the prevailing therapy — are subsumed under the doctrine of non-maleficence.

As is further elucidated below, both provisos are problematic, the former more so than the latter. However, considering the role of medical professional monitoring boards in professional output regulation, it can be contended that the goal of patient safety is central to health freedom provisos, especially those legislative amendments that focus on the occurrence of harm simpliciter for a finding of professional misconduct. The version of the harm principle that advises against the use of a therapy that poses a greater or higher risk of injury to a patient than the conventional treatment is arguably a reasonable standard expected of physicians, especially considering the ethical guidelines within which physicians must operate. However, both forms of the principle are contentious, with the “greater risk” proviso debatably raising some challenging questions with no straightforward answers.

The primary problem that the provisos raise is the absolutism in the treatment of the occurrence of medical harm. Underlying the first proviso — that is, the construction that invokes legal liability on the mere occurrence of harm — is the assumption that all medical harms are culpable. The factual and legal foundations of this version of the principle are flawed because the proviso, prima facie, ignores the justificatory and excusatory conditions in the occurrence of medical harm. Under the tort of negligence, a medical practitioner is guilty of professional negligence only after an assessment of a number of factors.

1. The existence of a duty of care as between the health provider and the patient;
2. Breach of the duty of care;
3. The occurrence of injury or harm;
4. The existence of a nexus between the breach and the injury.

These four factors simply require a health provider to have a duty of care to the patient, a requirement satisfied by the provider—patient relationship that exists between the parties; that the provider breach that duty of care through negligent or fault-based action; that the patient suffer harm or injury; and that the harm or injury be the result of the breach of duty. Hence, critical to this process of assessment is the existence of “fault” in the conduct of the professional - that is, the existence of a connection between the violation of a medical standard and the occurrence of harm. The “fault” requirement distinguishes harm that is the result of a breach of the minimum standards of care required by the medical professional body from injury that is within the foreseeable outcomes or side-effects of a therapy administered or procedure conducted non-negligently. Thus, a successful cause of action in negligence would require proof that a given healthcare professional failed to meet the expectations of his or her professional peers in the treatment of the patient. This traditional understanding of liability rules therefore calls into question the utility — and perhaps, objective — of the impugned form of the harm principle under health freedom laws. As Beauchamp and Childress have noted:

A harm is a thwarting, defeating, or setting back of some party's interests, but a harmful action is not always a wrong or unjustified. Harmful actions that involve justifiable setbacks to another's interests are not wrong — for example, justified punishment of physicians for incompetence or negligence. Nevertheless, the principle of nonmaleficence is a prima facie principle that requires the justification of harmful actions.34
Thus, whether the “agent of harm” is legally responsible for the harm depends on the result of a legal equation animated by the standard of due care and defined in the four elements for proof of liability outlined above. Indeed, the spheres of law and morality both identify “a standard of due care that determines whether the agent who is causally responsible for the risk is legally or morally responsible as well.” According to Beauchamp and Childress, “this standard is a specification of the principle of non-maleficence.” The standard of due care requires a health provider to practice with proper care within established professional guidelines to avoid causing harm to a patient.

Another component of the standard of due care, which arguably problematizes the second version of the harm principle, is that health providers must ensure the goals of treatment “justify the risks” imposed to attain the goals. A serious or grave risk must, therefore, be proportionate to the goals sought to be achieved, and be undertaken with due care, if the agent is to avoid violating moral and legal rules. In the present context, whether or not the choice of an alternative therapy with higher safety risks than the prevailing treatment would meet this proportionality test would depend on the given circumstance. A few questions help place the challenges with this proviso in some perspective: If the alternative therapy would serve a “commensurately momentous” goal desired by the given patient in spite of its higher safety risks, does the proportionality test thereby displace the requirements of the health freedom law? If the goal of the alternative therapy is commensurate with the greater risks imposed by the treatment — and therefore meets the proportionality test, is the health freedom proviso thereby displaced? Or, perhaps, the more fundamental question is whether there is ever to be a (CAM treatment) goal that is so momentous that the CAM therapy is acceptable, in spite of possessing a higher risk than the conventional treatment, as a preferred alternative to the prevailing option.

Overall, the rules regarding harm, risks of harm and liability can be stated simply: even if the therapeutic encounter or relationship between a health provider and the patient “proves harmful or unhelpful, malpractice occurs if and only if physicians do not meet professional standards of care.” The question that arises, therefore, is: should a provider who administers a CAM therapy with the appropriate care, complying with appropriate standards, and avoiding the imposition of an unreasonable risk on the patient comparative to the goals sought to be achieved be held liable in negligence (or for malpractice) based on the mere occurrence of an adverse consequence? A “yes” answer — which is the response provided by the impugned health freedom laws in their current construction — flagrantly disregards the four factors identified above. As Sharpe and Faden have noted, the first of two principal justifications for “harm-causing actions and the imposition of risk” is valid consent by a competent patient or consent by a surrogate. The assumption of risk principle further explicates this first justification. The principle, which is an absolute defense to malpractice, allows patients to voluntarily consent to the risks that may arise from a medical procedure. The consent is, however, conditional on the physician’s full disclosure of all likely or foreseeable risks associated with the given procedure. The second justification is that the expected harm is central to achieving patient health benefit and “is proportionately less harmful than the condition for which the patient sought care.” Elsewhere, I have discussed informed consent and patients’ interest in self-determination, which come within the first of the justifications for medical injury indicated above; however, the central theme of the present discourse is more closely linked to excusatory grounds.

Excusatory conditions for liability recognize the agency of intervening factors in the occurrence of harm. These factors are usually beyond the direct or immediate control of the medical actor. Legally accepted excusatory grounds, which often include systemic failures or unforeseeable medical outcomes, do not represent a denunciation of the ethics of non-maleficence or beneficence. The physician retains understanding — expectedly at least — of the “priority” of these ethical principles, but appeals for an appreciation of the exigencies of the circumstances under which the harm occurred. The impugned version of the harm principle discounts important excusatory conditions for harm, such as unfortunate shortcomings in the best available medical information, fiscal problems and managerial or systemic difficulties beyond the control of medical personnel, inadequate public resources and “good-faith error,” amongst others. By creating a rule that disregards these possibilities and imposes a strict liability standard on practitioners on the mere occurrence of harm, the law rules out the possibility of an unforeseen adverse outcome from CAM practice that is not based on fault, which can happen in normal, everyday CAM practice, and which is in fact traditional in biomedical practice. By implication, therefore, the proviso creates a higher standard of liability for CAM practice than the traditional standard under negligence or malpractice law.

IV The harm principle: impact on integrated medical practice

While the underlying objective of the harm principle may be patient safety, its effect on integrated medical practice can hardly be overlooked. The problematic requirement that unprofessionalism will be determined in the context of CAM or integrated medical practice by the sole occurrence of injury creates a legal problem and burden that interested or would-be practitioners of CAM may not be ready to bear. Besides creating a hierarchy between the two systems of medical practice, the requirement refines the uncompromising characterization of CAM as practice “deviating from or operating ‘beyond’ the standard of biomedicine” — deviation that is tolerated except where harm occurs. This characterization hardly enhances the development of CAM or integrated medicine as legitimate fields of medical practice. It is noteworthy, however, that at least one CAM and integrated medicine scholar espouses the harm principle. Michael Cohen suggests that medical negligence law should be recontextualized to incorporate the type of amendments in health freedom laws; that is, the standard for a finding of negligence should be amended to de-emphasize the aspect of the rule that requires “deviation from minimum standards of acceptable practice” while accentuating the resultant injury. By implication, this would lead to a reconstruction of the age-old standard of negligence in which case liability attaches to the conduct of an agent on the mere occurrence of harm, rather than on deviation from the standards acceptable in the given profession of the agent in order to accommodate the emerging set of health freedom provisos. This recommendation, itself reflective of the harm principle, may be interpreted — at one level — as a legitimate cautionary proviso which, through its stipulation of a different standard of liability for CAM practice, fulfills the objective of patient safety to the extent that it dissuades potentially interested physicians from CAM practice except after a thorough consideration of the utility, safety and effectiveness of the chosen therapy. At another level, however, it achieves the result of impeding CAM practice and integrated medicine. Fear of automatic liability that attaches to the occurrence of harm, no matter how minor, can stifle medical practice. While a similar assertion may be made within the arena of biomedical practice, the difference is simply that the law of medical negligence or malpractice provides a different, more nuanced, better considered criteria for professional medical liability. Thus, while the evolving nature of many CAM therapies might influence a reading of Cohen’s suggestion and the identification of the standard of due care, it is indeed true that a meaningful reformulation of the harm principle would offer a competitive alternative to the prevailing health freedom laws; that is, the standard for a finding of negligence should be amended to de-emphasize the aspect of the rule that requires “deviation from minimum standards of acceptable practice” while accentuating the resultant injury. By implication, this would lead to a reconstruction of the age-old standard of negligence in which case liability attaches to the conduct of an agent on the mere occurrence of harm, rather than on deviation from the standards acceptable in the given profession of the agent in order to accommodate the emerging set of health freedom provisos.

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Finally, the acknowledgement of the practice of CAM by biomedical practitioners — and, specifically, the ostensive authorization of the practice by and within the traditional medical establishment — through the instrumentation of health freedom laws is analogous to the “co-option” of CAM into biomedicine. As I have observed elsewhere, the state policy “to support through legislative provisos the delivery” of CAM by physicians “is hardly different from the state’s predilection towards the model of co-option in which biomedical professionals exclusively provide alternative medical services.” Health freedom laws by design “accommodate” the delivery of CAM by biomedical professionals who have acquired the skill to do so. While the delivery of CAM by bio-medically trained health professionals has its rewards in terms of safety and quality assurances that may be non-existent with some unlicensed CAM practitioners, the moral problem lies with the “concomitant denial of legitimacy” to CAM practitioners, the systemic and regulatory hierarchies in the field of CAM, and the consequent diminished status of the CAM paradigm.

V Reforming the harm principle

Any recalibration of the harm principle to ensure that health freedom laws serve the objectives of protecting freedoms and ensuring access must be founded on an “egalitarian framework” that recognizes that the institutional changes in healthcare delivery are the corollary of patients’ aspirations and choices. The increasing physician and provider interest in CAM and other alternative therapies and the associated emerging evolution in the delivery of care involving a transition to more integrated forms of...
healthcare and greater attention to patients’ needs are influenced by the patient-led interest in the personalized care embodied in CAM. As patients continue to opt for alternative medical options or seek these options when all else has failed, it is necessary to have laws that facilitate these needs while addressing the complex and unproven nature of many CAM therapies. It is important that the conflict is resolved with a primary focus on protecting patients’ safety and wellbeing, without necessarily sacrificing the autonomy of patients and practitioners. A reasonable compromise may be reached by prioritizing well-founded medical and legal rules for healthcare delivery.

The proposition, therefore, is that the harm principle may reasonably be reformulated around the standard of care. Adjudication and possible legislative amendment of the principle should be based on the failure of a physician to meet minimum acceptable medical standards. This ground of assessment of a physician’s liability reflects the central role of “fault” or “blameworthiness” in imputing liability on an otherwise cautious and principled practitioner. On the basis of this assessment, the medical disciplinary tribunals or courts would have to consider whether the physician has complied with relevant professional guidelines for the administration of a particular treatment. For example, has the physician ascertained the safety of the CAM therapy? Is the physician properly informed about and trained in the administration of the therapy? Did the physician record the clinical state of the patient and changes in the state? Did the physician refer the patient to another physician or specialist when the clinical indications necessitated such referral? Some of these guidelines were laid down for physicians practicing non-traditionally in the Ontario case of Ravikovich. According to the disciplinary committee of the college:

The drug must be proven safe. The physician must record in considerable detail the clinical state of the patient and the changes in this state, both good and bad, that are produced by the medication. The physician should be aware of all of the pertinent publications that bear on the clinical problem as well as on the proposed treatment.

Furthermore, in consonance with the substance of the less contentious version of the harm principle, judges may assess whether the CAM therapy chosen by the physician was indeed the ideal choice, considering safety, benefits, possibility of harm and treatment goal, among several of the prevailing options — options that include CAM or biomedicine. In line with this arm of the harm principle, Cohen has suggested three factors to be evaluated by the courts determining malpractice liability in the alternative medical context:

1. the risk of danger or injury created by the specific therapy,
2. the extent to which the patient’s condition was likely to result in death or disability irrespective of complementary or alternative care,
3. the extent to which the complementary and alternative therapy displaced conventional care and the extent to which the neglect of conventional care was the actual and proximate cause of the injury.

Underlying the first factor and central to the suggestions outlined above, is that the CAM therapy administered by a physician should be backed by evidence of safety and effectiveness and the associated risks should be commensurate with the treatment goal. It should also pose less risk of harm than other “traditional” options, and going further than the first factor and the provisos, these options should include both CAM and biomedical options. Therefore, unlike Cohen’s third proposition, which arguably suggests biomedicine as the standard to which physicians must have first recourse, adjudicators should determine whether the therapy employed by the physician displaced a more effective or less risky therapy — whether biomedicine or CAM. This suggestion counters the hierarchical subtext of the harm principle. Thus, central to one of my suggestions above — specifically assessment of whether the CAM therapy administered by the physician is the safest and most effective choice among different options — is the legal requirement that the physician must not be negligent in choosing a therapy or course of treatment.

The ideal of protecting patients’ wellbeing and ensuring safety must be pivotal to the practice of CAM, especially as patient advocacy groups and practitioners continue to advocate for legitimacy for CAM and integrated medicine. While the harm principle ostensibly recognizes the importance of patient safety and wellbeing to medical practice, the goal will be better served by legislative and judicial focus, not mechanically on the occurrence of adverse results, but on the underlying causes of those outcomes and the extent to which practitioners’ non-adherence to the medico-legal and ethical standards that govern medical practice or specific procedures created the result. Such an interpretative approach serves the interests of both patients and practitioners interested in CAM, and better fosters the growth of the field.

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- College of Physicians and Surgeons of Ontario, Discipline Committee Decisions: Dr. Felix Ravikovich (undated) www.cpso.on.ca Reported in CPSO, Member’s Dialogue, January 1996: Case no. 4.
- Health Professions Act, RSBC 1996, c. 183.
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- Patient Protection and Affordable Care Act (PPACA).
- Re Guess, 393 S.E.2d.
- Tatoryn, D. J.; Verhoeof, M. J. “Combining Conventional, Complementary and Alternative Health Care: A Vision of Integration” in Perspectives on Alternative and

https://search.credoreference.com/content/entry/outdoam/the_harm_principle_and_liability_for_cam_practice_a_comparative_analysis_of_canadian_and_united_states_health_freedom_laws/0


5  Ibid.


8  If the legal challenges against the PPACA (most of which revolve around the individual mandate) are resolved in favor of the Act —just as Congress’ power to enact the individual mandate has been upheld — then these newly styled “health freedom laws” promulgated to negate provisions of the PPACA will be rendered ineffective based on the Supremacy Clause of the United States Constitution, under which federal laws are the Supreme Law of the Land: US Const. Art. VI, cl. 2; See H. Chaikand; C. W. Copeland; C. S. Redhead; J. Staiman, “PPACA: A Brief Overview of the Law, Implementations, and Legal Challenges” (CRS Report for Congress, 2011), online, http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R41664.pdf (last accessed May 20, 2014).


10  Ibid.

11  Col. Rev. Stats., Title 12, Art. 36., §12-36-117.


14  Re Guess, 393 S.E.2d. In Re Guess, a physician who administered homeopathy to his patients after they failed to respond to biomedical treatment was indicted for unprofessional conduct. The North Carolina Board of Medical Examiners indicted the physician for departing from “standards of acceptable and prevailing medical practice in North Carolina”. In refuting the charge that homeopathy was not an “acceptable and prevailing” therapy in North Carolina, Guess provided evidence that homeopathy is recognized in three US states and several foreign countries. Guess’ patients testified to the benefits they had derived from Guess’ treatment and that they had not been harmed by it. In spite of these testimonies, the board revoked his license. On appeal, the court citing the harm exception observed that the board “neither charged nor found that Dr. Guess’s departure from approved and prevailing medical practice either endangered or harmed his patients or the public”. Reversing the board’s decision, the court held that the physician’s license would be appropriately revoked if his practice causes harm to the public. According to the court, “conduct that is merely different from that of other practitioners” is not a sufficient ground for revoking a physician’s license. On further appeal, the North Carolina Supreme Court decided that the law did not require proof of harm to support a finding that a physician was liable for misconduct in the circumstances outlined in the relevant legislation.


“Strict liability”, which is liability without fault under Canadian tort law, is used here to capture the nature of the general rule that health professionals cannot practice outside their professional scopes of practice without incurring malpractice liability. Fault-based liability, of course, involves negligent actions or the intention to harm. As already discussed above, physicians were stricto sensu liable for malpractice for practicing CAM whether or not they conducted the CAM practice negligently. The mere act of deviation from what is considered “standard or prevailing practice” was sufficient to incur liability.


La Reg. tit. 46, §7103—7107 (2001) (Professional and Occupational Standards);
Sanbar, Legal Medicine, ibid. at 69.


This principle is recognized under Ontario Law: O. Reg 52/95, made under the Medicine Act, 1991.

Tom L. Beauchamp; James F. Childress, Principles of Biomedical Ethics, 7th edn (Oxford University Press Oxford, 2013) at 150 [“Beauchamp and Childress, Principles of Biomedical Ethics”].


Beauchamp and Childress at 153.
Ibid. at 155.

43

Ibid. Emphasis added.

44

V. A. Sharpe; A. I. Faden, Medical Harm: Historical, Conceptual, and Ethical Dimensions of Iatrogenic Illness (Cambridge University Press Cambridge, 1998) at 124. ["Sharpe and Faden, Medical Harm"].

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Schneider v Revici, 817 F.2d 987(2nd Cir 1987). See also


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Sharpe, Faden, Medical Harm at 132.

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For more on this issue, see

Iyioha, Health Governance, supra.

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For a discussion of the co-option model of integration, see

D. J. Tataryn; M. J. Verhoef, "Combining Conventional, Complementary and Alternative Health Care: A Vision of Integration" in Perspectives on Alternative and Complementary Health Care: A Collection of Papers Prepared for Health Canada (Health Canada Ottawa, 2001); see also

Iyioha, Health Governance, chapter 5.

56

For a discussion of this ethical conflict is beyond the scope of this paper. For a comprehensive discussion of this and medical ethics generally, see

Beauchamp, Childress, The Principles of Biomedical Ethics, supra.

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College of Physicians and Surgeons of Ontario, Discipline Committee Decisions: Dr. Felix Ravikovich (undated) (www.cpsso.on.ca) Reported in CPSO, Member’s Dialogue January 1996: Case no. 4.

61

Cohen, Beyond Complementary Medicine at 34.
Cohen's meaning is disputable depending on whether the author employs "conventional care" to simply mean "biomedicine" or whether the term is to be read as an omnibus expression for both biomedicine and CAM.

63

Iyioha, Health Governance at 373.

64

Ibid.

65

Ibid.

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