



Legal and ethical issues in complementary medicine: a United States perspective

Michael H Cohen

The way forward involves not only preventing negligence and fraud, but also facilitating therapeutic exchanges between various healthcare providers and their patients

United States physicians, like their Australian counterparts, are deeply interested in the legal and ethical issues surrounding patient use of complementary and alternative medicine (CAM) therapies.¹⁻³ Key legal questions of concern to physicians include (i) malpractice liability for negligent care and for inadequate informed consent; (ii) licensure and credentialing; (iii) scope of practice (the legally authorised practice boundaries for non-physicians, including CAM providers); (iv) regulation of dietary supplements; (v) professional discipline; (vi) third-party reimbursement; and (vii) healthcare fraud.¹ This article briefly highlights key aspects of the first and second issues, comparing them, where possible, with the situation in Australia, and then brings an ethical perspective to the discussion.

Duty of care regarding informed consent

A major issue confronting physicians in everyday clinical practice is the extent to which they have a duty to discuss CAM therapies with their patients. Kerridge and McPhee's article (*page 164*) argues that, in Australia, physicians have a "proactive and reactive" duty to do so.⁴ In the US, as part of the legal and ethical obligation of informed consent, physicians have a duty to disclose and discuss reasonable and feasible treatment alternatives, together with the risks and benefits of each option.^{2,3} While no court has yet held a physician liable for failure to disclose a CAM option, such a rule would be the logical extension of a 1993 federal appeals court case involving a patient's claim that the physician should have disclosed the possibility of trying EDTA chelation therapy rather than bypass surgery to treat a carotid artery. The court stated that disclosure of such a therapeutic alternative would be required if the CAM therapy in question were generally accepted within the medical community.⁵

The question of liability connected with referring patients to CAM providers has also been of concern within the US medical community. In the US, mere referral to a medical specialist does not generate malpractice liability for the specialist's negligence; similarly, mere referral to a CAM provider should not leave the referring physician liable for subsequent negligence by that provider.^{6,7} There are, however, a number of potentially applicable exceptions to this rule. The first involves delay of necessary medical treatment, resulting in patient harm.^{6,7} The second involves referral to a CAM provider that the referring physician knew or "should have known" might be "incompetent" (this rule

SERIES EDITORS: A BENSOUSSAN, G T LEWITH

Harvard Medical School, Osher Institute, Boston, MA, USA.

Michael H Cohen, JD, Assistant Professor of Medicine, and Attorney at Law.

Reprints will not be available from the author. Correspondence: Mr Michael H Cohen, Harvard Medical School, Osher Institute, 401 Park Drive 22-W, Boston, MA 02215, USA.

www.michaelhcohen.com; michael_cohen@hms.harvard.edu

suggests an obligation of due diligence in vetting both the provider's credentials and, through reasonable inquiry, the provider's general competence, skill, and practice).^{6,7} A third exception involves "joint treatment" of the patient, a fairly ambiguous term that could conceivably encompass situations in which the physician and CAM provider share information by telephone or email as part of the treatment plan.^{2,8} The possibility of such shared liability suggests exercising great care in selecting CAM providers to whom one will refer, and moving from a posture of distance from the CAM provider to one of closeness, in the hope of gaining a clear clinical understanding of the potential contribution — and risks — of the CAM therapeutic route and/or its interaction with conventional care.

Licensure and credentialing

A second issue of concern to physicians in everyday clinical practice is understanding the legal authority that CAM providers have to deliver healthcare services. In the US, healthcare licensure is a matter of state law. Thus, there is great diversity among the states as to who can be licensed, and the scope of practice authority allocated to each class of provider by the licensing laws in each state. Across the US, the four professional groups which are licensed in most states are chiropractors (every state), practitioners of acupuncture and traditional oriental medicine (over 40 states), massage therapists (over 30 states), and naturopathic physicians (about 12 states).^{9,10} The numbers vary depending on what legal authority one counts as licensure to practise. For example, different forms of licensure include mandatory licensure, title licensure, mere registration, and combinations of these. In addition, a number of states allow a wide variety of unlicensed CAM providers to practise under certain circumstances.¹¹

Further, compared with the limited scope of practice allocated by licensing laws to both allied health professionals (such as nurses and physical therapists) and CAM providers (such as chiropractors and acupuncturists), physicians in the US have an "unlimited" scope of practice, which means they can generally use all methods that their profession generally accepts as safe and effective to treat a given disease.¹ However, there are several caveats. When physicians practise CAM therapies such as acupuncture, they must be properly trained and appropriately credentialled (although such training and credentialing requirements tend to be far less extensive than for non-physician acupuncturists);^{6,10} and, if they provide the patient with CAM therapies that are unsafe and ineffective, they are likely to be sued for medical malpractice and be disciplined by the state medical board.^{1,6}

Ethical considerations

Whether or not liability results, physicians may find, at times, that their beliefs and commitment to the kind of evidence-based

Framework of considerations for drawing ethical conclusions

- Severity and acuteness of illness
- Curability with conventional treatment
- Invasiveness, toxicities, and side effects of conventional treatment
- Quality of evidence of safety and efficacy of the CAM treatment
- Degree of understanding of the risks and benefits of conventional and CAM treatments
- Knowledge and voluntary acceptance of those risks by the patient
- Persistence of patient's intention to use CAM treatment

practice they practise in conventional care conflicts with patient interest in some CAM therapies. One useful approach to help negotiate such conflicts involves balancing the major bioethical principles (eg, non-maleficence, autonomy, beneficence, and justice) on a case-by-case basis,¹² bearing in mind that shared decision-making is preferred to the older, more authoritarian model in which doctors simply disclose options without engaging patients in negotiated conversations.¹³ Thus, there may be a trade-off between granting the physician's desire to avoid all harm to the patient (expressing non-maleficence), and honouring the patient's persistent desire to try a CAM therapy for a time (expressing an autonomy interest) while continuing conventional monitoring.^{1,6,13}

A slightly more sophisticated approach involves balancing seven factors (Box), to draw an appropriate ethical conclusion about the best course of action. This framework somewhat parallels the analysis of liability considerations in the US.^{6,13}

For example, consider the following two cases taken from clinical practice.

- The patient has a premalignant condition that can be completely cured through surgery, but, if left untreated, can progress to invasive cancer. The patient tells her MD that she plans to pursue meditation, colonics and yoga, and to work with her Reiki master, rather than have surgery.¹³
- The patient, a woman with recurrent metastatic ovarian adenocarcinoma, asks her oncologist to provide her with conventional treatment, but to be open to evaluating and guiding her regarding available CAM therapies.¹³

In the first case, the patient's illness can be cured with conventional, although invasive, treatment (surgery); the evidence for CAM is low, but the patient understands and accepts the risks, and insists on trying CAM therapies. It would be ethical for the physician to allow the patient to try her regimen of CAM therapies, as long as she continues to monitor her condition conventionally.¹³ If the risk of cancer increases past a tolerable threshold, the physician should intensify attempts to persuade the patient that it is time to return to conventional methods of treatment.¹³ In the second case, the clinician should be aware of pertinent evidence and be willing to consider any intervention (CAM or allopathic) that has an acceptable risk-benefit balance.¹³

Whatever approach is used, physicians are still learning ways to fruitfully discuss integration of CAM therapies with their patients, as differing value systems and bases of knowledge about these therapies may leave a gap that only skilful negotiation can bridge.¹⁴ In this respect, the question is less about legal rules alone and more about relationship, conversation, and how the law may help or hinder these. The way forward for Australian legislators, judges and policymakers, as for their US and international coun-

terparts, involves focusing not only on preventing negligence and fraud, but also on finding ways to facilitate therapeutic exchanges between a variety of healthcare providers and their patients.⁸ Framed in this light, the need for international dialogue around common legal and ethical issues pertinent to CAM therapies becomes ever clearer.

Michael H Cohen

Attorney at Law and Assistant Professor of Medicine
Harvard Medical School, Boston, MA, USA
michael_cohen@hms.harvard.edu
www.michaelhcohen.com

- 1 Cohen MH. Complementary and alternative medicine: legal boundaries and regulatory perspectives. Baltimore: Johns Hopkins University Press; 1998.
- 2 Cohen MH. Beyond complementary medicine: legal and ethical perspectives on health care and human evolution. Ann Arbor: University of Michigan Press; 2000.
- 3 Ernst EE, Cohen MH. Informed consent in complementary and alternative medicine. *Arch Intern Med* 2001; 161: 2288-2292.
- 4 Kerridge IH, McPhee JR. Ethical and legal issues at the interface of complementary and conventional medicine. *Med J Aust* 2004; 181: 164-166.
- 5 *Moore v Baker*, 989 F2d 1129, 1132 (11th Cir 1993).
- 6 Cohen MH, Eisenberg DM. Potential physician malpractice liability associated with complementary/integrative medical therapies. *Ann Intern Med* 2002; 136: 596-603.
- 7 Studdert DM, Eisenberg DM, Miller FH, et al. Medical malpractice implications of alternative medicine. *JAMA* 1998; 280: 1610.
- 8 Cohen MH. Future medicine: ethical dilemmas, regulatory challenges, and therapeutic pathways to health and human healing in human transformation. Ann Arbor: University of Michigan Press; 2003.
- 9 Cohen MH. Holistic health care: including complementary and alternative medicine in insurance and regulatory schemes. *Ariz L Rev* 1996; 38: 83-164.
- 10 Eisenberg DM, Cohen MH, Hrbek A, et al. Credentialing complementary and alternative medical providers. *Ann Intern Med* 2002; 137: 965-973.
- 11 Cohen MH. Healing at the borderland of medicine and religion: regulating potential abuse of authority by spiritual healers. *J Law Relig* 2004; 18: 373-426.
- 12 Kemper K, Cohen MH. Ethics in complementary medicine: new light on old principles. *Contemp Pediatr* 2004; 21: 61-72.
- 13 Adams KE, Cohen MH, Jonsen AR, Eisenberg DM. Ethical considerations of complementary and alternative medical therapies in conventional medical settings. *Ann Intern Med* 2002; 137: 660-664.
- 14 Cohen MH. Negotiating integrative medicine: applying negotiation analysis to decision-making involving complementary and alternative medical therapies. *Negotiation J* 2004. In press.

(Received 29 Apr 2004, accepted 25 May 2004)