# A CHIMERA IN EVERY SENSE: STANDARD OF CARE FOR PHYSICIANS PRACTICING COMPLEMENTARY AND ALTERNATIVE MEDICINE

J. Brad Kallmyer, M.D.*

## INTRODUCTION

Custom has generally defined the standard of care in medical malpractice claims against physicians. Nevertheless, commentators and courts have been reluctant to hold the practice of complementary and alternative medicine ("CAM") by physicians to be a per se breach of the standard of care even though CAM is by definition not customary. Despite this inconsistency, there has been little discussion and no consensus concerning what the standard of care is or should be for physicians practicing CAM. This Note concludes that a reasonable and prudent physician standard rather than custom better addresses the complexities of standard of care for physicians practicing CAM. Moreover, informed consent—usually a concept distinct from standard of care—must enter the standard of care analysis for physicians practicing CAM because the patient's consent defines the extent of permissible deviation from the otherwise applicable non-CAM standard. Because this deviation can be defined by the patient, the standard has the potential to be different for two patients with identical medical problems. Individual patient desires notwithstanding, the physician maintains a duty to abstain from unreasonable practices.

Part I of this Note discusses the background, scope, and complexity of the standard of care issue for CAM physicians. Part II examines the validity of reasons to look beyond custom as the standard for practitioners of CAM and concludes that CAM warrants an exception to the use of custom as a determinant of standard of care. Part III addresses the need for an informed consent contract. Part IV analyzes the standard of care for CAM through the lenses of alternative standard of care formulations, addressing some evidentiary and policy issues. This Note concludes that a patient-specific reasonable physician standard best addresses the standard of care difficulties raised by CAM.

## I. BACKGROUND

Increasingly accessible information has educated both providers and consumers of medical services about a wide array of nontraditional medical

---

* B.A. Earlham College 1984, M.D. Indiana University School of Medicine 1988, J.D. candidate, Indiana University School of Law, Indianapolis 2005. The author thanks Christopher L. Riegler from the law firm of Hall, Render, Killian, Heath & Lyman, P.S.C., for his assistance with this Note.

therapies outside the arsenal of modern, science-based biomedical treatment, the predominant treatment methodology taught in American medical schools.[1] These nontraditional therapies comprise CAM. Serious consideration of CAM by allopathic medicine ("biomedicine") followed recognition of the prevalence of CAM use.[2] Even a decade ago, nearly sixty percent of mainstream physicians had referred patients to CAM practitioners.[3] Currently, many physicians provide CAM directly to their patients, obviating the need for referral. Information about CAM now appears commonly in the biomedical literature, and CAM is part of the curriculum in many allopathic medical schools.[4]

In response to this surge in interest, the National Institutes of Health ("NIH") established the National Center for Complementary and Alternative Medicine ("NCCAM").[5] NCCAM defines CAM as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine."[6] NCCAM notes that "[t]he list of what is considered to be CAM changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge."[7] CAM practices

---

1. *See* Nat'l Ctr. for Complementary & Alternative Med., Health Information: What is Complementary and Alternative Medicine (CAM)?, *at* http://www.nccam.nih.gov/health/whatiscam (last modified Apr. 5, 2005) (on file with the Indiana Health Law Review) [hereinafter NCCAM].

> Conventional medicine is medicine as practiced by holders of M.D. (medical doctor) or D.O. (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses. Other terms for conventional medicine include allopathy; Western, mainstream, orthodox, and regular medicine; and biomedicine. Some conventional medical practitioners are also practitioners of CAM.

*Id.* Although osteopathic physicians frequently provide all of the services that a medical doctor provides, osteopathic physicians may provide additional services. "Osteopathic medicine is a form of conventional medicine that, in part, emphasizes diseases arising in the musculoskeletal system.... Some osteopathic physicians practice osteopathic manipulation, a full-body system of hands-on techniques to alleviate pain, restore function, and promote health and well-being." *Id.*

2. *See generally* David M. Eisenberg et al., *Unconventional Medicine in the United States: Prevalence, Costs and Patterns of Use*, 328 NEW ENG. J. MED. 246 (1993) (revealing, through a national survey, much greater use of unconventional therapies than previously reported).

3. Jeffrey Borkan et al., *Referrals for Alternative Therapies*, 39 J. FAM. PRAC. 545, 549 (1994).

4. WHITE HOUSE COMM'N ON COMPLEMENTARY & ALTERNATIVE MED. POL'Y, FINAL REP. 51 (2002) [hereinafter WHITE HOUSE COMM'N], *available at* http://www.whccamp.hhs.gov/pdfs/fr2002_document.pdf.

5. NAT'L CENTER FOR COMPLEMENTARY & ALTERNATIVE MED., U.S. DEP'T OF HEALTH & HUMAN SERVS., NIH PUB. NO. 01-5001, EXPANDING HORIZONS OF HEALTHCARE, FIVE-YEAR STRATEGIC PLAN 2001-2005 4, 11 (Sept. 25, 2000) [hereinafter HORIZONS OF HEALTHCARE], *available at* http://nccam.nih.gov/about/plans/fiveyear/fiveyear.pdf.

6. NCCAM, *supra* note 1.

7. *Id.* It also bears noting that as some CAM therapies are shown to be detrimental to health, their use may be restricted. For example, the FDA issued an advisory after the supplement kava was shown to cause liver abnormalities. Letter from Christine Lewis Taylor,

include homeopathic, naturopathic, chiropractic and herbal medicine; Ayurveda; meditation; prayer; qi gong; and bioelectromagnetic medicine.[8] Further, CAM refers to acupuncture and some medical therapies that appear biomedical in nature but are labeled alternative by their practitioners, such as chelation therapy,[9] hydrogen peroxide infusion,[10] or ozone therapy.[11]

From a legal standpoint, the practice of alternative medicine has thus far been primarily an issue for medical licensing boards.[12] All states require licensure for chiropractic practice, while many states require licensure to practice acupuncture, homeopathy, naturopathy, or massage therapy.[13] Although there are relatively few reported medical malpractice cases involving physicians practicing CAM, an increasing number are likely to emerge as medical plans offer coverage for CAM,[14] the number of physicians offering CAM increases, and potential cases wind their way through often lengthy pre-trial processes. Additionally, the dynamics of the patient-practitioner relationship in CAM practice and the personal characteristics of many CAM practitioners may have contributed to the historically reduced propensity of CAM patients to sue.[15] As a broader constituency of physicians add CAM to their practice repertoire

---

Director, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, U.S. Food & Drug Admin., to Health Care Professionals, FDA Issues Consumer Advisory That Kava Products May Be Associated with Severe Liver Injury (Mar. 25, 2002), *at* http://www.cfsan.fda.gov/~dms/ds-ltr29.html (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review).

8. NCCAM, *supra* note 1. This list is far from exhaustive. *See also* WHITE HOUSE COMM'N, *supra* note 4, at 9-10. Some of the commissioners were disconcerted at co-optation of spirituality as a CAM modality. Joseph Fins & Tieraona Low Dog, *Appendix* to WHITE HOUSE COMM'N, *supra* note 4, at 231. The commissioners also noted that "spirituality transcends any arbitrary designation of conventional and non-conventional medicine and cannot be claimed by any particular group. Furthermore, the conflation of spirituality and/or religion with CAM could lead to an abridgement of the free exercise of religion by subjugating its practice to a regulated modality." *Id.*

9. Moore v. Baker, No. 491-93, 1991 U.S. Dist. LEXIS 14712, at *2 (S.D. Ga. Sept. 5, 1991).

10. Johnson v. Tenn. Bd. of Med. Exam'rs, No. M2002-00048-COA-R3-CV, 2003 Tenn. App. LEXIS 226, at *16-17 (Tenn. Ct. App. Mar. 19, 2003).

11. Atkins v. Guest, 601 N.Y.S.2d 234, 236 (N.Y. Sup. Ct. 1993); Gambee v. Bd. of Med. Exam'rs of Or., 923 P.2d 679, 680 (Or. Ct. App. 1996).

12. While there are significant differences between malpractice cases, administrative physician disciplinary cases, and insurance coverage cases, some disciplinary and insurance cases provide exceptional analysis of issues that have not yet been discussed in the malpractice context. Because their issues are pertinent here, a few of these cases have been discussed in this note.

13. Licensing statutes vary by state and are obviously subject to amendment or repeal. For a relatively recent listing of state licensure statutes, see David A. Studdert et al., *Medical Malpractice Implications of Alternative Medicine*, 280 JAMA 1610, 1611 (1998); *see also* WHITE HOUSE COMM'N, *supra* note 4, at 102 (showing 2002 provider licensing requirements by state and specialty).

14. Deborah A. Grandinetti, *Your Newest Competitors: Alternative-Medicine Networks*, MED. ECON., May 24, 1999, at 44; Studdert, *supra* note 13, at 1610-11.

15. Studdert, *supra* note 13, at 1612.

and nascent malpractice claims involving physicians' misadventures with CAM advance to trial, courts will reckon with novel CAM malpractice issues, the chief of which will be standard of care.

Standard of care defines the physician's duty in medical malpractice actions. Determination of the standard of care for CAM presents dilemmas and paradoxes. Two have been discussed in the context of Canadian law.[16] First, a standard of care paradox is created when a physician providing unproven CAM therapy is at the same time generally expected to use only therapy proven to be safe and efficacious.[17] Second,

> courts will be faced with the factual problem of deciding whether the physician-homeopath acted as a physician or as a homeopath . . . . While this may be easily discerned in the case of prescribing a homeopathic solution, other elements of treatment may plausibly be characterized as either medical or homeopathic. In such a situation, should a physician be able to declare that she acted as a homeopath or should the applicable standard be based on the patient's perception?[18]

Physicians who provide CAM in the United States have yet another problem: in the United States, physicians in most states are held to the standard of prevailing practice or custom as determined by expert witnesses.[19] CAM, by definition, is not customary.

---

16. Timothy Caulfield & Colin Feasby, *Potions, Promises and Paradoxes: Complementary Medicine and Alternative Medicine and Malpractice Law in Canada*, 9 HEALTH L.J. 183, 200 (2001).

17. *Id.* at 200-02.

18. *Id.* at 201. This very issue recently arose in *Bd. of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 146, 149 (Mo. 2003) (en banc). In *McDonagh*, the Board of Registration disciplined osteopathic physician McDonagh based on the physician's unconventional treatment of vascular disease. *Id.* An Administrative Hearing Commission ("AHC") reversed, and this opinion was affirmed by the circuit court. *Id.* The Missouri Supreme Court reversed the circuit court and remanded because the standard of care was not identified, and it appeared that the AHC judged McDonagh's conduct by reference to expert witness physicians using McDonagh's unconventional treatment rather than by reference to the standard of care of physicians treating patients with vascular disease. *Id.* The case also turned on evidentiary issues. *See* discussion *infra* Part IV.A.4.

19. *See also* Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millenium*, 57 WASH. & LEE L. REV. 163 *passim* (2000) (describing the decline of use of custom in favor of reasonableness, and categorizing states by type of standard). *See generally* BARRY R. FURROW ET AL., HEALTH LAW § 6-2 (2d ed. 2000). Generally, under the national custom standard of care, a physician must conform to the practices that have become customary in the profession nationally, with allowable local variation in care based on resource availability.

## II. SHOULD ALTERNATIVE MEDICINE EVER BE WITHIN THE STANDARD OF CARE?

Any discussion of standard of care for the CAM physician must address the frequently cited issue raised by a New York court in *Charell v. Gonzalez*: "[I]t would seem that no practitioner of alternative medicine could prevail . . . as the reference to the term 'non-conventional' may well necessitate a finding that the doctor who practices such medicine deviates from 'accepted' medical standards."[20] For a number of reasons, however, non-conventional care should not necessarily be considered deviant or unacceptable.

### *A. Patient Autonomy*

Patient autonomy provides the most compelling argument for acceptance of physicians' incorporation of CAM into their practices. Biomedical paternalism has steadily eroded from the time of Cardozo's landmark opinion in *Schloendorff v. Society of the New York Hospital*.[21] With the erosion of the physician's ability to dictate the patient's treatment, the biomedical profession's ability to dictate what is considered acceptable treatment has likewise eroded. Quoting *Schloendorff*, the Court of Appeals for the Second Circuit made this explicit in *Schneider v. Revici*:

> [W]e see no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment. While a patient should be encouraged to exercise care for his own safety, we believe that an informed decision to avoid surgery and conventional chemotherapy is within the patient's right "to determine what shall be done with his own body."[22]

---

20. Charell v. Gonzalez, 660 N.Y.S.2d 665, 668 (N.Y. Sup. Ct. 1997).

21. Schloendorff v. Soc'y of the N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914), *overruled on other grounds by* Bing v. Thunig, 143 N.E.2d 3, 9 (N.Y. 1957). The court noted that a surgeon operating without patient consent is not merely negligent, but is committing an assault.

22. Schneider v. Revici, 817 F.2d 987, 995 (2d Cir. 1987) (quoting *Schloendorff*, 105 N.E. at 93). *But cf.* AM. MED. ASS'N, CODE OF MEDICAL ETHICS § E-10.01 (2004) [hereinafter CODE OF MEDICAL ETHICS], *available at* http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/E-10.00.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/H-525.998.HTM&nxt_pol=policyfiles/HnE/E-0.01.HTM&. The "patient has the right to make decisions regarding the health care that is *recommended by his or her physician*." *Id.* (emphasis added). This implies a greater degree of control by the physician over the direction of treatment.

The White House Commission on Complementary and Alternative Medicine Policy[23] extended this position in its recommendation that individuals participate "in *all* aspects of their care, including the development of new research agendas."[24] Thus, individuals are not only permitted to determine what is done to their own bodies, but are also encouraged to participate in choosing which therapies should be available to the public at large.[25]

*1. The Changing Nature of the Physician-Patient Relationship*

The increasingly collaborative nature of the physician-patient relationship involves physicians in the CAM choices of their patients whether physicians desire this role or not. The NIH urges patients to be informed and to "take charge of [their] health," but adds that patients should involve their primary care doctor in the treatment plan for their safety.[26] This implies the reciprocal: that primary care doctors be involved in their patients' decisions to seek CAM treatment. Furthermore, as part of its five-year strategy, NCCAM sees integration of CAM as a necessary part of "an expanded repertoire of safe and effective treatments that include a focus on the whole person."[27] One NCCAM goal is to "work to overcome the reluctance of conventional health-care providers to consider CAM therapies for their patients."[28] This reluctance is implied in the American Medical Association ("AMA") Principles of

---

23. The White House Commission on Complementary and Alternative Medicine Policy was created by President Clinton and Congress in 2000 with the mandate of developing "legislative and administrative recommendations that would help public policy maximize potential benefits, to consumers and American health care, of complementary and alternative medicine (CAM) therapies . . . ." James S. Gordon, *Chairman's Vision,* WHITE HOUSE COMM'N, *supra* note 4, at x.

24. *Id.* at xii (emphasis added).

25. Public participation in developing research agendas seems to go beyond autonomy. When individuals participate in determining what is to be provided (or not provided) to the rest of society, the participation becomes political. Indeed, many current issues in medicine have become politicized. The examples of fetal stem cell use and partial birth abortion illustrate the capability of political processes to control the availability of medical treatment. Broad popular opinion, based on numerous factors in addition to science, drives legislation and funding decisions.

26. Nat'l Ctr. for Complementary & Alternative Med., Health Information: Are You Considering Using Complementary and Alternative Medicine (CAM)?, *at* http://nccam.nih.gov/health/decisions/index.htm (last modified Feb. 5, 2004) (on file with the Indiana Health Law Review).

27. HORIZONS OF HEALTHCARE, *supra* note 5, at 21; *see also* MICHAEL H. COHEN, BEYOND COMPLEMENTARY MEDICINE 33 (2000) (suggesting that as CAM gains ground, "physicians could be liable in malpractice for failing to provide complementary and alternative treatments"). Be that as it may, the standard of care is defined in the here-and-now and cannot be based upon speculation about care in the future any more than it can continue to accept past standards that have lost their support through scientific progress. When confronted with the argument that an alternative treatment may one day be accepted, one court responded succinctly that "the Court does not have a crystal ball." Moore v. Baker, No. 491-93, 1991 U.S. Dist. LEXIS 14712, at *15 (S.D. Ga. Sep. 5, 1991).

28. HORIZONS OF HEALTHCARE, *supra* note 5, at 15.

Medical Ethics, which add that the "physician has an obligation to cooperate in the coordination of *medically indicated* care."[29] Here, the Principles of Medical Ethics preserve the physician's ability to exclude therapies unilaterally through the definition of medically indicated care.

Despite the paternalistic bias of this section of the AMA Principles of Medical Ethics, the Principles otherwise roughly conform to modern consensus in acknowledging that the doctor-patient relationship has progressed from being merely consensual to collaborative.[30] The physician is urged to seek "common ground" with the patient, so both doctor and patient are involved in the decision-making process.[31] Finding common ground may require physician concession to reasonable patient requests for treatment outside of biomedicine. This give-and-take negotiating, in which a physician considers (or proposes) CAM at an early stage in treatment, opens communication and thus strengthens the doctor-patient relationship.[32] Improved communication is likely to facilitate patient acceptance of conventional treatment if it is clearly safer and more efficacious or if an attempted CAM treatment is ultimately unsuccessful.[33] Patients undergoing CAM at the direction of a physician can have the benefit of the physician's diagnostic and prognostic skills even if they are not undergoing optimal treatment by conventional standards.[34]

### 2. *Cultural Minorities, Indigenous People and CAM*

Biomedicine is at least to some degree ethnocentric.[35] The names alone of many CAM modalities reveal an origin outside of Western European tradition. Existing biomedical standards may be in place not because they are superior, but because biomedicine was already entrenched when proponents of a competing practice arrived on the scene,[36] or because biomedicine

---

29. CODE OF MEDICAL ETHICS, *supra* note 22, at § E-10.01(5) (emphasis added).

30. CODE OF MEDICAL ETHICS, *supra* note 22, at § E-10.02; Jerry A. Green, *Collaborative Physician-Patient Planning and Professional Liability: Opening the Legal Door to Unconventional Medicine*, 15 ADVANCES IN MIND-BODY MED. 83, 88-89 (1999).

31. Teaching this skill has become part of the family practice curriculum. *See, e.g.*, East Tenn. State Univ. Dept. of Family Med., Doctor Patient Communication: Resources, *at* http://qcom.etsu.edu/communication/Resources.htm (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review).

32. Green, *supra* note 30, at 84.

33. If the patient were not to agree to this plan, the physician's treatment amounts to little more than acquiescence to the patient's demands.

34. Some states mandate a conventional evaluation and detailed informed consent before CAM can be offered. *See, e.g.*, 22 TEX. ADMIN. CODE § 200.1-200.3 (West 2003).

35. Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 199 (1998) (asserting, even more narrowly, that "[m]edicine remains substantially a white male profession . . .").

36. GUIDO CALABRESI, IDEALS, BELIEFS, ATTITUDES AND THE LAW 28-30 (Syracuse Univ. Press 1985). A group is not assimilated until it has learned "to behave like the previously dominant group." It remains to be seen whether CAM can survive mainstreaming.

obtained dominance over competing practices through political processes[37] or the westernization of indigenous people.[38] Until the recent resurgence of alternatives, biomedicine had been spectacularly successful in driving out other schools of thought through educational reform in the early twentieth century.[39]

Considering CAM to be within the standard of care may promote the health of those who may be part of a minority culture otherwise averse to biomedical treatment.[40] Indeed, the White House Commission concluded that CAM be provided *with* biomedicine, rather than as an alternative to biomedicine.[41] People with limited means and a cultural preference for CAM should not be forced to choose between unproven but culturally preferred CAM and proven biomedicine.[42]

Additionally, some CAM practices represent part of the "intrinsic uniqueness" of an indigenous (or immigrant) culture that deserves preservation.[43] Conferring legitimacy solely upon biomedicine may deprive a minority of part of its culture and hasten that culture's extinction.[44] This loss deprives biomedicine and "Western" culture not of a medical curiosity, but of something of practical significance. For example, Navajo methods of treatment have the potential for use in therapeutic jurisprudence, approaching crime "as an opportunity for healing rather than retribution and punishment."[45] Obviously, if this means of rehabilitation were to be employed, practitioners (potentially physicians) would need to be trained in its use. Thus, loss of alternative treatments may have wider consequences than the mere lost chance to treat individuals.

---

37. *See generally* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 79-144 (1982) (discussing the processes through which the practice of medicine in the United States became more uniform).

38. *See* Robert B. Porter, *Pursuing the Path of Indigenization in the Era of Emergent International Law Governing the Rights of Indigenous Peoples*, 5 YALE HUM. RTS. & DEV. L.J. 123, 131 (2002); James W. Zion, *Navajo Therapeutic Jurisprudence*, 18 TOURO L. REV. 563, 566 (2002).

39. WHITE HOUSE COMM'N, *supra* note 4, at 13.

40. *See* Kelly S. Croman, Note & Comment, *One Size Does Not Fit All: The Failure of Washington's Licensing Standards for Alcohol and Drug Treatment Facilities to Meet the Needs of Indians*, 72 WASH. L. REV. 129 (1997). "[N]eglecting cultural differences in means of communication and healing models" has led to failure of efforts to treat alcohol abuse in Indians. *Id.* at 141.

41. WHITE HOUSE COMM'N, *supra* note 4 at 100.

42. *Id.* at 17, 98-99. Income may be a confounding factor in determining the preferences of some ethnic groups. *Id.* The report also noted that in the context of populations with limited access to conventional care, "CAM becomes neither a complementary nor integrative intervention, but rather a less validated alternative to conventional care." Joseph Fins & Tieraona Low Dog, *Appendix* to WHITE HOUSE COMM'N, *supra* note 4, at 228.

43. Porter, *supra* note 38, at 131.

44. *Id.* at 140-42.

45. Zion, *supra* note 38, at 566. The author notes that "Navajos have persistently traditionally kept their traditional medical practices while accepting western medicine." *Id.* at 584-85 (footnote omitted).

### 3. *Regulatory Limitation of Patients' Treatment Options*

Autonomy-based arguments for a libertarian approach to treatment notwithstanding, the physician is not completely unbridled in granting patient requests; various regulatory bodies may curb a physician's scope of practice. The Supreme Court has held that it is within the police power of the state to regulate physician's licensure[46] and therapies that the physician may provide.[47] Indeed, "there is no right to practice medicine which is not subordinate to the police power of the States."[48] Some aspects of medicine such as education (through licensure requirements for specific professions), human experimentation, and use of controlled substances are heavily regulated.[49] However, regulation of specific therapies is sparse.[50] Allowing a physician latitude in treatment is probably wise policy: government-imposed standards could potentially mandate unsubstantiated treatment or preclude progress if a previously prohibited treatment were found to be beneficial when used in a different manner or within a different context.[51]

States have used their police powers in recent years to limit the ability of physicians in some jurisdictions to practice CAM. For example, in *In re Guess*, the North Carolina Supreme Court reversed lower court rulings and upheld a medical licensing board decision to revoke Guess' medical license because he practiced a limited amount of homeopathic medicine.[52] Discounting that Guess' treatment presented no threat of harm to his patients or to the public, and further discounting that Guess' practices were allowed in other jurisdictions, the court based its decision solely on Guess' deviation from "the

---

46. Crane v. Johnson, 242 U.S. 339, 344 (1917) (holding that a state may distinguish between Christian Science faith healers and drugless practitioners for licensure purposes); Dent v. West Virginia, 129 U.S. 114, 128 (1889) (holding that states may establish conditions for medical licensure for the protection of society).

47. United States v. Rutherford, 442 U.S. 544, 552 (1979) (validating FDA evidentiary standards for effectiveness and upholding a decision to deny laetrile to cancer patients: "Congress expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures"); Lambert v. Yellowley, 272 U.S. 581, 596-97 (1926) (upholding limitation on quantity of alcohol physicians could prescribe for medicinal purposes).

48. *Lambert*, 272 U.S. at 596.

49. *See, e.g.* 42 U.S.C. § 289 (2004) (concerning institutional review boards, ethics and protection of human subjects); 21 C.F.R. §§ 50.1-50.56 (2004) (concerning protection of human subjects); 21 C.F.R. §§ 56.101-56.124 (2004) (concerning institutional review boards); *see also* Controlled Substances Act, 21 U.S.C. §§ 801-830 (2004) (concerning standards, schedules, registration, and authority to control). States also regulate both human research and controlled substances.

50. *See, e.g.*, ARIZ. REV. STAT. §§ 32-1401(gg), 32-1501, 32-2901 (2003) (prohibiting use of EDTA chelation therapy as a CAM treatment, but permitting its use for other specified purposes); COLO. REV. STAT. § 12-30-113 (2003) (proscribing the use of Laetrile).

51. BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 13 (4th ed. 2001) (quoting Alain Enthoven, *Health Plan: The Only Practical Solution to the Soaring Costs of Health Care* (1980)).

52. In re Guess, 393 S.E.2d 833, 834 (N.C. 1990).

standards of acceptable and prevailing medical practice" as defined by the board.[53]

Licensing and other regulations usually operate in broad terms with respect to treatment, such as prohibiting practice of homeopathy *in general.* However, scrutiny has also been directed at *specific* practices collateral to delivery of medical care, such as marketing. The White House Commission noted that "misleading and fraudulent health claims exist and are a cause for great concern."[54] Especially susceptible to these fraudulent claims of efficacy are those "who are ill, have limited language or educational skills, or lack access to the conventional health care system . . . ."[55]

These unsubstantiated claims of efficacy have triggered Federal Trade Commission ("FTC") action. For example, the FTC investigated the advertising and promotion of ethylene diamine tetraacetic acid ("EDTA") by the American College for the Advancement of Medicine ("ACAM") as an effective treatment for atherosclerosis.[56] Because the claim of efficacy was not supported by research, the FTC found ACAM's promotion of EDTA therapy false and misleading.[57] The FTC noted that in the health care field, "the consequences of deception can be especially serious, causing not only economic injury by undermining consumers' ability to make informed choices, but creating risks to consumer health and safety."[58] Although the FTC notes that its ruling applies only to "commercial speech, disseminated to consumers[,]" and not to "doctors acting in their individual capacities giving advice to [or treating] their patients",[59] the ruling may chill physicians' enthusiasm for the use of EDTA chelation therapy.[60]

Thus, potentially unlimited patient demands, legitimatized by patients' recognized right of autonomy, are balanced by regulation and pressure from professionally controlled bodies such as licensing boards that may confine physicians' scope of practice. Outside of these control measures, case law suggests physicians are generally granted wide latitude in exercising their

---

53. *Id.* at 835, 839, 840; *see also* WHITE HOUSE COMM'N, *supra* note 4, at 145 (recommending specifically that states not sanction practitioners solely because they are engaged in otherwise medically ethical CAM research (as opposed to treatment)).

54. WHITE HOUSE COMM'N, *supra* note 4, at 69, 72.

55. *Id.* at 69.

56. *Prepared Statement of the Fed. Trade. Comm'n on "Agency Lockout on the Off-Label Use of EDTA Chelation Therapy": Hearing Before the House Comm. on Gov't Reform*, 106th Cong. (Mar. 10, 1999) (presented by Jodie Bernstein, Director, Bureau of Consumer Protection) [hereinafter *Fed. Trade Comm'n*], *available at* http://www.ftc.gov/os/1999/03/acamtestimony.htm; *see also* Press Release, Fed. Trade Comm'n, Medical Association Settles False Advertising Charges Over Promotion of "Chelation Therapy," (Dec. 8, 1998), *available at* http://www.ftc.gov/opa/1998/12/acam.htm (on file with the Indiana Health Law Review).

57. *Fed. Trade Comm'n*, *supra* note 56.

58. *Id.*

59. *Id.*

60. *See also* WHITE HOUSE COMM'N, *supra* note 4, at 82-83 (discussing other FTC actions).

professional judgment.[61] Under this regime, as long as a CAM treatment is provided by a physician exercising reasonable judgment, CAM should not be dismissed outright as a violation of standard of care until legislatures speak and prohibit it.

### *B. The Conundrum of Taxonomy*

Probably the most radical argument supporting CAM suggests, with possible irony, that biomedicine could be considered a *subset* of energy medicine (CAM) based on issues of legitimacy, precedence, and priority of beliefs.[62] However, it is unlikely that the American health care establishment will ever accept this theory. CAM practitioners are more properly considered to be operating within a separate paradigm from biomedicine, although the boundaries of the paradigms are sometimes far from distinct.[63] Philosophers of science would probably conclude that neither paradigm is likely to be explicable in terms of the other.[64] This precludes either CAM or biomedicine subsuming the other.

---

61. Although this may be more the case when courts address issues outside of malpractice. *See, e.g.*, Lesley v. Chie, 250 F.3d 47, 49 (1st Cir. 2001) (holding in a suit alleging disability discrimination of an HIV-infected patient "that the doctor's judgment is to be given deference absent a showing by the plaintiff that the judgment lacked any reasonable medical basis"); McAleese v. Owens, 770 F. Supp. 255, 258, 259 (M.D. Penn. 1981) (noting that in prisoners' Eighth Amendment claims concerning their medical treatment, the propriety or adequacy of treatment is a question of sound professional judgment not to be second-guessed by the court, and that courts must exercise only a limited form of review); Cowan v. Myers, 232 Cal. Rptr. 299, 305-306 (Cal. Ct. App. 1986) (noting that for purposes of the Medicaid Act, legislatures may determine what general services are covered, but may not exclude a specific service for a covered condition if the physician determines that it is medically necessary and the plan makes the service otherwise available); State Bd. of Med. Exam'rs v. Rogers 387 So.2d 937, 939 (Fla. 1980) (noting that a medical board's restrictions on a physician's practice "must be reasonably related to the public health and welfare and must not amount to an arbitrary or unreasonable interference with the right to practice one's profession . . .").

62. COHEN, *supra* note 27, at 81.

63. Theodore Pincus, *Differences Between Acute and Chronic Illness May Clarify Issues of Orthodox Versus Alternative Medicine and Tort Law Versus Collaborative Planning*, 15 ADVANCES IN MIND-BODY MED. 99, 100 (1999) (responding to Green, *supra* note 30). *But cf.* WHITE HOUSE COMM'N, *supra* note 4, at 5 (noting that many of the commissioners agreed that "scientifically tested" and "scientifically untested" are better distinctions than "conventional" and "alternative" medicine).

64. *See* THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 200 (2d ed., enlarged, Univ. of Chicago Press 1970) (1962). Kuhn claims "[t]here is no neutral algorithm for theory-choice . . . ." *Id.* Kuhn points out that even though one view can never be proven "true" to the other, learning about the opposing view is nevertheless still possible:

> [In making a choice between competing paradigms,] the choice is not and cannot be determined merely by the evaluative procedures characteristic of normal science, for these depend in part upon a particular paradigm, and that paradigm is at issue. When paradigms enter, as they must, into a debate about paradigm choice, their role is necessarily circular. Each group uses its own paradigm to argue in that paradigm's defense.
>
> The resulting circularity does not, of course, make the arguments wrong or even ineffectual. The man who premises a paradigm when arguing in its

Moreover, each group of practitioners will resist incorporation into the other. The more dominant biomedical paradigm has historically demonstrated antipathy toward CAM.[65] Evidence also suggests that many CAM practitioners are not seeking legitimization through scientific explanation of their practices.[66] For example, despite biomedicine's ability to explain the effectiveness of some herbal CAM therapies in pharmacological terms, "many complementary and alternative medicine practitioners regard herbs as sacred, having properties beyond the pharmacological."[67]

Similarly, advocates of post-modernist and feminist theory argue that CAM therapies which defy biomedical explanation do not require validation by biomedicine to be legitimate.[68] Some CAM proponents question even the statistical methods used by biomedicine to validate efficacy.[69] A Texas court

---

> defense can nonetheless provide a clear exhibit of what scientific practice will be like for those who adopt the new view of nature.

*Id.* at 94; *see also* MICHAEL POLANYI, SCIENCE, FAITH AND SOCIETY 38 (Univ. of Chicago Press 1964) (1946). Polanyi suggests that the scientist cannot be a neutral arbiter:

> Viewed from outside as we described him the scientist may appear as a mere truth-finding machine steered by intuitive sensitivity. But this view takes no account of the curious fact that he is himself the ultimate judge of what he accepts as true . . . far from being neutral at heart, he is himself passionately interested in the outcome of the procedure.

*Id.* Western culture's predilection for scientific explanations suggests that an accepted explanation of CAM's effectiveness will probably be based on conventional biomedicine, rather than visa-versa.

65. *See, e.g.*, Wilk v. Am. Med. Ass'n, 895 F.2d 352, 378 (7th Cir. 1990) (affirming a district court's holding that the American Medical Association violated Section One of the Sherman Antitrust Act by conducting an illegal boycott directed at chiropractors). *See generally* STARR, *supra* note 37, at 116-27. The American Medical Association was phenomenally successful in establishing academic, science-based medicine as the preeminent school in the first decades of the twentieth century. *Id.* In conjunction with other forces of reform and economics, the well-known Flexner report, created under somewhat concealed AMA auspices, led to the homogenization of medical education through wide-scale elimination of non-scientific programs. *Id.*

66. Green, *supra* note 30, at 92.

67. COHEN, *supra* note 27, at 107; *see also* MICHAEL H. COHEN, COMPLEMENTARY AND ALTERNATIVE MEDICINE 11 (1998).

> When traditional Chinese doctors prescribe herbs, they are basing their prescriptions not on Western chemistry and pharmacology but on the effect that these herbs, which have multiple active ingredients, will have on the patient's chi. Similarly, acupuncturists' diagnostic and therapeutic roadmap . . . does not correspond to Western anatomical systems.

*Id.*

68. Caulfield & Feasby, *supra* note 16, at 189-91. The authors note that some consider scientific truth to be merely a point of view. *Id.* at 191. However, CAM *is* amenable to scientific study to the extent it makes specific claims. *Id.*

69. Green, *supra* note 30, at 92; *see also* WHITE HOUSE COMM'N, *supra* note 4, at xviii, 33-35 (recommending that the National Science Foundation develop methodology suitable for the study of CAM); Kathleen M. Boozang, *Is the Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567, 602 (2000). CAM proponents offer two alternative models for evaluating efficacy: *pragmatic efficacy*, which "concentrates on the treatment setting to determine what is necessary to make a good clinical decision" in terms of the greatest total effect, and *performative efficacy*, which focuses on subjective factors such as patients' "symbols, belief, suggestion, expectation and persuasion . . . ." *Id.*

has agreed that CAM may be valid despite lack of scientific explanation:

> There are a number of problems with [the] finding [that acupuncture is an experimental procedure with unestablished safety and effectiveness.] To begin with, it appears to have been based on no evidence . . . . [Acupuncture] is no more experimental as a mode of medical treatment than is the Chinese language as a mode of communication. What is experimental is not acupuncture, but Westerners' understanding of it and their ability to utilize it properly.[70]

In addressing access, the White House Commission further suggested that CAM provides value in its distinction from biomedicine, noting a "need to maintain CAM styles of practice, rather than allowing them to be subsumed into the conventional medical model . . . ."[71] Market forces also function to keep the schools of practice apart. Patients and other consumers of medical services who are dissatisfied with biomedicine as a profit-motivated industry may desire the separation so that they are not viewed as acquiescing to the tenets of that industry.[72] This consumer viewpoint is validated by apparent government skepticism of physicians' ability to self-regulate as demonstrated by rising fraud, antitrust and kickback concerns.[73]

Despite paradigmatic incompatibility and the apparent desire of patients and physicians to keep CAM and conventional medicine distinct, some courts have refused to distinguish the two. Treating biomedicine and CAM similarly prevents arrival at the logical conclusion that practitioners of nonstandard therapies are not practicing medicine, which would shield CAM practitioners from prosecution for unlicensed practice.[74] Courts reason the practice of medicine does not exclude certain methods of arriving at a diagnosis or per-

---

70. Andrews v. Ballard, 498 F. Supp. 1038, 1053 (S.D. Tex. 1980); *cf.* KUHN, *supra,* note 64, at 184-85. Kuhn addressed the evaluation of one discipline using the paradigm of another, noting that the importance of values emerge when they are used to choose between incompatible ways of practicing a discipline:

> [T]hey must, first and foremost, permit puzzle-formulation and solution; where possible they should be simple, self-consistent, and plausible, compatible, that is, with other theories currently deployed . . . . Other sorts of values exist as well—for example, science should (or need not) be socially useful . . . .

*Id.* at 185. *But see* Joseph Fins & Tieraona Low Dog, *Appendix* to WHITE HOUSE COMM'N, *supra* note 4, at 227. Two of the commissioners noted that "[w]hile dogmatic disbelief of everything that is not currently explainable is foolish, and indeed unscientific, it seems equally foolish to ask the taxpayer to bear the enormous expense of sorting out those areas that are plausible from those that are improbable." *Id.*

71. WHITE HOUSE COMM'N, *supra* note 4, at xxvi.

72. Peters, *supra* note 19, at 196-97.

73. *Id.*

74. *See, e.g.*, People v. Amber, 349 N.Y.S.2d 604, 607, 611-12 (N.Y. Sup. Ct. 1973) (holding that an acupuncturist was engaged in the practice of medicine even though acupuncture does not conform to the tenets of biomedicine).

forming treatment.[75] This argument has less weight in the malpractice context than in the licensing context, and the underlying concern is likely to become moot as states expand licensing laws that address CAM practices.

Biomedicine and CAM are properly considered distinct schools of the healing arts, both recognized and valued, but with only biomedicine largely validated by science and CAM remaining largely inexplicable in terms of science. As noted in Part II.C.1, *infra*, until scientists have nothing further to discover, biomedicine's scientific explicability must be qualified as incomplete, so lack of explicability alone is insufficient to invalidate the use of any broad category of therapy. Going further, schools that are so different that they are inexplicable in mutual terms may require judgment by different standards.[76]

### *C. Arguments Against a Standard of Care for CAM*

Arguments against a standard permitting non-customary treatment tend to be more formalistic or based upon collateral concerns.

#### *1. Standard of Care Should Be Professionally Determined and Science-Based*

Because simply being reasonable and prudent supplies an inadequate basis upon which to make a good decision in a highly complex and technical field, medical professionals are not held to the standard of ordinary care that applies in most tort law. Physicians are expected to apply specialized knowledge that neither the ordinary reasonable person nor the patient possesses. Paternalism, whether good or bad, is inevitable whenever decision-making power and responsibility is allocated in proportion to knowledge in the presence of gross information asymmetry.[77] Relying upon the profession to determine its own standards and protecting the integrity of the profession through medical licensing laws probably results in a higher standard of care.[78] Allow-

---

75. *Id.*

76. *See* CALABRESI, *supra* note 36, at 30. When a minority strives for equal footing, one must ask, "Equality on *whose terms, under which standard*?" *Id.* (emphasis in original).

77. In contrast to paternalism's usual negative connotation, it may be characterized positively as consumer protectionism in the relationship between physician and patient. *See* Boozang, *supra* note 35, at 211. Regulation of health care through a state's police powers for consumer protection is also paternalism. *Id.*

78. Hayne E. Leland, *Quacks, Lemons, and Licensing: A Theory of Minimum Quality Standards*, 87 J. POL. ECON. 1328, 1342 (1979); *cf.* Randall G. Holcombe, *Eliminating Scope of Practice and Licensing Laws to Improve Health Care*, 31 J.L. MED. & ETHICS 236 *passim* (2003) (considering whether health care quality would improve without government regulation and posing an argument for private sector regulation of health care); Clark C. Havighurst, *The Professional Paradigm of Medical Care: Obstacle to Decentralization*, 30 JURIMETRICS J. 415, 415-16 (1990) (maintaining that taking health care decision-making from the overly powerful medical profession and placing its control in the hands of consumers will benefit health care).

ing standard of care to be dictated to any significant degree by popular sentiment or patient intuition and misperception risks compromising the scientific rigor that establishes medicine as a profession,[79] negates the element of the physician's specialized knowledge in establishing a professional standard of care, and removes the floor of acceptable treatment that a professionally defined standard provides.

From the premise that the medical profession is distinguished by its specialized knowledge may rise the belief that standard of care should not include any inexplicable treatment.[80] CAM may be viewed as transcending mere inexplicability and entering the realm of religion or faith, rather than medicine.[81] Some fields, such as energy healing, do not fit neatly into either school.[82] Allowing non-professional appendages to the standard corrupts its protection of consumers from charlatans.

Even the White House Commission, a strong CAM advocate, expressed concern that recognition of and demand for treatment should not preempt a rigorous standard:

> [M]ost CAM modalities have not yet been scientifically studied and found to be safe and effective. The fact that many Americans are using CAM modalities should not be confused with the fact that most of these modalities remain

---

79. *See* Boozang, *supra* note 35, at 209 (asserting that physician assent to unproven CAM treatments affirms patients' beliefs in the benefits of CAM and "perpetuate[s] a system in which patients' ignorance results in their pursuit of care that they likely would not have elected had they been better informed").

80. FED'N OF STATE MED. LICENSING BDS. OF THE U.S., MODEL GUIDELINES FOR THE USE OF COMPLEMENTARY AND ALTERNATIVE THERAPIES IN MEDICAL PRACTICE § III.5. (2002) [hereinafter MODEL GUIDELINES], *available at* http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/cam_model_guidelines.htm. "All physicians must be able to demonstrate a basic understanding of the medical scientific knowledge connected with any method they are offering or using in their medical practices as result of related education and training." *Id. See also* Boozang, *supra* note 35, at 206-11 (arguing that unproven treatments should not be provided).

81. COHEN, *supra* note 27, at 3; *see also* Lauren A. Greenberg, Comment, *In God We Trust: Faith Healing Subject to Liability*, 14 J. CONTEMP. HEALTH L. & POL'Y 451, 465 (1998). Greenberg points out that faith healing has been given the status of medical treatment through Medicare reimbursement for Christian Science healers, sanatoriums and skilled nursing facilities. *See* 42 U.S.C.A. § 1395x(e) (West 2004) (defining "hospital" to include "a religious nonmedical health care institution").

82. COHEN, *supra* note 27, at 72-73. The author questions whether energy healers would be protected if credentialed as ministers. *Id.* How far energy healing may depart from biomedicine is well illustrated by discussion of the theory behind energy healing:

> The dominant assumption of energy healing is that disease originates in the biofield and precipitates into the physical body. This assumption correlates with the notions in holistic health that much of physical disease stems from emotional and spiritual imbalance, that illness is a message from the body, and the healing involves not only eradicating physiological symptoms and curing disease but also leading the person on an inner journey.

*Id.* at 81.

> unproven by high-quality clinical studies. The Commission believes that conventional and CAM systems of health and healing should be held to the same rigorous standards of good science.[83]

In *Gambee v. Board of Medical Examiners of the State of Oregon*, the defendant Board applied the principles of both scientific purism and protection of professional integrity in making its decision to revoke the medical license of John Gambee, an allopathic physician who provided ozone therapy to a patient:

> Alternative methods of treatment are available from alternative providers. When a patient goes to a Medical Doctor or a Doctor of Osteopathy, he or she is entitled to presume that the physician will practice pursuant to scientific, orthodox principles. One of those principles is that unproven or unscientific therapies will not be provided, even for the best of motives, because of the risk of exploitation. Dr. Gambee's use of Ozone with patient D.B., and his rationale for it, [that it would be harmless for a terminal patient,] is not dissimilar to the use of Laetrile. Patients in these conditions are extremely vulnerable to offers of hope of any kind from anybody for any price . . . . The principle is that the modality be scientifically based and justifiable. This Board must protect that principle and the principle will protect the population.[84]

During the course of Dr. Gambee's litigation, the Oregon legislature amended the Unprofessional Conduct Statute—under which the Board had revoked Gambee's license—to provide that "the use of an alternative medical treatment shall not by itself constitute unprofessional conduct."[85] Because the Board had additional grounds upon which to revoke Gambee's license, the court did not need to enter into what would have been a very interesting standard of care analysis to determine whether Gambee's provision of unconventional treatment no longer required prevention.[86]

When viewed from a practical rather than formalist standpoint, however, the Board's concerns in *Gambee* diminish considerably, especially if lack of scientific basis for treatment is disclosed to the patient. Moreover, the assertion that medicine is "scientific" may be overstated. Efficacy and physiologic

---

83. WHITE HOUSE COMM'N, *supra* note 4, at xviii.

84. Gambee v. Bd. of Medical Exam'rs for Or., 923 P.2d 679, 680-81 (Or. Ct. App. 1996) (quoting the Board of Medical Examiners).

85. *Id.* at 681 (quoting 1995 Or. Laws Spec. Sess. ch. 2 § 1 (OR. REV. STAT. § 677.190(1))).

86. *Id.* at 682.

explicability are distinct concepts. Efficacy of a CAM treatment may be proven before a physiologic basis is discovered,[87] and even lack of proof of efficacy is not necessarily sufficient to prove that a treatment is not beneficial.[88] Notably, some CAM treatments are equal in efficacy to biomedical treatments that have potentially greater risk. For example, efficacy of spinal manipulation is similar to that of biomedical management of uncomplicated back pain;[89] however, spinal manipulation does not entail the significant potential adverse effects of anti-inflammatory and pain pharmaceuticals.[90]

Biomedicine likewise has a history of providing some minimally beneficial "treatments" in response to popular demand. Male circumcision is an obvious example. Although the procedure is generally not performed for reasons of medical necessity and has been performed for generations by non-physicians, there is nevertheless a standard of care for its execution.[91] Another example is the requirement in some states that tattooing be performed by or under the supervision of a physician—a bizarre co-optation of a non-medical practice by medicine (or an assignment of the duty by state legislature).[92]

---

87. While poorly understood from the standpoint of biomedicine, acupuncture is apparently effective as treatment for cocaine addiction. *See* HORIZONS OF HEALTHCARE, *supra* note 5, at 9 (citing S. Kelly Avants et al., *A Randomized Controlled Trial of Auricular Acupuncture for Cocaine Dependence*, 160 ARCHIVES INTERNAL MED. 2305 (2000) (claiming that use of acupuncture resulted in 53.8% of cocaine addicts testing negative for cocaine at the end of an eight-week study, while only 23.5% of those addicts treated with sham acupuncture tested negative)).

88. For example, current family practice literature recommends that physicians counsel patients on increasing physical activity even though

> published evidence for the effectiveness of routine behavioral counseling to promote physical activity is currently insufficient for the [United States Preventive Services Task Force] to recommend for or against including it in the periodic health examination . . . . "[I]nsufficient evidence to recommend" does not mean that such counseling has been shown to be ineffective.

SUSANNA E. GUZMAN, AM. ACAD. OF FAMILY PHYSICIANS, PRACTICAL ADVICE FOR FAMILY PHYSICIANS TO HELP OVERWEIGHT PATIENTS 13 (2003) (citing U.S. Preventive Servs. Task Force, Behavioral Counseling in Primary Care to Promote a Healthy Diet: Recommendations and Rationale, *at* http://www.ahrq.gov/clinic/3rduspstf/diet/dietrr.htm (current as of Dec. 2002)); *see also* U.S. Preventive Servs. Task Force, Physical Activity Counseling, *at* http://www.ahrq.gov/clinic/uspstf/uspsphys.htm (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review) (providing the same recommendation).

89. Willem J.J. Assendelft et al., *Spinal Manipulative Therapy for Low Back Pain: A Meta-Analysis of Effectiveness Relative to Other Therapies*, 138 ANNALS OF INTERNAL MED. 871 (2003).

90. CECIL TEXTBOOK OF MEDICINE 100-01, 116-18 (James B. Wyngaarden et al. eds., 19th ed. 1992) (discussing narcotic and anti-inflammatory medication side effects).

91. *See, e.g.*, McGuigan v. Weiss, 52 Pa. D. & C.4th 308, 312 (2001) (noting that use of non-absorbable sutures in a circumcision violates the standard of care).

92. *See, e.g.*, CONN. GEN. STAT. ANN. § 19a-92a (West 2004) (providing that "[n]o person shall engage in tattooing except a physician" or certain medical personnel "under the supervision, control and responsibility of a physician"); MASS. GEN. LAWS ANN. ch. 265 § 34 (West 2004) (providing that "[w]hoever, not being registered as a qualified physician . . . , marks the body of any person by means of tattooing, shall be punished by a fine . . . or by imprisonment . . . or both"). Although tattooing may be performed for medical purposes such

*2. Economic Factors*

In the interest of stewardship of funds, the scope of reasonable and necessary medical treatment covered by insurance is usually confined to efficacious treatments in order to maximize the benefit of money spent on health care. Since most of CAM is of unproven efficacy, it follows that CAM should not be covered.[93] While this conclusion strongly disfavors requiring third party reimbursement for CAM, applying this argument more broadly reveals the argument's limited applicability. Subjecting all medical treatments to a cost-benefit test to determine whether a treatment is within the standard of care raises difficulties in the analysis of nearly cost-free CAM modalities and extremely expensive heroic treatments.

### *D. Conclusion*

When "balanced against the wish to grant patients every opportunity to access healing, alleviate suffering, and move toward wholeness at every level of being,"[94] arguments that CAM necessarily resides outside the scope of physicians' permissible practice and is essentially malpractice per se seem weak. Although absolute exclusion of CAM from permissible treatment may protect some consumers who would otherwise obtain less effective treatment, if CAM is not malpractice per se, the consumer still has the protection of medical malpractice law if injured by CAM, and the physician must still practice within the loose confines of state regulation. Allowing the practice of CAM may provide opportunities for innovation, may strengthen the relationship of trust and respect between patients and physicians, and is in step with emerging concepts of autonomy. Allowing biomedical physicians to practice CAM may encourage some patients that would not otherwise seek conventional care, but need it, to enter the system. Permitting CAM preserves practices that may have a broader cultural value.

Lastly, a standard of care must emerge for physicians practicing CAM because, in a sense, the horse is already out of the barn. Patients, courts, professional societies, and governmental agencies and commissions expect physicians to provide, or at least coordinate, CAM services. In response to these demands, as well as their own perception of appropriate medicine, physicians are providing the services and are being reimbursed. The argument that CAM

---

as marking of areas for radiation therapy, the statutes do not confine use of tattooing to medical purposes.

93. Kathleen M. Boozang, *Is the Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567, 571, 606 (2000); *see also* Boozang, *supra* note 35, at 202-03. "Patients are likely to interpret health plans' inclusion of a particular treatment as an imprimatur on its efficacy, especially because patients perceive health plans in today's market to be restrictive in their coverage decisions." *Id.*

94. COHEN, *supra* note 27, at 18.

is a per se breach of standard of care because it is distinct from customary, traditional biomedicine seems inadequate in this light.

## III. INFORMED CONSENT

While informed consent and standard of care are generally distinct concepts, informed consent is critical to the standard of care analysis for CAM physicians.

> [D]isclosure is rooted in patient autonomy and is characterized by an exchange of material information between physician and patient such that the patient can make an informed health care decision. In contrast, standard of care refers to the physician's exercise of reasonable care in the treatment of a patient and is characterized by the alleviation of patient suffering through the employment of physical and pharmacological means supported by professional custom and experience. Standards of care are developed from within professions and, consequently, acceptable practices vary among the conventional and unconventional healing arts.[95]

Informed consent must assume a greater role in CAM than in conventional practice because CAM involves a much greater degree of patient participation in directing and conducting treatment—for example, through nutrition, meditation, and exercise—than in conventional medicine.[96] Because in many cases results are not judged by quantifiable, biomedical standards, there may be no clear indication of treatment success or failure, so success or failure must be judged subjectively.[97] Informed consent in CAM must not only address the items traditionally included in informed consent,[98] but must also address the question of who is to judge treatment success, and, derivatively, which parameters determine whether therapy is to be continued or discontinued.[99] The type of consent necessary for CAM, setting forth which decisions are to be made by the physician, which by the patient, and which are to be made

---

95. James A. Bulen, Jr., *Complementary and Alternative Medicine. Ethical and Legal Aspects of Informed Consent to Treatment*, 24 J. LEGAL MED. 331, 334 (2003) (footnotes omitted).

96. Green, *supra* note 30, at 86.

97. *Id.*

98. *See* FURROW ET AL., *supra* note 19, § 6-11 (listing the traditional informed consent documentation requirements as including: diagnosis, nature and purpose of treatment, risks and outcomes, skill or status risks, alternatives, prognosis with and without proposed treatment, and conflicts of interest).

99. Green, *supra* note 30, at 89-93.

jointly,[100] is therefore more in the nature of a contract than informed consent would be in the case of conventional treatment.

### *A. Contract Issues*

Defining duty through contract is nothing new. Furthermore, in application of the assumption of risk doctrine, there is precedent for application of a contractual definition of duty in CAM medical malpractice cases.[101]

The collaborative nature of the physician-patient relationship in CAM makes the importation of contractual concepts less problematic in some respects than it would be in the case of conventional, more paternalistic, medicine. Moreover, because the medical profession controls standard of care both in tort law and through its influence on licensing and state medical board actions, it is largely self-regulatory and is ideally situated to provide the parameters and boundaries of contract concerning type of care.[102]

Several lines of arguments support allowing contractual definition of standard of care through an informed consent document. First, the contract respects autonomy because limitations on treatment in part constitute patient *refusal* of conventional care, rather than physician *dictation* of CAM. That a physician's acceptance of this refusal is not contrary to public policy has some well accepted precedent: policy favors honoring Jehovah's Witnesses' express refusal of blood even when refusal threatens the individual's life and receiving

---

100. *Id.* at 89; *see also* Havighurst, *supra* note 78, at 428-29. The author also notes a potential economic benefit of determining standard of care through contract:

> [P]roviders and consumers could come to their own arrangements with respect to how the risks of medical treatment should be borne. Not only might parties to such contracts redefine their respective rights and responsibilities in the event of an injury, but they might also redefine the standard of care by specifying particular services that a patient would or would not be entitled to receive.

*Id.* at 428.

101. *See* Schneider v. Revici, 817 F.2d 987, 989 (2d Cir. 1987) (holding that *express* assumption of risk was available as a total defense in the case of a physician providing non-conventional cancer treatments) (emphasis added); *cf.* Boyle v. Revici, 961 F.2d 1060, 1061-62 (2d Cir. 1992) (holding that absence of a writing does not justify keeping an express assumption of risk issue from the jury); *see* Havighurst, *supra* note 78, at 429. Havighurst questions "[w]hether courts would respect contractual alterations of consumers' tort and other rights...." *Id.* Apparently some courts are willing to consider it.

102. Some state legislatures have enacted statutes permitting such use of contract and mandating inclusion of certain provisions. *See, e.g.*, IND. CODE ANN. § 25-22.5-1-2.1 (West 2004). The patient may consent to nonconventional treatment if (1) a physician personally examines and agrees to treat the individual, (2) the risk of the treatment is not unreasonable or significant, and (3) written and oral informed consent is obtained which discloses the nonconventional nature of the treatment, the unapproved status of any drugs or devices used, and the material risks of the treatment's side effects. *Id.* Furthermore, "[t]he medical licensing board shall develop protocols" for these treatments with which the physician must comply or be subject to discipline. *Id. See also, e.g.*, MO. CODE REGS. ANN. tit. 4, § 150-2.165 (2004) (providing the consent form to be used for EDTA therapy).

blood is strongly recommended by the physician.[103] Second, because CAM is by definition non-customary, parties' expectations cannot be reasonably assumed, and a contract is desirable in that it defines these expectations. Third, public policy, general tort law and general contract law will still provide boundaries to protect health care consumers. For example, CAM physicians will not be able to enforce contracts of adhesion, contract out of negligent behavior, or enforce contracts that violate federal or state law.[104]

### *1. Documentation of Refusal of Conventional Treatment*

While informed consent of some sort is usually required before provision of medical treatment, if the treatment is unproven or has been shown to be less effective than the conventional treatment, the consent assumes additional importance. Informed consent would show not only that the patient *chose* a *less* efficacious or proven therapy, but also that the patient specifically *refused* the *more* efficacious or proven treatment with knowledge of the risks. The document is a necessary part of a communication and educational tool that makes doctor and patient expectations explicitly and clearly delineated.[105] The consent form should demonstrate that the patient was indeed informed of the conventional treatment, its benefits, and perceived superiority over the CAM treatment, as well as any harm that may come to the patient by foregoing the conventional treatment. Furthermore, the informed consent document should expressly describe the treatment plan to set the expectations of both the physician and patient.

In 2002, the House of Delegates of the Federation of State Medical Boards of the United States approved Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice ("Model Guidelines"), developed by its Special Committee for the Study of Unconventional Health Care Practices.[106] Two of the committee's goals were to "protect legiti-

---

103. *See, e.g.*, Shorter v. Drury, 695 P.2d 116, 124 (Wash. 1985) (en banc) (holding that Jehovah's witness that refused blood and died during a medical procedure did not assume the risk of doctor's negligence, but did assume the risks associated with her refusal to permit a blood transfusion).

104. *See, e.g.*, Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 447 (Cal. 1963) (holding that definition of rights concerning duty of care through contract at the time of hospital admission is contrary to public policy as a contract of adhesion); Vodopest v. MacGregor, 913 P.2d 779, 785-87 (Wash. 1996) (holding that an exculpatory clause in a human research project on high altitude sickness would release defendant from liability only if plaintiff's high altitude sickness on a Mt. Everest trek occurred as a result of a recreational activity, but enforcing the clause would be prohibited by public policy and by federal human research regulations if defendant's injury was caused by research).

105. COHEN, *supra* note 27, at 41 (footnote omitted). "[S]cholars have urged a shift from the authoritarian, formulaic, and inflexible disclosure of informed consent, to a partnership between physician and patient in an atmosphere of conversation and shared exploration. This shift suits complementary and alternative medicine's emphasis on patient responsibility for self-care." *Id.*

106. MODEL GUIDELINES, *supra* note 80, at *Introduction*.

mate medical uses of CAM while avoiding unacceptable risk" and to "encourag[e] the medical community to adopt consistent standards . . . ."[107] Among other things, the Model Guidelines note that the medical record should document "whether or not certain options have been refused by the patient."[108] Adoption of the Model Guidelines by state medical boards would aid in a consistent approach to standard of care determination for CAM by requiring this documentation.[109] One commentator has suggested that:

> State medical boards could issue approved forms of informed consent for various forms of alternative medicine and provide the patient with all relevant information. If a competent, adult patient, being fully informed as to all the pros and cons of a particular treatment, nevertheless elects to go ahead with the treatment, then where is the harm? The state has fulfilled its legal duty to insure safe and effective medical care by requiring full disclosure to the patient. The physician is protected from medical board disciplinary action for the mere use of an alternative or complementary treatment which does not meet the generally accepted standard of care. The patient has autonomy and the physician has medical freedom.[110]

This advice has been implemented to a limited extent: Missouri has promulgated a consent document specifically for provision of EDTA chelation therapy of "no medical or osteopathic value . . . ."[111]

### 2. *Definition of the School of Practice and of the Expectations of the Parties*

Informed consent is the most reasonable solution to the physician-homeopath as physician or homeopath dilemma discussed above.[112] Because practice and standard of care vary among the biomedical and the numerous CAM schools, the school must be defined prior to treatment so that both doctor and patient know which standard applies.

Several courts have noted that when a patient calls upon a physician for treatment, it is the patient that has chosen the school of practice, and the

---

107. *Id.*

108. *Id.* § III.1.

109. Glenn E. Bradford & David G. Meyers, *The Legal and Regulatory Climate in the State of Missouri for Complementary and Alternative Medicine—Honest Disagreement Among Competent Physicians or Medical McCarthyism?*, 70 UMKC L. REV. 55, 98-99 (2001).

110. *Id.*

111. MO. CODE REGS. ANN. tit. 4, § 150-2.165 (2004).

112. *See supra* note 18 and corresponding text.

patient cannot later hold the physician to the standard of a different school.[113] If a physician practices within two schools, the traditional biomedical school and CAM, the patient should expressly indicate the school in which he or she is seeking treatment.

If no consent has been obtained and the physician and patient dispute which school should apply, the law should favor the patient as the less sophisticated party, and the school providing the more efficacious treatment—biomedicine by definition—should supply the standard. This acknowledges that CAM creates an exception to the usual formulation of standard of care, and that proof of the exception must be shown (with burden of proof on the physician) before it can be invoked.

### *B. Informed Consent Does Not Excuse Physicians from the Duty to Exercise Sound Judgment or the Duty to Refer*

Documentation that the patient desires CAM treatment exclusively does not immunize the CAM physician from liability for exercising unsound judgment. In *Kelly v. Carroll*, the Washington Supreme Court ruled in favor of the plaintiff when a drugless practitioner prescribed castor oil, pineapple juice treatments and abdominal massage for appendicitis.[114] The court reasoned that "[a] knowledge of what *not* to do may, in some instances, be indispensable to the patient's safety."[115] A CAM methodology may not be applied in the wrong context. The *Kelly* court reasoned:

> While it is true that a [drugless] practitioner . . . is not, in his limited field, required to be an insurer of results any more than a doctor of medicine, still, if he steps out of his limits and undertakes to treat a disorder for which, in the highest level of medical science, there is a generally recognized treatment, such interloper must be held accountable to the accepted standard of treatment.[116]

---

113. Van Sickle v. Doolittle, 169 N.W. 141, 142 (Iowa 1918). The court held that objection to testimony of an allopathic physician concerning standard of care in the trial of a homeopathic physician should have been sustained:

> In calling a physician, a person is presumed to elect that the treatment shall be according to the system or school of medicine to which such physician belongs, and it would be unfair to measure such treatment by any other than the standards of such school; and the law will not tolerate testing treatment according to one school by the standards of another.

*Id.* at 142; *see also* Spead v. Tomlinson, 59 A. 376, 378 (N.H. 1904) (*aff'd on reh'g*) (holding that when plaintiff employed a Christian Science faith healer, plaintiff could not later hold the faith healer to the standard of an allopathic physician).

114. Kelly v. Carroll, 219 P.2d 79, 81-82 (Wash. 1950).

115. *Id.* at 85 (emphasis added).

116. *Id.* at 86; *see also* Wilcox v. Carroll, 219 P. 34, 36 (Wash. 1923) (attaching significance to commonalities of diagnostic training and some portions of treatments of both drugless practitioners and allopathic physicians in the care of patients with appendicitis).

Other states have likewise ruled that an alternative practitioner must recognize when treatment in that practitioner's alternative school will be ineffective.[117] Minnesota has gone so far as to require that CAM providers recommend that their clients see a licensed health care provider "if there is a *reasonable likelihood* that the client needs to be seen by a licensed or registered health care provider."[118] Applying this standard only to physicians, the Model Guidelines also recommend that the medical record document "that proper referral has been offered for appropriate treatment . . . ."[119] Neither the Minnesota statute nor the Model Guidelines *require* referral, however, so analysis of the applicability of either requires inquiry into reasonable professional judgment.

Thus, both case law and statutes have required that CAM practitioners recognize the limitations of their schools and recommend that patients seek conventional care if indicated. In jurisdictions that adopt a Minnesota-type requirement, the reasoning behind the requirement for non-physician CAM practitioners should logically apply to CAM physicians as well, requiring them to discuss and provide for biomedical treatment if indicated. Thorough documentation is necessary not only to show that proven treatment or a referral was offered and rejected, but also to show that both physician and patient recognize the risks of pursuing CAM treatment and foregoing biomedical treatment.[120]

### *C. Conclusion*

Informed consent assumes a broader role in CAM than in conventional medicine. First, because a physician providing CAM services may practice in either of two schools, the school must be identified to establish the expectations of both provider and patient. Second, because much of CAM is unproven, the patient must specifically and expressly refuse treatments shown to be efficacious before the unproven treatment is provided, and the consent should document both risks of CAM treatment and risks of foregoing biomedical treatment. Third, contingencies signaling treatment endpoint, failure, or need for referral or change in treatment plan need to be determined up front. Fourth, because the patient may be an active participant rather than a passive recipient in the treatment, the responsibilities of the patient and physician must be delineated.

---

117. Rosenberg v. Cahill, 492 A.2d 371, 379 (N.J. 1985) (noting that a chiropractor has the duty to recognize tumors on x-rays of a child and refer the child for conventional treatment).

118. MINN. STAT. ANN. § 146A.08(x) (2004) (emphasis added).

119. MODEL GUIDELINES, *supra* note 80, § III.1.

120. If a CAM modality has not been shown to be effective, foregoing biomedical treatment and receiving CAM treatment may amount to receiving no treatment at all. The consent should make this clear. If CAM is provided to augment a biomedical treatment, the consent should make clear what benefit the patient is receiving from the biomedical treatment and from the CAM treatment.

## IV. STANDARD OF CARE

The standard of care imposes a minimum level of acceptable medical service. Although medical treatment may sometimes be obvious malpractice by any standard,[121] medical custom, as defined by the medical profession, generally defines standard of care in medical malpractice.[122] However, custom is not the only means by which standard of care can be defined. Comparing the standard of care analyses for CAM using the tests of the alternative standard of care doctrines illustrates the strengths and weaknesses of each.

### *A. Present Standard of Care Formulations*

The standard of care as it is currently understood in most jurisdictions evolved from the locality rule, which based standard of care on the prevailing practice or custom of physicians in the same or a similar community.[123] The primary criticism of the locality rule was that it exonerated physicians performing to a low local standard and encouraged a conspiracy of silence to protect an incompetent local colleague.[124]

#### *1. The National Standard*

As medical education became uniform across the country and communities were no longer isolated from medical progress, a standard of care based upon practices in the locality became antiquated, and a national standard evolved.[125] The standard is national because it is established by experts who are not required to be from a community similar to the defendant physician's

---

121. In Guerrero v. Smith, 864 S.W.2d 797, 798-99 (Tex. App. 1993), a licensed, self-styled "homeopathic" physician injected a patient with concoction of vitamins, minerals and dimethylsulfoxide in numerous locations without using sterile technique. When the patient developed infection, the doctor refused to prescribe antibiotics but "told her to drink her morning urine instead." *Id.* at 799.

122. The reasonable person standard is otherwise the norm in tort law.

123. *See generally* FURROW ET AL., *supra* note 19, § 6-2.

124. *Id.*

125. *See* Hall v. Hilbun, 466 So.2d 856, 866-875 (Miss. 1985) (tracing the history of the locality rule both in Mississippi and other states, and providing justification for limiting its applicability in favor of a "competence-based national standard of care"); *see also* Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?*, 25 AM. J.L. & MED. 403, 406-07 (1999). The author notes:

> A physician earns a degree based on standardized and highly scientific education, takes standardized medical boards and specialty tests and thereafter attends continuing medical education (CME) and periodic recertification courses. Most professional medical training and education concentrates on eliminating marginal, unproven and incompetent physicians through uniform institutional processes.

*Id.*

community.[126] The standard is customary in that the experts testify to customary or prevailing practice.[127] The advantage of the national standard for the plaintiff patient is that the minimum standard that a patient may expect in a backwater can be no worse than the minimum acceptable standard in a medically sophisticated community, taking into account availability of relevant resources.

Medical standard of care determined by custom of any sort has increasingly come under attack due to improved dissemination of information and the proliferation of practice guidelines in the past two decades.[128] Courts, while continuing to invoke custom, have placed growing emphasis on reasonableness,[129] which has replaced custom as the standard of care in a substantial minority of states.[130] Additionally, as the trend toward increasing patient autonomy places more of the decision-making power in the hands of the patient, custom may lose any remaining relevance because of non-uniformity in patient risk preferences.[131] Custom is also dependent upon economic factors that do not have their origin within the profession: treatment is influenced by what is considered economically feasible,[132] as well as by what is covered by insurance. "Funktionlust,"[133] the doctor's love of doing (and continuing to do) what the doctor does, and inertia both tend to make practices self-perpetuating, extending the life of customs even though superior treatments might be available.[134] That custom closely follows the development of new technologies and ideas may also be a myth: the convergence of custom and technological progress requires an unrealistic assumption of informational homogeneity and

---

126. FURROW ET AL., *supra* note 19, § 6-2b.

127. *Id.*

128. *See generally,* Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 HEALTH MATRIX 67, 93-95 (2000); Donald E. Kacmar, *The Impact of Computerized Medical Literature Databases On Medical Malpractice Litigation: Time for Another* Helling v. Carey *Wake-Up Call?*, 58 OHIO ST. L.J. 617, 633-44 (1997) (discussing the possibility of incorporating physicians' accessing of internet databases into standard of care).

129. Reasonableness in the medical malpractice context requires expert testimony just as medical custom requires expert testimony.

130. *See* Peters, *supra* note 19, at 164.

131. James A. Henderson, Jr., & John A. Siliciano, *National Healthcare Reform on Trial: Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1392 (1994). The authors note, "In short, because highly complex medical decisions must ultimately pass through the portal of patient ignorance and fear, the kind of common understanding upon which custom depends is unlikely to arise." *Id.*

132. *Id.* at 1394.

133. Joseph H. King, Jr., *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1267 (1975).

134. Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?*, 25 AM. J.L. & MED. 403, 413-14 (1999) (discussing barriers to physicians' use of practice guidelines).

denies any disparity among physicians in understanding of innovation, acceptance of innovation, and application of innovation to practice.[135]

### 2. *Two Schools of Thought and Respectable Minority Standards*

One response to the observation that physicians do not move in lock-step has been development of the doctrinally similar "two schools of thought" and "respectable minority" doctrines. These doctrines posit that a practice can be within the standard of care if it is an accepted alternative manner of treatment.[136] At first blush, the two schools of thought standard appears to be ideal with respect to CAM; however, in application it becomes problematic.

First, the standard is unreasonably advantageous for the defendant physician because it greatly expands the pool in which a defendant may find experts with similar potentially bizarre views,[137] setting the minimum level of care to which a patient is entitled unreasonably low. For example, although EDTA chelation therapy for atherosclerosis has been thoroughly discredited by the biomedical community, an expert in *Moore v. Baker* estimated that "approximately one thousand physicians routinely treat occlusive arterial disease with EDTA . . . ."[138] Almost any practice, no matter how harmful, engaged in by a considerable number of practitioners could be presented as the standard of care under this formulation.[139]

---

135. Henderson & Siliciano, *supra* note 131, at 1391.

136. Jurisdictions vary widely in the language used to define the standard. For an excellent overview of jurisdictional variation, see Michael Kowalski, *Applying the "Two Schools of Thought" Doctrine to the Repressed Memory Controversy*, 19 J. LEGAL MED. 503, 505-24 (1998). Pennsylvania courts, despite a long experience with two schools of thought doctrine, have struggled with its definition and application. In *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992), the Pennsylvania supreme court settled long confusion over the doctrine by holding the correct statement of law to be:

> Where competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise.

*Id.* Non-specific terms "considerable number," "recognized and respected," and "area of expertise" are all problematic with respect to CAM practitioners.

137. Robert L. Park, *Translating Science into law: Lessons from Doctors, Judges, and Lawyers about the use of Medical Evidence in the Courtroom: Science in the Courts*, 36 NEW ENG. L. REV. 575, 576 (2002). The author comments that "there is no claim so preposterous that a Ph.D. scientist cannot be found to vouch for it." *Id.* There is no reason to suppose that espousal of preposterous ideas is limited only to non-medical doctors.

138. Moore v. Baker, No. 491-93, 1991 U.S. Dist. LEXIS 14712, at *13 (S.D. Ga. Sep. 5, 1991).

139. In a sense, this may be criticized as taking the locality standard at its worst and "simply enlarg[ing] the professional frame of reference." King, *supra* note 133, at 1240-41.

While some precedent exists as to the absolute number of physicians necessary to define a minority,[140] defining who should be included in the minority or secondary school is more problematic. Should the minority include practitioners solely of CAM or dual CAM-biomedicine practitioners? The first group is likely to be large, and the second very small. Moreover, the former does not closely match the characteristics of the defendant physician because its members are generally not considered to have the knowledge and skills of a physician, which has been a key determinant of the non-physician CAM practitioner's standard of care.[141] Given the wide range of CAM practices, difficulty also arises in finding a comparable dual practitioner.[142] Even if a practitioner can be found, "the court may still have trouble discerning a coherent standard of care—one that is somehow distinct from either conventional or alternative medicine—against which to judge the defendant's conduct."[143]

Second, even if the minority can be defined, the difficulty of paradigm still exists. For example, in *Murray v. State Health Benefits Commission*, insurance coverage of colonic irrigation for treatment of dysbiosis[144] was at

---

140. This number may be significantly less than 1000, which would suggest a very small minority. *See, e.g.*, Leech v. Bralliar, 275 F. Supp 897, 899, 902 (D. Ariz. 1967) (noting that a total of sixty-five physicians nationally sufficed to establish a minority view).

141. Wengel v. Herfert, 473 N.W.2d 741, 743 (Mich. Ct. App. 1991) (noting that a chiropractor cannot be held accountable for failing to do what he is prohibited by law from doing); Spead v. Tomlinson, 59 A. 376, 378 (N.H. 1904) (noting that law cannot require a Christian Science faith healer to exercise the skill he is known not to possess); *see also* Kerkman v. Hintz, 418 N.W.2d 795, 802 (Wis. 1988) (holding that if a patient presented with a problem which is outside of a chiropractor's license to treat, the chiropractor only has a duty to inform the patient of that and does not have a duty to refer to a medical doctor). *But see* MINN. STAT. ANN. § 146A.08(x) (West 2004) (requiring a CAM provider to provide clients "with a recommendation that the client see a health care provider who is licensed or registered by a health-related licensing board or the commissioner of health, if there is a reasonable likelihood that the client needs to be seen by a licensed or registered health care provider); Salazar v. Ehmann, 505 P.2d 387, 390 (Colo. Ct. App. 1972) (holding that a duty to refer to medical practitioners exists because of an oath chiropractors take pursuant to state law); Roberson v. Counselman, 686 P.2d 149, 152 (Kan. 1984) (noting that testimony of another chiropractor that defendant chiropractor had a duty to refer was sufficient evidence of duty to withstand a summary judgment motion when defendant chiropractor had treated rather than referred a patient having chest and arm pain and known to have heart disease).

142. David M. Studdert, *Legal Issues in the Delivery of Alternative Medicine*, 54 J. AM. MED. WOMEN'S ASS'N 173, 175 (1999).

143. *Id.*

144. This diagnosis, known under a variety of names (such as "systemic candidiasis") is not widely recognized by biomedicine, and its somewhat bizarre treatments have generated at least one malpractice claim against a CAM physician. *See* Johnson v. Tenn. Bd. of Med. Exam'rs, No. M2002-00048-COA-R3-CV, 2003 Tenn. App. LEXIS 226, at *18 (Tenn. Ct. App. Mar. 19, 2003). In *Johnson*, patient E.H. had a stroke when Johnson, a physician with additional training in alternative medicine, used intravenous hydrogen peroxide, ozone treatments, and vitamin C injections for polysystemic candidiasis, which the board of medical examiners found constituted gross malpractice. *Id.* The court of appeals concluded that "there was ample evidence that, regardless of whether it is considered 'alternative medicine,' Johnson's treatment of E.H. went well beyond unorthodox, that it was below the standard of

issue.[145] Among reasons that coverage was denied was that although the therapy "was prescribed by a doctor, the prevailing medical opinion within the appropriate specialty was that such services were not safe and effective."[146] Considering testimony of both CAM experts and the state's gastroenterologist, the commission reasoned that "[c]olonic hydrotherapy is prescribed only by a few doctors practicing integrative or alternative medicine. Since it is not deemed safe and effective by the appropriate specialty, it follows that the procedure needs further evaluation before it would be accepted as appropriate treatment."[147] Furthermore, the commission did not accept the argument that because there were no ongoing studies, the treatment was not "experimental or investigational" (and by default, appropriate and warranting coverage); the commission noted that this reasoning could lead to the possibility that "treatments that were totally bizarre and unworthy of study could not be declared experimental or investigational."[148]

On appeal, the court was "somewhat concerned" with the commission's rationale: "Despite the lack of definitive medical studies, the [c]ommission found that because the procedure was prescribed only by doctors practicing alternative medicine and was not deemed safe by traditional doctors, 'it follows that the procedure needs further evaluation before it would be accepted as appropriate treatment.'"[149] The commission had ruled that gastroenterologists established the appropriate custom.[150]

> In essence, the [c]ommission has stated that because few to no traditional doctors prescribe this treatment, then the alter-

---

care, and was in fact dangerous." *Id.* at *24. Johnson's medical license was revoked. *Id.* at *19. The existence of an actual disease state corresponding to what has been variously labeled systemic candidiasis, dysbiosis, or yeast allergy has spawned heated debate among physicians. For opposing points of view on the legitimacy of this diagnosis, see H. Santelmann et al., *Effectiveness of Nystatin in Polysymptomatic Patients. A Randomized, Double-blind Trial with Nystatin Versus Placebo in General Practice*, 18 FAMILY PRACTICE 258 (2001) (finding effectiveness of treatment despite no firm diagnostic criteria) and Stephen Barrett, *Dubious "Yeast Allergies,"* QUACKWATCH, Dec. 18, 2002, *at* http://www.quackwatch.org/01QuackeryRelatedTopics/ candida.html (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review) (lambasting the diagnosis as pseudoscience). The polarizing issue is the level of scientific rigor needed to make or even to justify the existence of the diagnosis.

Similar problems have arisen in recognition of the diagnosis of multiple chemical sensitivity. *See generally* Jack W. Snyder et al., *Injury and Causation on Trial: The Phenomenon of "Multiple Chemical Sensitivities,"* 2 WIDENER L. SYMP. J. 97 (Fall 1997).

145. Murray v. State Health Benefits Comm'n, 767 A.2d 509, 510 (N.J. Super. Ct. App. Div. 2001).

146. *Id.* at 512.

147. *Id.*

148. *Id.* at 513. The plaintiff categorized the therapy as appropriate (covered) because it was not experimental, while the commission viewed it as experimental (not covered) because it was inappropriate.

149. *Id.* at 513-14.

150. *Id.* at 514.

> native practices must be experimental or investigational. And, therefore, under this rationale, the converse is true, that a treatment will become non-experimental only when traditional doctors begin prescribing or become supportive of the treatment.[151]

The court admonished that in future cases, "the [c]ommission should carefully consider whether the 'appropriate specialty' should be alternative licensed medical practitioners of the proposed treatment rather than whatever traditional medical specialty may be related to the treatment."[152]

Whether or not one agrees with the court's reasoning, from a practical standpoint, the court did not change the outcome that would have been obtained by the commission's reasoning. After apparently opening the door to recognition of the CAM physicians as a respected minority, the court immediately slammed the door shut by couching the conditions for acceptance of a minority standard in terms that only conventional treatment could fulfill:

> If a licensed alternative medical provider indicates that the treatment is based on *sound medical, biological or scientific principles*; widely prescribed and recognized by other alternative medical providers; *and considered efficacious* and safe, the Commission should not reject the treatment solely because traditional doctors do not yet utilize the treatment or are completely unfamiliar with the practice.[153]

As discussed in Part II, scientific explanation and proof of efficacy generally occur only within the framework of the biomedical paradigm, which is not the paradigm in which a "licensed alternative medical provider" operates. Furthermore, the CAM treatment at issue will not, by definition, have a basis in medical, biological, or scientific principles.

In determining whether a CAM practice falls within the standard of care under the "two schools of thought" doctrine, a trier of fact would experience confusion similar to that of the court in *Murray*. Determining whether CAM is an accepted alternative manner of treatment would involve a similar battle of experts speaking from the perspectives of paradigms lacking commonality.[154]

---

151. *Murray*, 767 A.2d at 514.

152. *Id.*

153. *Id.* (emphasis added).

154. Alternatively, if the applicable rules of evidence require that expert testimony meet rigorous scientific standards, there may be no qualified expert to serve as a proponent of the CAM minority. *See* discussion *infra* Part IV.A.4.

### 3. *The Reasonable Physician Standard: Best Basis for an Approach to CAM*

The reasonable physician standard is similar to the accepted practice standard articulated by Professor Joseph King.[155] Simply stated, "[p]ractices approved by the profession, not necessarily those customarily followed by its members, would be controlling."[156] This standard provides three advantages when applied to medical malpractice: first, the model would foster a higher standard of care, the "best standards of the day"; second, it would be in keeping with use of an "ideal paradigm" as a standard; and third, it is less dependent on professional consensus.[157] In theory, even an unprecedented practice would be within the standard of care if it were considered sound.[158]

The Texas Supreme Court applied a similar standard in *Hood v. Phillips*.[159] In *Hood*, a surgeon who had performed carotid body surgery on a patient with emphysema acknowledged that his treatment was not generally accepted, but that this treatment had been successful in his hands.[160] Experts testified variously that the procedure had been found ineffectual and abandoned, or was potentially harmful.[161] The jury did not find the doctor grossly negligent.[162] The court of appeals reversed, finding that an ordinary negligence standard should apply, with the method of treatment supported by a respectable minority.[163] The Texas Supreme Court reached the same conclusion on different grounds, concluding that in the case of treatments that are unaccepted—experimental, outmoded, or rejected—the jury should be asked, "[d]id the physician undertake a mode or form of treatment which a reasonable and prudent member of the medical profession would not undertake under the same or similar circumstances?"[164] The court further noted that using an unaccepted treatment could show a "conscious indifference to the welfare" of the patient and warrant "submission to the jury of an issue concerning gross negligence and, accordingly, an issue regarding exemplary damages."[165]

The Texas Supreme Court noted that the circumstances juries are to consider may "include, but are not limited to the expertise of and means avail-

---

155. *See generally* King, *supra* note 133, at 1213.
156. *Id.* at 1213, 1236.
157. *Id.* at 1213, 1237-39.
158. *Id.* at 1238.
159. Hood v. Phillips, 554 S.W.2d 160 (Tex. 1977).
160. *Id.* at 162.
161. *Id.*
162. *Id.*
163. *Id.* at 164. The respectable minority evidently had to comprise more than the defendant alone.
164. *Id.* at 165. The rule of law is: "A physician who undertakes a mode or form of treatment which a reasonable and prudent member of the medical profession would undertake under the same or similar circumstances shall not be subject to liability for harm caused thereby to the patient." *Id.*
165. Hood, 554 S.W.2d at 166.

able to the physician-defendant, the health of the patient, and the state of medical knowledge."[166]

This approach would offer clear benefit if, in addition to application to cases involving outmoded, rejected, or experimental treatment, it were applied to CAM as well.[167] This standard obviates the need to determine whether a therapy prescribed as CAM more properly fits in one of these other categories, since all non-accepted (non-customary) therapies are treated similarly.

To the factors to be considered by the jury (expertise of physician, health of patient, and state of medical knowledge) should be added the enhanced informed consent or collaborative plan, which documents the dialogue between CAM practitioner and patient. Testifying experts would not only examine the treatment with respect to the patient's medical problem, but also the treatment *with respect to the specific patient's desires*, taking into account both patient expectations and "notions of professional responsibility."[168] This approach values any "special insight"[169] the physician gains through familiarity with the patient as an unique individual, rather than mere familiarity with the patient's pathology.

In addressing CAM practice by licensed physicians, the State of Ohio took a similar tack in its statutory treatment of alternative medical treatments by including an element of reasonableness in its definition of CAM: "'alternative medical treatment' means care that is complementary to or different from conventional medical care but is reasonable when the benefits and risks of the alternative medical treatment and the conventional medical care are

---

166. *Id.* at 165.

167. There is significant overlap of these categories. For example, homeopathic medicine had its origins in a European theory of pathology that had been disproven by subsequent scientific discovery. *See* Boozang, *supra* note 35, at 195 (describing the history and theory of homeopathy); *see also* Park, *supra* note 137, at 578-80 (discrediting homeopathic theory on well-established chemical and mathematical grounds). Use of chelation therapy for atherosclerosis could be considered both rejected and outmoded in favor of less toxic therapies. Many CAM therapies are still undergoing study, while others involving vital energy seem to defy scientific explanation but nonetheless may still be considered reasonable, especially as adjuncts or in the case of health concerns that have proven intractable to other treatment.

168. King, *supra* note 133, at 1242-43.

169. *See* Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 OKLA. L. REV. 49, 55 (1999). King discusses allowing variation in practice based on "superior knowledge or special insights," based on Restatement (Second) of Torts § 289(b). *Id.* "The actor is required to recognize that his conduct involves a risk of causing an invasion of another's interest if a reasonable man would do so while exercising . . . such superior attention, perception, memory, knowledge, intelligence, and judgment as the actor himself has." RESTATEMENT (SECOND) OF TORTS § 289(b) (1965).

Patients with the "same" illness may require different approaches based on a host of individual characteristics. Henderson & Siliciano, *supra* note 131, at 1390. Varying the customary treatment for a condition based on individual characteristics creates "micro-customs," fragmenting any standard of custom to the degree that it is no longer distinctly discernable. *Id.*

compared."[170] The fluidity of this statute offers protection to the CAM provider who is providing a treatment of uncertain efficacy but little risk when the treatment is compared with conventional treatment of uncertain efficacy or high risk.

The Federation of State Medical Boards takes this approach as well. The Model Guidelines state that "[r]egardless of whether physicians are using conventional treatments or CAM in their practices, they are responsible for practicing good medicine . . . ."[171] The Model Guidelines also recommend a balancing of risks and benefits. In evaluating whether a physician is practicing appropriate medicine, boards should ask whether the treatment is effective and safe; effective, but with some real or potential dangers; inadequately studied, but safe; or ineffective and dangerous.[172]

Under the reasonable physician standard, after finding that a physician's practice was not customary (if relevant) and that a consent document was signed, the inquiry would proceed to whether the practice was nevertheless reasonable and prudent under the circumstances. This would entail examining the expertise of physician, health of patient, state of medical knowledge, risk of the treatment, benefit of the treatment, the consent document, and other patient-specific factors that may have influenced the choice of treatment.

*4. Evidentiary Concerns*

Rules of evidence have the potential to loom large in CAM cases. The expectation is that evidence poorly supported by scientific literature would be inadmissible; however, whether this is actually the case is dependent upon jurisdiction.

The role of rules of evidence is well illustrated by medical malpractice cases in Pennsylvania over the past dozen years. In *Gala v. Hamilton*, a medical malpractice case not involving CAM, a divided Pennsylvania Supreme Court held that the standard for admissibility must be highly flexible and may consist solely of testimonial evidence without support of scientific literature.[173] Whether the evidence is sufficient to establish a second school of thought defense is a matter for the jury.[174]

Only four years previously, the Pennsylvania Supreme Court in *Commonwealth v. Crews* had re-affirmed the state court applicability of the United States Supreme Court's decision in *Frye v. United States*, that "the thing from which the deduction is made must be sufficiently established to have gained

170. OHIO REV. CODE ANN. § 4731.227 (West 2004).
171. MODEL GUIDELINES, *supra* note 80, § I.
172. *Id.*
173. Gala v. Hamilton, 715 A.2d 1108, 1111, 1114-15 (Penn. 1998).
174. *Id.* at 1114-15.

general acceptance in the particular field to which it belongs."[175] The *Crews* decision occurred shortly *after* the United States Supreme Court's decision in *Daubert v. Merrell Dow*, which had liberalized the *Frye* rule.[176] Despite its departure from the Supreme Court's decisions in both *Daubert* and *Frye*, the Pennsylvania Supreme Court's holding in *Gala* was not necessarily outrageous; the conventional wisdom that juries are easily flummoxed by slick experts may be erroneous.[177]

Counterintuitively, rules of evidence requiring scientific proof may in some cases benefit the defendant CAM physician because the plaintiff has the burden of proof. In the post-*Daubert* case of *Ballinger v. Atkins*, a low-carbohydrate diet adherent suffered neurologic complaints which his experts, an internist and a biochemist, attributed to excessive use of artificial sweeteners.[178] Neither expert could adequately support his theory with scientific evidence, so neither was allowed to testify.[179]

In contrast, the expected outcome did occur in *Board of Registration for the Healing Arts v. McDonagh*, in which the Missouri Supreme Court grappled with the question of whether *Frye*, *Daubert*, or a Missouri statute should apply to admission of scientific evidence in the case of a physician facing discipline for use of EDTA chelation therapy for vascular disease.[180] The court noted that even where the Federal Rules of Evidence and the analogous state provision are "nearly identical," the federal construction is not controlling in state court.[181] Missouri law required that admissible expert opinion "be based on facts or data of a type reasonably relied upon by 'experts in the field.'"[182] The court noted further that:

> The relevant field must be determined not by the approach a particular doctor chooses to take, but by the standards in the field in which the doctor has chosen to practice. As relevant here, Dr. McDonagh chose to treat patients with vascular

---

175. Commonwealth v. Crews, 640 A.2d 395, 399 (Penn. 1994) (quoting Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)).

176. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592-94 (1993) (interpreting Federal Rules of Evidence Rule 702 to liberalize the Court's holding in *Frye*, establishing the judge's role as gatekeeper for expert testimony, and suggesting falsifiability, peer-review and publication, known or potential rate of error and general acceptance as factors in determining admissibility).

177. *See also* Jack W. Snyder et al., *Injury and Causation on Trial: The Phenomenon of "Multiple Chemical Sensitivities,"* 2 WIDENER L. SYMP. J. 97, 143-49 (1997) (discussing use of scientific experts, "junk" science, and implications with respect to the Supreme Court's *Daubert* decision). *See generally* Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 BROOK L. REV. 1121, 1140-65 (2001).

178. Ballinger v. Atkins, 947 F. Supp. 925, 926 (E.D. Va. 1996).

179. *Id.* at 928-29.

180. Bd. of Registration for the Healing Arts v. McDonagh, 123 S.W.3d 146, 153 (Mo. 2003) (en banc).

181. *Id.* at 155.

182. *Id.* at 156.

> disease. The Board's claim is that Dr. McDonagh engaged in repeated negligence . . . in his provision of chelation therapy for these patients. Therefore, the relevant field is doctors treating persons with vascular disease.[183]

Interestingly, like the Pennsylvania Supreme Court in *Gala*, the Missouri Court did not require that Dr. McDonagh's experts support their views with scientific literature; however, their evidence was nonetheless inadmissible because it was not of the type that would be reasonably relied upon by doctors treating vascular disease.[184]

Thus, whether a standard is based on custom or reasonableness, some claims *against* CAM providers may be dismissed because of the impossibility of providing the scientific evidence needed to establish a prima facie case of malpractice. In a much greater number of claims, there may be little admissible evidence *for* the CAM physician (at least in jurisdictions adhering to federal rule construction) given that CAM, by definition, is generally not scientifically proven. In other jurisdictions, testimony from CAM experts might be excluded, not because it lacks scientific support, but because it is in a sense not relevant from the perspective of the applicable school (as defined by the court). Courts may also apply a "flexible" standard, allowing expert testimony unsupported by scientific literature.

### *B. Other Potential Sources of a Standard*

All current methods of arriving at a standard of care rely predominantly on the testimony of experts chosen by the parties. Disinterested third parties may also aid in defining the standard.

#### *1. Licensing and Regulation*

Standard of care can be established through statute; violation of a standard of care mandated by licensing requirements or statute would essentially constitute malpractice per se. Absent a statute, professional discipline by a medical licensing board would create a strong inference that a standard of care has been breached if the discipline is tied to the same conduct that led to the malpractice action.[185] One such example is *Charell v. Gonzalez*, in which a physician treated a terminal cancer patient with coffee enemas and

---

183. *Id.*

184. *Id.* at 156-57.

185. There is, however, a large measure of circularity in the inference; medical licensing boards may also investigate a physician and revoke the physician's license in response to negligence claims. *See* Glenn E. Bradford, *The "Respectable Minority" Doctrine in Missouri Medical Negligence Law*, 56 J. MO. B. 326, 328 (2000).

monitored the patient's progress with unproven hair tests.[186] The plaintiff's claim asserted first negligence, for the doctor's persuading the plaintiff to forego traditional treatment for treatment of no therapeutic value, and second, lack of informed consent.[187] The trial court held for the patient and also awarded punitive damages because the physician had a secondary financial interest in the patient's treatment.[188] Except for the award of punitive damages, the decision was upheld on appeal.[189] The year before his case went to trial, the defendant physician, Gonzalez, had not prevailed on an appeal of an administrative review board's order that he undergo retraining because while "the vast majority" of Gonzalez' patients had cancer, he "lacked the basic understanding of the disease . . . ."[190] Gonzalez asserted that his patients had all consented to his treatment, and that no CAM practitioners were among the panel reviewing his case.[191] The court responded:

> Both the Hearing Committee and the Board recognized that alternative medicine involves a different treatment regime, but held [Gonzalez] to the same standard of care to which all physicians in New York are held . . . . Notably, 'it is well settled that a patient's consent to or even insistence upon a certain treatment does not relieve a physician from the obligation of treating the patient with the usual standard of care.'[192]

This standard and the court's view of the physician-patient relationship are reminiscent of those articulated by the North Carolina Supreme Court in *In re Guess*.[193]

Standard of care through regulation offers the advantage of origin in a less adversarial environment than the courtroom. If two apparently incompatible concepts must be amalgamated, or one chosen over the other, the infor-

---

186. Charell v. Gonzalez, 660 N.Y.S.2d 665, 666 (N.Y. Sup. Ct. 1997).

187. *Id.* at 666-67.

188. *Id.* at 669.

189. Charell v. Gonzalez, 673 N.Y.S.2d 685, 686 (N.Y. App. Div. 1998).

190. Gonzalez v. N.Y. State Dep't of Health, 648 N.Y.S.2d 827, 832 (N.Y. App. Div. 1996).

191. *Id.* at 830.

192. *Id.* (quoting Metzler v. N.Y. State Bd. for Prof'l Med. Conduct, 203 A.D.2d 617, 619 (N.Y. App. Div. 1994)).

193. In re Guess, 393 S.E.2d 833, 839-840 (N.C. 1990). The court noted first that it was within the police power of the state to limit Guess' methods of treatment to the acceptable and prevailing standards of medical practice; second, the court declined to recognize a fundamental right for patients to receive unorthodox medical treatment. *Id.* The court concluded that the North Carolina legislature "reasonably believed that a general risk of endangering the public is *inherent* in *any* practices which fail to conform to the standards of 'acceptable and prevailing' medical practice in North Carolina[,]" regardless whether the public was actually endangered by a particular practice. *Id.* at 837. *See also* discussion *supra* Part II.A.3.

mation gathering, debate, and ongoing opportunity to amend the law in response to new information make the legislature a better forum for decision-making.[194] Legislative acts or quasi-legislative rules could give deference to minority practices that are innovative, while determining that other minority practices are outmoded or too risk-laden to be justifiable. While determining standard of care through regulation does offer the advantage of certainty, establishing a standard of care by legislative fiat is likely to create the same sort of professional concern that *Helling v. Carey* created when standard of care was imposed by judicial fiat.[195] Moreover, the White House Commission noted that regulation through licensure is considered "not feasible" for some groups such as Native American and other traditional healers.[196] Other CAM practitioners consider themselves outside the realm of health professionals.[197] Additionally, licensure may stifle the "subjective, interpersonal and intuitive aspects" of CAM that make CAM valued by its practitioners and patients.[198]

From the patient's perspective, regulation may not necessarily be appreciated as protective, but rather perceived as unwarranted governmental pater-

---

194. *See* POLANYI, *supra* note 64, at 66. Polanyi illustrates how a society may resolve "[a] controversy between two fundamentally different views of the same region of experience. . . ." *Id.*

> I can see two main principles underlying the process of free discussion. One I will call fairness, the other tolerance, the words being used in a somewhat particular sense.
>
> Fairness in discussion is the effort to put your case objectively. When an expression of our conviction first comes to our minds it is couched in question-begging terms. Emotion breaks out uppermost and permeates our whole idea. To be objective we must sort out facts, opinions, and emotions and present them separately, in this order. This makes it possible for each to be separately checked and criticized. It lays our whole position open to our opponent. It is a painful discipline which breaks our prophetic flood and reduces our claims to a minimum. But fairness requires this; and also that we ascribe our opponent his true points, while the limitations of our own knowledge and our natural bias be frankly acknowledged.
>
> By tolerance I mean here the capacity to listen to an unfair and hostile statement by an opponent in order to discover his sound points as well as the reason for his errors. It is irritating to open our mind wide to a spate of specious argument on the off-chance of catching a grain of truth in it; which, when acknowledged, would strengthen our opponent's position and be even unfairly exploited by him against us. It requires great strength of tolerance to go through with this.

*Id.* at 68. This argument is presented before "[a] judicious public with a quick ear for insincerity of argument . . . ." *Id.* The candor and selflessness required in this sort of discussion is inconsistent with the adversarial process. That some authors have lamented lack of legislative assistance to CAM, while others have claimed legislatures have gone too far in legitimizing CAM, suggests that legislatures may be dealing with the issue evenhandedly.

195. In *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974), the court imposed a standard of care based upon reasonable prudence that was independent of the expert testimony presented at trial.

196. WHITE HOUSE COMM'N, *supra* note 4, at 90.

197. *Id.*

198. *Id.* at 94.

nalism.[199] Other reasonable arguments in opposition to increased regulation of CAM include regulations' interference with market mechanisms; the low level of actual urgency of many conditions treated by CAM; and a more permissive attitude of government toward a large number of more dangerous consumer choices.[200]

In contrast to a regulatory standard, a profession-based standard offers the advantage of being much more responsive to changes in medical knowledge. Standard of care has changed overnight when a previously respected therapy was unexpectedly found to carry significant risk.[201] Determination of standard of care at trial also offers advantages to both plaintiffs and defendants because the particular and probably unique circumstances of the case can be considered. Last, legislative determination of a standard may be viewed as an indirect application of the standard of the biomedical experts which advised it, confounded by special interests and politics. Compounding the confusion, there is no reason to suppose that state standard of care statutes would be uniform from state to state. This may have the effect of decreasing uniformity in medical care and education from state to state. The more direct approach of determination of standard of care by the profession itself obviates these problems.

*2. Practice Guidelines and Surveys*

Practice guidelines based on efficacy studies have been useful in establishing conventional standards of care and have been available in the past as affirmative malpractice defenses in some jurisdictions.[202]

Practice guidelines are of limited utility when evaluating CAM, which, as CAM's name suggests, stands in contraposition to the treatment conformity sought through application of guidelines. Moreover, guidelines are developed through compilation of the results of large scientific studies; CAM has not yet received this level of scientific scrutiny.

---

199. Holcombe, *supra* note 78, at 243.

200. *Id.* at 243-44.

201. *See, e.g.*, David M. Herrington & Timothy D. Howard, *From Presumed Benefit to Potential Harm—Hormone Therapy and Heart Disease*, 349 (6) NEW ENG. J. MED. 519 (2003); David M. Herrington, *Hormone Replacement Therapy and Heart Disease: Replacing Dogma with Data*, 107 CIRCULATION 2 (2003). Epidemiologic data showed that hormone replacement therapy, prescribed for many post-menopausal women and for years believed to be beneficial, conferred an increased risk of mortality. The resulting turnabout in treatment recommendation received national lay media attention; *see Red Flag on Hormone Replacement*, CBSNEWS .COM, July 9, 2002, *at* http://www.cbsnews.com/stories/2002/07/09/health/main514513.shtml (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review); *see also, e.g., Aleve Newest Drug Linked to Risk*, CBSNEWS.COM, Dec. 21, 2004, *at* http://www.cbsnews.com/stories/2004/12/07/health/main659540.shtml (last visited Apr. 18, 2005) (on file with the Indiana Health Law Review) (discussing recent findings that some commonly prescribed anti-inflammatory medications increase risk of heart attack).

202. *See, e.g.*, ME. REV. STAT. ANN. tit. 24, §§ 2971-78 (West, repealed 1999).

An additional problem in the application of guidelines comes from CAM's "exceedingly complex mosaic of . . . practices, therapies, modalities, disciplines, and professions . . . ."[203] Although some practices such as chiropractics have extensive education and training standards, many other CAM therapies are only just developing any sort of uniform educational or accreditation standards.[204] Variations in state licensing requirements and scope of practice regulations cause CAM practices with the same or similar titles to vary from state to state.[205] Standardized education, licensure requirements, and scope of practice regulations would seem to be a necessary precursor to development of treatment guidelines for CAM.

Surveys of physicians used to establish a standard of care, when the results are presented by experts, have been admissible in court; however, random sampling may not find doctors familiar with CAM, and the technique has recognized drawbacks when applied to minority views.[206]

### *C. Policy—Tossing a Spanner into the Works*

Legislatures may base decisions to limit or to expand the varieties of licensed medical practices upon popular demand[207] or other policy grounds even in the face of strong scientific evidence disfavoring the law. Court decisions as well may run contrary to the result urged by science, basing a holding upon legislative intent or non-science-based policy.

For example, EDTA has been approved by the FDA for use in some heavy metal intoxication but not for treatment of atherosclerosis.[208] In a case questioning whether a physician may use EDTA to treat atherosclerosis, the Fifth Circuit Court of Appeals in *United States v. Evers* looked to legislative intent to conclude "the regulations of the FDA that are now in force do not prevent [a physician] from prescribing for uses not approved by the FDA drugs

---

203. WHITE HOUSE COMM'N, *supra* note 4, at 63.

204. *Id.*

205. *Id.* at 75.

206. *See* Tim Cramm et al., *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 745-46 (2002).

207. POLANYI, *supra* note 64, at 69. Polanyi describes the potential role of politics in scientific decision-making:

> [T]he public . . . [generally] accepts, or rejects, the opinion 'of science' or the teachings 'of religion' in their entirety without trying to discriminate between the views of different scientists or of different theologians. Yet occasionally they will intervene even in the internal question of one or the other great domain of the mind, particularly where an altogether new point of view is in rebellion against the ruling orthodoxy. . . . The rise to scientific recognition in our own time of psycho-analysis, manipulative surgery, and most recently of telepathy, owe much to popular support. . . .

*Id.* More pointedly, "[i]n fields where scientific criteria allow wide latitude of judgment (e.g. medicine, agricultural science, or psychology) the crank who can enlist political support will find easy openings for establishing himself in a scientific position." *Id.* at 79.

208. United States v. Evers, 643 F.2d 1043, 1047 (5th Cir. 1981).

which have been approved by the FDA for some other purpose."[209] Rather than addressing the case from a scientifically justified consumer protection standpoint,[210] the court looked to legislative history and adopted Congress' rationale, approaching the case from the policy standpoint of not interfering with the physician-patient relationship:

> [T]here were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.[211]

Thus, a physician may use FDA approved medications in an unapproved manner at the physician's (and perhaps patient's) peril, with an understanding that authorization to use the medications in an unapproved manner does not immunize the physician from malpractice claims if the standard of care is violated.

Similarly, in *State Board of Medical Examiners v. Rogers*, the Florida Supreme Court held that a physician may use EDTA for chelation therapy, reasoning that the restraint of the use of EDTA "was an arbitrary and unreasonable exercise of the state's police power."[212] The court overruled the Board of Medical Examiners, which had found that EDTA "chelation therapy can best be classified as investigational, that it more likely can be classified as quackery, and that its use outside a controlled environment such as a research institute fails to conform to acceptable and prevailing medical practice."[213]

In 1989, the FDA listed EDTA treatment as one of the nation's "Top 10 Health Frauds," lending additional credence to the medical boards' stance in *Evers* and *Rogers*.[214] Nevertheless, in the case of EDTA, non-malpractice common law and statutory construction have permitted broader use than had been considered within the standard of care as determined by the medical profession and, later, the FDA itself. Even with the FDA's opinion backing them,

---

209. *Id.* at 1049.

210. *Id.* at 1048. At Dr. Evers' trial, "[t]hree physicians testified that several deaths had been caused by Dr. Evers' use of chelation therapy, and the court concluded that the doctor's practices were indeed a serious danger." *Id.* at 1045.

211. *Id.* at 1048 (quoting letter from the acting director of the Office of Scientific Evaluation of the Bureau of Drugs (March 7, 1974)).

212. State Bd. of Med. Exam'rs v. Rogers, 387 So. 2d 937, 937, 940 (Fla. 1980). This case illustrates the danger of applying the analysis that one would expect to be applicable in a medical malpractice case to licensing or pharmaceutical use cases.

213. *Id.* at 939.

214. *Top 10 Health Frauds*, 23 FDA CONSUMER 29, 31 (Oct. 1989).

medical boards may remain unable to enforce a standard of care with respect to EDTA so long as EDTA has approved uses. While violating a specific statutory prohibition creates a reasonable inference of a violation of the standard of care, failing to limit treatments to those approved by the FDA and medical licensing boards creates a weaker inference.

## V. CONCLUSION

Malpractice claims involving CAM challenge the use of custom in determining standard of care. Requiring adherence to custom has the theoretical effect of making the practice of CAM a per se breach of the standard of care. Patient autonomy, preservation of valuable cultural practices, and existence of other avenues for consumer protection present compelling arguments that the inevitability of this result is undesirable and that an alternative to custom should be sought. Whatever the standard of care formulation, a decision to approve CAM practices necessarily entails a decision to reject a purely scientific basis for treatment.

The reasonable and prudent physician standard offers an alternative to custom without the fatal flaws of other standard of care formulations. The standard is also consistent with the trend of state tort law toward application of a professional reasonableness standard rather than a customary practice standard.

Because standard of care may differ depending on whether reasonableness is defined from the perspective of biomedicine or CAM, any offering of CAM should be accompanied by augmented informed consent that expressly documents whether treatment will be biomedical or CAM, that sets the expectations of both physician and patient, and that identifies risks of obtaining and foregoing both CAM and biomedical treatments. Absent informed consent, the reasonable treatment should be presumed to be biomedical, for without justification, there would be no reason to offer a treatment that has not been proven safe and efficacious. Informed consent for CAM should be more in the nature of a contract than typical informed consent, and should be crucial to definition of the physician's duty. Because such a contract is unlikely to be boilerplate, the reasonableness standard based on duties defined in this contract would be patient-specific.

The boundaries of permissible care can be defined by legislatures and may co-exist with a reasonableness standard. This approach offers the advantages of certainty and origin in a less adversarial environment than the courts, but has the disadvantages of slow response to innovation and a high likelihood of state to state variability. Adoption of the Model Guidelines and other measures to increase uniformity in education and licensure requirements can remedy these issues. States may also protect consumers by adoption of informed consent templates or guidelines for CAM practices.