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Complementary and Alternative Medicine: Longstanding Legal Obstacles to Cutting Edge Treatment

Michael Ruggio and Lauren DeSantis-Then

ABSTRACT: As growing numbers of Americans try complementary and alternative medicine, or CAM, treatments, such as acupuncture, chiropractic, and herbal remedies, the healthcare legal and regulatory structures face changes, particularly relating to the concept of medical integration, or using CAM therapies in conjunction with conventional medicine. First, this article examines the desirability of medical integration, documenting the popularity and growth of CAM. Second, the article discusses the legal barriers to CAM integration, ranging from professional discipline by state medical boards for unauthorized practice of medicine to liability risks and the need for third-party coverage of CAM treatments. Finally, the article concludes that although medical integration is a desirable goal, many changes in the healthcare legal and regulatory system will need to occur to facilitate that transition.

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LEGAL OBSTACLES TO CAM

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Introduction

One of the fastest growing fields in America is complementary and alternative medicine (CAM) therapy. As the number of patient visits to conventional medical practitioners has declined, the number of CAM visits has risen dramatically since 1990, when scholarly attention focused upon the field.¹ With many laws regulating the healthcare profession nearing their centennial, changes are occurring.² These longstanding laws have inhibited the growth of CAM treatments, while failing to protect the health and medical interests of patients effectively. Through litigation and legislation, however, progress is being made. Assessing where healthcare regulation has succeeded and failed is critical to identifying the major legal hurdles to integrative medical practice, and to developing a model of successful CAM regulation. This article explores the definition of complementary and alternative medicine and its rise as a popular source of health treatment, then presents the major arguments for and against the integration of CAM into conventional medicine. Next, the article will examine the legal obstacles facing CAM practitioners and patients:

- the licensing implications of CAM, including the risk of professional discipline by state medical boards;
- the risk of malpractice and informed consent suits;
- the need for a CAM-specific standard of care;

- the need for an extension of the current duties to inform and refer to include CAM practices; and
- the growing need for third-party reimbursement for proven and licensed CAM treatments.

Finally, the article briefly reviews the mechanisms for, and benefits of, CAM integration into conventional medicine.

**What Is CAM?**

CAM comprises a group of diverse medical and healthcare systems, practices, and products that are not presently considered part of conventional medicine. As the terms are used by the National Center for Complementary and Alternative Medicine (NCCAM), CAM therapies used in lieu of conventional Western medicine are considered alternative medicine. When used in addition to conventional medicine, CAM therapies are considered complementary medicine, and the combination of conventional and complementary medicine is integrative medicine.

NCCAM classifies CAM modalities into five categories:

1. alternative medical systems;
2. mind-body interventions;
3. biologically based treatments;
4. manipulative and body-based methods; and
5. energy therapies.

Understanding what CAM is requires first understanding what it is not: CAM is not conventional Western medicine, sometimes called biomedicine or orthodox medicine. NCCAM defines conventional medicine as “[m]edicine as practiced by holders of M.D. (doctor of medicine, or allopathic medicine) or D.O. (doctor of osteopathy) degrees and by their allied health professionals such as physical therapists, psychologists, and registered nurses.” CAM thus includes the set of medical approaches falling outside of the M.D./D.O. professional sphere, a definition that serves as something of a catchall, including everything from nasal irrigation and chiropractic to shamanism and apitherapy, or “the use of bee products from the European honey bee.

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4 See id. The site offers a helpful example: Aromatherapy, when used “to help lessen a patient’s discomfort following surgery,” is an example of complementary medicine. Aromatherapy and surgery together would be considered integrative medicine.
5 NAT’L CT R. FOR COMPL EMe N TAr y & Al t e r nAt i v e Me d., exP An di n g Ho r i z o n s o f HeAl t H C Ar e: fi v e-yeAr st rAt e g iC PlAn 2001–2005 (2000), available at http://nccam.nih.gov/about/plans/fiveyear/fiveyear.pdf.
6 NCCAM, What is CAM?
to promote health and healing.” The definition is fluid; as the field of conventional medicine grows and changes, “some therapies deemed CAM today may eventually be recognized as conventional, based on evidence over time.”

Many physicians, as well as a great many CAM practitioners, desire a single healthcare system, rather than separate conventional and complementary/alternative systems. A single system would incorporate the best of CAM into conventional medicine to ensure that patients get consistent high-quality care and that conventional medicine and CAM work alongside, rather than against, one another. There are two approaches to such integration. The first is cooperation, where physicians provide referrals to CAM practitioners in appropriate circumstances. For instance, primary care physicians who refer patients to chiropractors are integrating through cooperation. The second form is cooption, where a physician personally performs CAM. For example, physicians who perform spinal manipulations upon patients are operating within the cooption form of medical integration.

The Growth of CAM

Although the terms “alternative” and “complementary” to describe CAM might suggest a medical fad, the history and growth of CAM suggest otherwise. Many CAM modalities are much older than conventional medicine treatments. For example, herbal therapy and touch-based therapy (including massage and acupuncture) are two of the most ancient forms of medical care. Many traditional Chinese medical remedies predate modern conventional medicine by millennia, as do many faith-based remedies. At the start of the Revolutionary

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War, there were fewer than 4,000 physicians in the thirteen colonies, and no more than forty of these physicians had any formal training in medicine. What we now call conventional medicine was itself once the novel alternative.

CAM is a widely used and rapidly expanding field of medicine. A survey conducted by NCCAM in 2008 found that thirty-eight percent of U.S. adults use some form of alternative remedy. Another survey, headed by Dr. David Eisenberg, director of Harvard Medical School’s Osher Institute, found that between 1990 and 1997, the number of visits to CAM providers rose nearly fifty percent, from approximately 427 million to 629 million visits, while use of herbal remedies rose 380 percent. By way of comparison, there were 387 million visits to primary care physicians in 1990, and that number actually shrank slightly over the same seven-year span, to 385 million. CAM represents “a major and growing proportion of health care as a whole,” with estimates suggesting that at least a third of consumer demand for healthcare services is directed at CAM. The prospect for long-term growth is promising, as evidence for first-time users suggests that “the younger you are, the more likely you are to use some form of alternative care.” Because the heaviest users of CAM are in their early fifties, these young first-time users are likely to create increased demand for CAM treatments as they age.

Although CAM visits per year outnumber primary care visits, the cost difference between CAM and conventional medicine is stark—a fact of considerable import given the rapidly rising costs of healthcare in many parts of the United States. Eisenberg’s study on CAM found that

15 Eisenberg et al., Trends, at 1572.
although between 21.2 and 32.7 billion dollars were spent on CAM in 1997, this constituted only 1.9 to 3.0 percent of total healthcare expenditures for the year.\textsuperscript{20} Although insurers fear that increased coverage of CAM will lead to skyrocketing costs, empirical analysis of spending in Washington State, where CAM inclusion is mandated, suggests that this will not be the case.\textsuperscript{21} A 2004 study of three of the state’s major insurers found that while all three had seen CAM utilization increase (especially for non-chiropractic services), “CAM expenditures are still such a small percentage of the premium dollar that the increase has not yet induced these companies to take any draconian actions.”\textsuperscript{22} In 2002, six years after mandated coverage began statewide, CAM use in Washington accounted for only 2.9 percent of private health insurance expenditures, which fell within the national range estimated by Eisenberg in 1997.\textsuperscript{23}

CAM may have large, unseen cost-saving potential. Treating patients with relatively inexpensive herbal remedies, acupuncture, and dietary supplements can save insurers money. For example, “researchers in two randomized trials found that pre-term babies who received massage and comforting touch had greater weight gain and were discharged earlier than babies who did not receive this care,” leading to significantly shorter stays, and an average savings of more than $10,000 per infant.\textsuperscript{24} Contrary to the concerns expressed by insurers, available data suggests that CAM integration is a popular and relatively inexpensive goal, and may have the potential to help alleviate the rising healthcare costs plaguing the industry as a whole.

**Recent milestones**

There are signs that policymakers and many conventional medical practitioners have begun to take CAM, and the promise of medical integration, more seriously than in the past. In 1992, Congress responded to the growing interest in CAM by creating the Office of Alternative Medicine (OAM).\textsuperscript{25} Starting with a budget of $2 million, the OAM grew into NCCAM, with a 2008 budget of $121.5 million.\textsuperscript{26}

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\textsuperscript{21} Id. at 401–402.


\textsuperscript{23} Lafferty et al., *Insurance Coverage*, at 402.

\textsuperscript{24} WHITE HOUSE FINAL REPORT, at 110–11.

\textsuperscript{25} COMM. ON THE USE OF COMPLEMENTARY & ALTERNATIVE MEDICINE BY THE AMERICAN PUBLIC, COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE UNITED STATES 20 (Nat’l Acads. Press 2005).

\textsuperscript{26} Nat’l Ctr. for Complementary & Alternative Med. (NCCAM), NCCAM Funding: Appropriations History, http://nccam.nih.gov/about/budget/appropriations.htm (last visited Apr. 21, 2009). While the 2008 NCCAM budget was sixty times larger than the 1993 budget,
States have responded as well, acknowledging the legitimacy of some forms of CAM by imposing educational and licensing requirements for CAM providers like acupuncturists and chiropractors, among others.27 Every state now has licensing requirements for chiropractors, and “about 85% of states license some of the other CAM providers such as naturopathic physicians, acupuncturists, or massage therapists.”28 Thirty-nine states currently license massage therapists,29 and nine of the eleven remaining states have introduced or are drafting legislation to regulate the practice.30

When Eisenberg published his groundbreaking 1993 study, the climate was one in which CAM “was at best ignored and at worst fought by the medical establishment.”31 Yet after the study showed that “34 percent of all U.S. adults had received at least one unconventional therapy in 1990,” and that “an estimated 15 million were risking adverse interactions between supplements and prescription drugs,” conventional medical institutions around the country were forced to respond.32 Recent years have seen increasing acclimation towards CAM by conventional medical institutions. A growing number of “premier academic medical centers, including Columbia, Duke, and Harvard, now have centers dedicated to the study of such treatment modalities as acupuncture, herbal supplements, tai chi, moxibustion, and Ayurvedic medicine,” and conduct clinical trials by trained physicians.33 Hospitals like Beth Israel’s Center for Health and Healing “have begun to provide patients with CAM modalities and to include CAM therapies within the conventional medical setting.”34 Even the American College of Physicians “has started to offer lectures on CAM during its Annual Convention.”35

Medical scholarship surrounding CAM is flourishing as well. Over the nine-year span from 1987 to 1996, “the percentage of articles in

NCCAM remains less than one-half of one percent of the National Institute of Health’s annual budget.

28 Lafferty et al., Insurance Coverage, at 397.
34 Lee, Attorney Professional Responsibility, at 883.
35 Knoll, The Reawakening, at 357.
mainstream medical journals about CAM reporting on clinical trials went from 2 to 10 percent." 36 CAM was the exclusive focus of an issue of the Journal of the American Medical Association, which was dedicated to reports of clinical investigations of CAM treatments. 37 In addition, there are a number of journals with a sole focus on CAM, including the Journal of Alternative and Complementary Medicine: Research on Paradigm, Practice, and Policy, Alternative Therapies in Health and Medicine, and Alternative Health Practitioner: The Journal of Complementary and Natural Care. 38 As these conventional and specialty publications indicate, scholarly research on CAM has intensified in recent years.

Perhaps the most important shift has come from the American Medical Association (AMA). The AMA has a record of intense opposition to nonphysician medical practitioners. Although osteopathy is now considered conventional medicine, it is instructive to remember that as recently as the 1960s, “the AMA considered osteopathy to be quackery and the association of its members with osteopathic physicians to be unethical behavior.” 39 A similar attitude toward chiropractic continued into the 1980s, 40 and the AMA was unafraid to use its considerable clout against competitors. Yet, “physicians are now permitted by the American Medical Association to refer patients to chiropractors.” 41 Although most non-chiropractic CAM treatments have enjoyed comparatively less public support, and have faced stronger opposition from the AMA, many such treatments “have begun to show up in the American Medical Association’s vast directory of billable procedures.” 42 In June 2006, the AMA passed Substitute Resolution 306, which resolved to “promote awareness among medical students and physicians of the wide use of complementary and alternative medicine, including its benefits, risks, and evidence of efficacy or lack thereof.” 43 Significantly, Resolution 306 had been proposed by the medical student section, and in its original form contained stronger language about the need to incorporate CAM “in medical education as well as continuing medical education curricula,” suggesting a possible generational gap among physicians. 44

37 Sade, Complementary and Alternative Medicine, at 183.
39 Knoll, The Reawakening, at 351.
40 Id.
41 James A. Bulen, Jr., Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed Consent to Treatment, 24 J. LEGAL MED. 331, n.6 (2003) [hereinafter Bulen, Informed Consent].
42 Cowley, Integrative Care.
With respect to osteopathy and chiropractic, the relaxation of the AMA’s opposition was a reflection of growing public acceptance of those fields. In both cases, this relaxation led to increased medical integration. The changes now being observed regarding CAM suggest that something similar is taking place again, and that “the high level of use of complementary and alternative medicine and its important contribution to health services means that it is economically and politically unrealistic to now prohibit or further limit the practice of complementary and alternative medicine.”

If history is any guide, this seems to signal increased institutional acceptance and medical integration of CAM modalities.

The role of efficaciousness

The growth of CAM is only promising if CAM is beneficial. If CAM were a medical fad—inefficient at treating patients—its growth would be a threat to be opposed. The critical determining factor, therefore, in the success or failure of CAM is an evaluation of efficaciousness. Unfortunately, such proof is often lacking in the field of complementary and alternative medicine. Numerous factors are responsible for this dearth of evidence, such as the fear of professional stigmatization that until recently prevented many researchers from investigating in the field, and unique barriers to creating reliable testing mechanisms. For example, it is impossible to perform double-blind testing with massage and acupuncture because a practitioner has the technical expertise to know whether he or she is administering an actual or sham treatment. A great number of CAM therapies rely in no small part upon interpersonal interactions between the therapist and the patient, which are hard to duplicate in an objective test setting. Finally, many CAM treatments rely on mechanisms not tested by conventional medicine. For example, Chinese herbology tends to rely on blended herbs, while Western medical tests are geared towards testing single medications. The combination of herbs known as huanglian (Coptis chinensis), for example, has been shown to kill cancer cells, but only as a blend

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46 Vlasis, The Doctor is Out, at 498 (as “recently as the mid-1990s, most academics would not conduct research in alternative medicine for fear of being shunned by their colleagues.”).
48 Id. (“Integrative practitioners value their individualistic approach to patient treatment, and do not want this essential quality to be lost in order to satisfy inflexible research methodology”).
The Growth of CAM

of thirty-seven compounds. Tested separately, the compounds do not behave the same way.49

Despite these hurdles, an increasing number of studies show which CAM treatments are demonstrably effective. “[T]housands of RCTs [randomized controlled clinical trials] now suggest that some CAM treatments offer benefits comparable to conventional medicine.”50 The results of some five thousand of these RCTs can be found in the Cochrane Collaboration, “an international attempt to develop evidence-based research about many treatments,” both conventional and CAM.51 The results are promising. For example, for the treatment of migraine prophylaxis, “acupuncture was associated with slightly better outcomes and fewer adverse effects” than a prophylactic drug treatment previously proven effective.52 As the White House Commission on Complementary and Alternative Medicine notes:

[A] number of Cochrane Collaboration systematic reviews of this worldwide research literature have identified the potential benefits of CAM and related approaches and products for a small number of chronic conditions, including: [l]ow-fat or modified fat diets for preventing cardiovascular disease, [a]cupuncture in the management of low back pain and recurrent headaches, [s]t John’s Wort for treating mild to moderate depression, [h]erbal and glucosamine therapy for treating osteoarthritis, and [n]utritional supplements for several neurological conditions.53

A 2004 study of Cochrane reviews found efficaciousness data for CAM comparable to that found for conventional medicine in a 1998 study. Although more CAM treatments (56.6% for CAM versus 21.3% for conventional medicine) were determined to have insufficient evidence of effect, “fewer reviews of CAM [classified] the therapy as harmful (8.1% for conventional medicine versus 0.69% for CAM) or as having no effect (20.0% for conventional medicine versus 4.8% for

50 Bulen, Informed Consent, at 358.
53 WHITE HOUSE FINAL REPORT, at 19.
The “percentage of therapies classified as having positive or a possibly positive effect were approximately equal for both CAM and conventional medical therapies (41.3% for conventional medicine versus 38.4% for CAM).”\textsuperscript{54} Other research has shown that CAM treatments work best in conjunction with conventional medicine. The National Institutes of Health (NIH), for example, has long since concluded that acupuncture is safe and reliable for the treatment of chemotherapy-related nausea.\textsuperscript{56} Although more research is needed, particularly regarding cost-effectiveness and longer-term effects, current research provides enough indicia to suggest specific CAM treatments, like acupuncture for migraine prophylaxis, worth integrating.

**Opposition to Integration**

The law ought to favor medical effectiveness over ineffectiveness, cost-effectiveness over waste, and safe treatments over unsafe ones. The reasons for this are self-evident, and undergird the principles behind governmental regulation of healthcare. Yet the law consistently favors conventional medicine, even in its most costly, dangerous and inefficient forms, over non-conventional treatments, regardless of cost, safety, and effectiveness. Opposition to medical integration of CAM has generally coalesced around four major points:

1. There is a lack of proven effectiveness for many or most CAM modalities.
2. Perceived effectiveness is the result of the placebo effect, rather than a CAM therapy’s intrinsic benefits.
3. Finite healthcare dollars would be better spent on modalities that are more effective.
4. CAM endangers the patient’s health, either actively (due to the effects of the treatment itself, including drug interactions) or passively (because the opportunity cost of using alternative care is that the patient may forgo effective conventional medicine).

Any one of these arguments risks undermining conventional medicine along with CAM. At least one commentator has contended that holding CAM and conventional medicine to the same standard “appears


\textsuperscript{55} Id.

to bode far worse for [conventional] medicine than for CAM.\textsuperscript{57} CAM practitioners “legitimately charge that alternative medicine is held to a higher standard than much of traditional medical practice.”\textsuperscript{58} The following examination of each argument illustrates the double standard.

### Efficacy

Perhaps the most oft-repeated refrain against CAM is that the efficacy of many CAM treatments remains unproven. For example, Dr. Schneiderman has argued that “any activity—if it calls itself medicine—whether it uses the term alternative, complementary, or integrated medicine, should be expected to adhere to [...] standards of evidence for efficacy.”\textsuperscript{59} Within the broad range of available CAM modalities, there are great variances in safety and efficacy, as well as variations in clinical support. It is in the interest of CAM practitioners as well as patients to ensure the best treatments are favored over less desirable alternatives. The demands of patient health create an impetus for more medical testing, particularly of commonly used treatments, and CAM should be no exception to this trend. However, conventional medicine itself frequently fails to meet these standards. The “absence of double blind studies does not render CAM any less effective than many conventional medical treatments,” and “[t]o the extent that uncertainty remains about the efficacy of various CAM modalities, it places them right alongside the many conventional medical treatments that also remain unproven.”\textsuperscript{60} In addition to a large number of conventional treatments performed for years before scientific review proved their validity, many conventional treatments have been discovered to be useless or dangerous when finally subjected to scrutiny. To provide a few examples, recent research suggests that “mammograms may not save lives as the public was previously led to believe, hormone replacement therapy for post-menopausal women may not only be ineffective, but perhaps dangerous, and arthroscopic knee surgery for arthritis may be useless.”\textsuperscript{61} In the case of arthroscopic debridement or lavage for osteoarthritis of the knee, “a gold-standard randomized, double-blind, placebo-controlled trial showed that this procedure is no better than a sham surgery in which no surgical invasion of the knee

\textsuperscript{57} E. Haavi Morreim, \textit{A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science}, 31 J.L. MED. \\ & ETHCS 222, 228 (2003) [hereinafter Morreim, \textit{A Dose of Our Own Medicine}].

\textsuperscript{58} Kathleen M. Boozang, \textit{Western Medicine Opens the Door to Alternative Medicine}, 24 AM. J.L. \\ & MED. 185, 208 (1998).

\textsuperscript{59} Schneiderman, \textit{The (Alternative) Medicalization of Life}, at 191.

\textsuperscript{60} Atwell, \textit{Mainstreaming}, at 610.

\textsuperscript{61} Atwell, \textit{Mainstreaming}, at 593.
took place,” despite 650,000 surgeries annually.\(^{62}\) In comparison to the majority of CAM treatments, these ineffective conventional treatments often were significantly more costly and physically invasive.

**Placebo effect**

Even though double-blind clinical trials to prove the effectiveness of many CAM treatments do not yet exist, anecdotal evidence suggests that patients believe they have been helped. Satisfaction with CAM is said to result from the placebo effect, rather than the effectiveness of the treatment in question.\(^{63}\) There is almost certainly an element of truth in this argument, just as there is with conventional medicine. Evidence of placebo effects can be found “in a wide range of mainstream treatments for ailments with objectively measured harms, from treatments for ulcers and high cholesterol to interventions that affect blood pressure and mental acuity.”\(^{64}\) The placebo effect seems to be caused either by expectancy, that is, “that bodily changes occur to the extent that the subject expects them to,” or conditioning, “that bodily changes occur when the subject is exposed to a stimulus that has been linked in the past to active processes that produce the change,” or some combination of both.\(^{65}\) This phenomenon is as true in CAM as in any other field of medicine.

Yet while CAM critics allege use of the placebo effect to promote false belief in treatments’ effectiveness, a nationwide survey of medical doctors has shown that “46 percent to 58 percent of U.S. physicians admitted using placebos regularly.”\(^{66}\) Of these, “[o]nly 5 percent said they tell patients explicitly that they are doing so,” despite a 2006 statement by the AMA denouncing this omission.\(^{67}\) Disturbingly,

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62 Morreim, A Dose of Our Own Medicine, at 223 (citing D.T. Felson & J. Buckwalter, Debridement and Lavage for Osteoarthritis of the Knee, 347 NEW ENG. J. MED. 132–33 (2002)).

63 Schneiderman suggests this may be true of acupuncture. See, e.g., Schneiderman, The (Alternative) Medicalization of Life, at 195.


67 Graham, Mind over Body. Additionally, the American Academy for Pain Management (AAPM) holds that placebo use for the treatment of pain outside the context of research settings is “usually considered unjustifiable, both for ethical and clinical reasons.” AM. ACADEMY FOR PAIN MGMT. (AAPM), ETHICS CHARTER 17 (2007), available at www.painmed.org/pdf/1207ethicscharter.pdf.
“[a]mong physicians who prescribed placebos, few said they used inert treatments such as saline injections or sugar pills,” opting instead for active agents such as “over-the-counter painkillers, vitamins, sedatives and antibiotics.” The dangers of these active placebos are seen in the growing frequency and potency of antibiotic-resistant organisms. Moreover, there are an estimated 5.2 million Americans who abuse painkillers annually, as well as an estimated 106,000 deaths annually from “nonerror, adverse effects of medications.” Whatever placebo effect may arise from the human contact that acupuncture provides is almost certainly of less concern than the widespread practice of providing drugs known to be ineffective and potentially dangerous.

Wasted funds

Proponents of CAM generally argue that as long as a particular CAM treatment is safe, no real damage comes from its use, even if it turns out to be ineffective, or effective only due to the placebo effect. Opponents counter that tens of billions of dollars are spent annually on CAM, no trifling sum, particularly if the treatments turn out not to work. CAM, along with conventional medicine, would benefit from further testing. For a great many treatments and techniques, further research is badly needed. Nonetheless, a great many CAM therapies are inexpensive, particularly in comparison with conventional medical alternatives. Conventional medicine also results in more waste, much of which comes in the form of regional practice pattern differences. On the basis of an analysis of government Medicare data from 1992 to 2006, the Dartmouth Atlas Project identified “considerable variation among regions” in the growth rates of Medicare spending, and found it “highly unlikely that these differences in growth could be explained by differences in health.” For example, while San Francisco and East Long Island, New York “started out with nearly identical per capita spending” in 1992, by 2006 “per capita spending in East Long Island

68 NCCAM, Half of Surveyed Physicians Use Placebo Treatments for Patients; Graham, Mind over Body.
69 Morreim, A Dose of Our Own Medicine, at 222 (“Overuse can be seen in the proliferation of antibiotics, which have been used with such unnecessary frequency and potency that resistant organisms are increasingly a problem”).
71 Sade, Complementary and Alternative Medicine, at 187. But see Lior J. Strahilevitz, Controlling the Costs of Alternative Medicine, 28 SW. U. L. REV. 543, 546 (arguing that “as access to alternative modalities, such as acupuncture, is greatly expanded in the coming years, alternative health care overutilization is likely to develop into an expensive problem”).
73 Id. at 849–50.
was $2,500 more than in San Francisco—which translates into about $1 billion in additional annual Medicare spending from this region alone.\footnote{Id. at 849.}  

Perhaps most surprisingly, “evidence suggests that the quality of care and health outcomes are better in lower-spending regions and that there have been no greater gains in survival in regions with greater spending growth.”\footnote{Id. at 850.} Although these regional variances cost billions annually, they fail to produce a discernable benefit. At least some of these variances in regional practice constitute “unnecessary care and thereby additional wasted money,” leading to “excess spending up to $40 billion per year,” greater than the total cost of CAM treatments.\footnote{Morreim, A Dose of Our Own Medicine, at 228.} All medical practitioners should strive to ensure that patient spending is targeted towards effective treatment. This is particularly true for CAM, because much of the spending is paid out-of-pocket. Yet the argument that CAM is exceptional in its potential to waste funds is unsupported by the available data.

### Medical risks

The final argument against CAM is that it is potentially medically risky. As with the previous arguments, there is an element of truth. Some CAM treatments certainly have potential medical risks. However, most tend to be fairly benign, and the majority involve minimally invasive or non-invasive procedures.\footnote{Id. at 227.} The review of RCTs found in the Cochrane Library suggests that conventional medicine is, in fact, much more dangerous than its CAM counterpart.\footnote{Boozang, Potential Pitfalls.} Even for the more physically invasive forms of CAM, like chiropractic, the “available data indicate the risk seems limited.”\footnote{Morreim, A Dose of Our Own Medicine, at 227.} In comparison, a “substantial body of evidence points to [conventional] medical errors as a leading cause of death and injury,” along with serious risks from side-effects and complications.\footnote{Inst. of Med., To Err Is Human: Building a Safer Health System 26 (L. Kohn, J. Corrigan, and M. Donaldson, eds., Nat’l Acad. Press 1999), available at www.nap.edu/openbook.php?record_id=9728&page=26 (estimating the number of Americans who die in hospitals as a result of medical errors as “at least 44,000 and perhaps as many as 98,000” annually, based upon two studies of “large samples of hospital admissions”).} Mistakes in hospitals have been estimated to cost the lives of “at least 44,000 and perhaps as many as 98,000” Americans annually, a death toll higher than that of AIDS.\footnote{Morreim, A Dose of Our Own Medicine, at 227.} In addition, an estimated 106,000 people die annually from non-error, adverse drug
Benefits of Integration

Integration of CAM would offer many unique benefits, particularly in the treatment of chronic pain. “[M]any conditions, especially chronic ones, remain poorly responsive to biomedical treatments.”84 A 2003 survey found that “roughly three-quarters of the public feels that it is somewhat difficult or very difficult to get adequate care for a chronic condition from either a primary care physician or a specialist, an opinion shared by over half of physicians and the vast majority of policy makers.”85 Fortunately, “most CAM is used for problems such as chronic illness or chronic pain, for which conventional medicine sometimes has rather little to offer.”86 Many CAM modalities seem to be effective for treating chronic pain, a fact that NIH recognized over a decade ago when it found “strong evidence” that a “number of well-defined behavioral and relaxation interventions now exist and are effective in the treatment of chronic pain.”87 Treatment of chronic pain is not insignificant. “Currently, over 130 million Americans report suffering from chronic conditions,” and the number is on the rise.88 In 2000, “expenditures for their care amounted to 78 percent of all health care costs.”89 This includes “$61 billion in lost productivity” and

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85 Goldstein, Persistence, at 939.
86 Morreim, A Dose of Our Own Medicine, at 230. See also Geoffrey Cowley, Now, “Integrative” Care, NEWSWEEK, Dec. 2, 2002, available at www.newsweek.com/id/66675/output/print [hereinafter Cowley, Integrative Care] (explaining that research shows Chinese traditional medicine to be strongest in areas where Western medicine is weakest—namely, chronic illness.).
88 Goldstein, Persistence, at 939.
89 Id.
much more in medical fees, with treating returning soldiers in upcoming years expected to “add at least $340 billion to the toll.”\textsuperscript{90} Integrating CAM with conventional medicine could save patients and healthcare providers significant sums of money while expanding patient treatment options and alleviating pain.

Medical integration also would benefit the well-being of patients who presently see both conventional physicians and CAM practitioners. Although CAM is a popular and growing field, its growth has occurred almost wholly out of view of conventional medicine. Eighty-nine percent of those who saw an alternative therapist in 1990 did so without the recommendation of their conventional doctor.\textsuperscript{91} Seventy-two percent of CAM users failed to inform their physicians of the alternative treatments they sought, a figure that remained virtually unchanged through 1997.\textsuperscript{92} This failure in communication not only allowed the conventional medical establishment to overlook and undervalue the significance of CAM, it meant “an estimated 15 million [people] were risking adverse interactions between supplements and prescription drugs.”\textsuperscript{93} St. John’s Wort, for example, often is taken as a natural antidepressant, yet can be dangerous with synthetic antidepressants, limiting their effects and increasing the risk of side effects.\textsuperscript{94} A 1996 Australian study determined that, although rare, herbal medicines did pose a risk when mixed with prescription drugs.\textsuperscript{95} Integrating CAM into or alongside conventional medicine would benefit patient safety by increasing physician awareness of the potential risks of interactions.

Integration also would enhance patient health by giving patients the opportunity to receive the best available cost-effective treatment for their particular conditions. The integration of CAM into conventional medicine opens doors for expanded treatment options. As medically trained physicians interact with CAM treatments, new pos-


\textsuperscript{91} James A. Bulen, Jr., Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed Consent to Treatment, 24 J. LEGAL MED. 331, n.5 (2003) [herein Bulen, \textit{Informed Consent}] (quoting David M. Eisenberg et al., Unconventional Medicine in the United States, 328 \textsc{New Eng. J. Med.} 246, 249 (1993)).


\textsuperscript{93} Cowley, Integrative Care.


sibilities emerge: Knowledge of chiropractic undoubtedly played a role in the advent of spinal manipulation by conventional physicians, and the possibilities that a CAM modality like acupuncture afford conventional medicine are promising. Finally, as long as patients continue to use alternative and complementary medicines, it is incumbent upon physicians to be informed about which CAM modalities, if any, are right for a particular patient, just as it is incumbent upon policymakers to design a regulatory system capable of responding to this medical development.

Legal Obstacles Facing CAM Practitioners and Patients

The existing regulatory structure poses hurdles for both physician and nonphysician practitioners of CAM. Doctors who attempt to integrate CAM into their practices may face malpractice suits if they fail to satisfy legal obligations, such as obtaining informed consent. Meanwhile, nonphysician CAM practitioners may face unauthorized practice of medicine suits if the treatment they prescribe or perform is considered within the scope of practicing medicine. In addition, third-party coverage generally is limited to conventional care, with patients bearing the cost of CAM treatments as insurers try to determine which aspects of an integrated practice fall sufficiently within conventional medicine to be covered by insurance. Physicians practicing CAM may be denied network participation or deselected. As integrative medicine takes hold in the United States, policymakers, insurers, and physicians must respond appropriately to the new challenges and opportunities it affords. The following list of legal hurdles is by no means exhaustive, but establishes the topography of the legal obstacles facing integrative medical practitioners.

Professional licensing of CAM practitioners

States tend to have broad medical licensing statutes that “provide a generalized definition of the profession in question, and do not spell out its practice boundaries.” This broad language “protect[s] medical doctors from competing with other health care providers except to the limited extent that the other health care providers are statutorily protected by their own scope of practice provisions.” The laws’ vagueness leaves statutory enforcement dependent upon courts. The results have

96 Cf. WHITE HOUSE FINAL REPORT, at 19.
99 Atwell, Mainstreaming, at 622.
varied extremely. Unfortunately, because “legislatures often broadly define the practice of medicine, CAM practitioners who practice at the limits of their scope of practice, but within their professional paradigm, may run afoul of the law and be charged with the unauthorized practice of medicine.”\textsuperscript{100} In an example from the authors’ practice, a client was investigated by the California Medical Board for doing Med-X training with clients.\textsuperscript{101} The Board argued that this constituted physical therapy that could only be performed by a licensed physical therapist. Non-licensed trainers who offer personal training in a licensed physical therapy facility walk a fine line.\textsuperscript{102} “Scope of practice provisions for non-physicians are narrowly tailored,” and even within that narrow tailoring, “the ambiguity and overlap in scope of practice statutes sometimes results in challenges to one’s practice.”\textsuperscript{103}

Unauthorized practice of medicine suits “can bring penalties of up to a $5,000 fine and 6 years imprisonment,” and have been brought “at the instigation of physicians against nonphysician practitioners such as chiropractors who give physical exams or nurse practitioners who provide routine breast and pelvic examinations.”\textsuperscript{104} Medical professional statutes exist “on the purported ground that licensure protects the uninformed public against incompetence or dishonesty, but invariably with the consequence that members of the licensed group become protected against competition.”\textsuperscript{105} This combination of broad statutory language, medical boards eager to bring actions against CAM practitioners, and severe penalties can leave nonphysician CAM practitioners on unclear footing in the absence of specific CAM medical licenses.\textsuperscript{106} As a result, these medical licensing laws constitute “the main barrier to expanded practice by alternative providers.”\textsuperscript{107} Courts must balance the legitimate need to

\begin{thebibliography}{9}
\bibitem{100} Knoll, \textit{The Reawakening}, at 364.
\bibitem{101} MedX-Therapy stabilizes and strengthens the entire spinal column by training specific movements on specialized exercise machines.
\bibitem{102} \textit{CAL. CODE} § 1399.28 (2007), Citations for Unlicensed Practice, states:

The executive officer of the board is authorized to determine when and against whom a citation will be issued and to issue citations containing orders of abatement and fines against persons, partnerships, corporations or associations who are performing or who have performed services for which licensure as a physical therapist or a physical therapist assistant is required under the Physical Therapy Practice Act. Each citation issued shall contain an order of abatement. Where appropriate, the executive officer shall levy a fine for such unlicensed activity in accordance with subdivision (b)(3) of section 125.9 of the code. The provisions of sections 1399.25 and 1399.27 shall apply to the issuance of citations for unlicensed activity under this subsection. The sanction authorized under this section shall be separate from and in addition to any other civil or criminal remedies.
\bibitem{103} Atwell, \textit{Mainstreaming}, at 622.
\bibitem{104} Andrews, \textit{The Shadow Health Care System}, at 1292.
\bibitem{105} \textit{Id.} at 1299 (quoting Walter Gellhorn, \textit{The Abuse of Occupational Licensing}, 44 U. Chi. L. Rev. 6, 11 (1976)).
\bibitem{106} \textit{Cf. id.} at 1300 (providing examples of prosecutions against chiropractors, midwives, acupuncturists, and health food store owners for unauthorized practice of medicine).
\bibitem{107} \textit{Id.} at 1298.
\end{thebibliography}
carefully protect public health against the risk of construing regulatory statutes in a way that inhibits legitimate medical competition.

State legislatures have an important role to play in addressing the problems created by unclear or overly broad statutes. The creation of CAM-specific medical licenses would immunize CAM practitioners from unauthorized practice of medicine suits and create a stable foundation for CAM practice. Many state legislatures have begun to take a more active role in creating a solution to the issue of CAM licensing, but much work remains. Although “all states license chiropractors,” for example, “a significant number of states do not license acupuncturists, despite acupuncture’s proven efficacy.”108 By creating modality-specific licenses for CAM practitioners, states not only protect nonphysician practitioners from unreasonable lawsuits, they also regulate the industry, create legal standards, and increase the likelihood of third-party reimbursement. For example, all thirty-nine states that currently license massage therapists require “at least 500 hours of in-class, supervised training” and mandate that the therapist “pass the National Certification Board of Therapeutic Massage and Bodywork certification exam,” as well as “maintain continuing education credits; and hold malpractice insurance.”109 These requirements are reasonable, particularly compared with the amount of work required for a professional degree, and help to raise the quality of complementary and alternative medicine within the state. Insurers sometimes respond to state licensing by voluntarily expanding coverage to include the licensed CAM practitioners. Conversely, before insurers can be expected to cover a particular CAM treatment, states should license and regulate those CAM practitioners. Finally, statewide licenses make it easier for hospitals to determine the credentials of CAM-practicing job applicants and ensure staffing with qualified practitioners.110

Professional discipline of physicians practicing CAM

Physicians and other providers who practice CAM face the specter of disciplinary actions pursued by state medical boards based on violations of conventional standards of care. These disciplinary actions “have been among the thorniest facing clinicians, particularly M.D.’s, [sic] offering CAM therapies,” in light of the fact that the medical board can largely “define who is subject to its jurisdiction and impinge on other professional definitions,” and its findings are treated with

108 Atwell, Mainstreaming, at 615.
Actions by medical boards bear more on the relationship between medical boards and conventional medical scope of practice than upon any relationship between CAM use and patient safety. CAM providers “have fewer malpractice cases brought against them than physicians.”112 Yet state medical boards often take action against CAM practitioners in the absence of demonstrable harm or risk. Simply practicing CAM is sufficient in many jurisdictions to risk medical board disciplinary actions.

Similarly, the North Carolina Board of Medical Examiners revoked the license of George Guess, M.D., the “only homeopath openly practicing in the State,” on the sole basis that homeopathy “departs from and does not conform to the standards of acceptable and prevailing medical practice in this State.”113 The Board offered to reinstate Guess, but only on the condition that he “renounce homeopathy.”114 The North Carolina Supreme Court deferred to the board, although there “was no evidence that Guess’ homeopathic treatment had ever harmed a patient,” and at least “anecdotal evidence that Guess’ homeopathic remedies had provided relief to several patients who were apparently unable to obtain relief through allopathic medicine.”115 In several cases, “patients provided informed consent and supported the physician before the medical board.”116 New York courts have held, for instance, that “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,” even if that standard creates a per se bar against CAM.117

Fortunately for would-be CAM practitioners, many “legislators have taken notice of the dual deprivation of the rights of patients to choose their health care and the rights of physicians to choose innovative therapies that effectively treat their patients.”118 In response, more than a dozen legislatures have passed what are known as Medical Freedom Acts (MFAs), carving out specific exceptions that prevent state medical boards from imposing disciplinary action upon physicians solely for

113 In re Guess, 393 S.E.2d 833, 835 (N.C. 1990).
115 In re Guess, 393 S.E.2d at 835.
practicing CAM. Alaska passed the first MFA in 1990 to ensure that “the board may not base a finding of professional incompetence solely on the basis that a licensee’s practice is unconventional or experimental in the absence of demonstrable physical harm to a patient.”

Similar laws have been passed by Colorado, Florida, Georgia, Massachusetts, New York, North Carolina, Ohio, Oklahoma, Oregon, Texas, and Washington State. Some state medical boards have sought to argue that CAM providers still must comport to conventional standards of care. Because these standards of care often rely on conventionally accepted practices and methods (see discussion below), this statutory interpretation creates something of a catch-22: Physicians are free to practice complementary and alternative medicine, as long as it is widely accepted by the conventional medical community. To avoid this conundrum, state legislatures should craft specific legislation addressing the standard of care, because “stronger or perhaps more accurate legislation is needed if MDs are truly to have the leeway they seek to provide responsible care that includes alternatives.”

Nevertheless, the passage of an MFA can send a clear signal to state courts that a distinct standard of care is required for determining liability for physicians practicing non-conventional medicine.

Malpractice and informed consent

Doctors who perform traditional CAM functions run at least some risk of malpractice suits. “Within the field of medical malpractice, physicians face liability and licensure loss if they employ treatments that

119 ALASKA STAT. § 08.64.326(a)(8)(A).
124 N.Y. Educ. Law § 6527(4)(e). Additional protections may be found in N.Y. Pub. Health Law § 230(1) and N.Y. Pub. Health Law § 230(10)(a)(ii), providing that “not fewer than two” of the eighteen physicians on the state’s medical board must “dedicate a significant portion of their practice to the use of non-conventional medical treatments.”
132 CAMLAW Blog, State Medical Board Disciplinary Investigations Continue for CAM Use.
133 Knoll, The Reawakening, at 365 (arguing that MFAs are an important first step in establishing that “physicians who utilize CAM techniques are not per se engaged in professional misconduct”).
deviate from professional custom and practice, even if the treatments are effective.\(^{134}\) In *Charell v. Gonzalez*, a New York court held that the “standard for proving negligence in a malpractice case is whether the treatment deviates from accepted medical standards.”\(^{135}\) The court admitted that this may establish negligence per se for CAM, “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,” meaning that “it would seem that no practitioner of alternative medicine could prevail on such a question.”\(^{136}\) Similarly, the Second Circuit Court of Appeals in *Schneider v. Revici* acknowledged as correct the trial court’s statement of the law that “the issue in medical malpractice is not whether a particular treatment is effective but whether that treatment is a deviation from accepted medical practice in the community.”\(^{137}\) Courts typically “look for a lack of general acceptance of medical procedures or a lack of FDA approval of pharmaceuticals to establish liability.”\(^{138}\) Such an interpretation favors the popular over the medically effective. Even a patient healed by a CAM treatment may sue the physician practitioner for medical malpractice.\(^{139}\) Malpractice suits strike at the heart of a physician’s earnings potential, and thus, for many physicians, are an effective deterrent against CAM.

Full disclosure to patients, coupled with documentation on well-designed informed consent forms, creates a legal defense against not only malpractice suits rooted in unmet expectations, but also claims for failure to obtain informed consent for CAM treatments. The general “touchstone for liability based upon lack of informed consent […] is whether the physician fully disclosed information material to a decision to undergo treatment.”\(^{140}\) The use of informed consent ensures patient autonomy and physician medical freedom, while the state fulfills its

\(^{134}\) Bulen, *Informed Consent*, at 335. For case law supporting this proposition, see, e.g., *In re Guess*, 393 S.E.2d 833 (N.C. 1990).


\(^{136}\) *Id.* But see J. Brad Kallmyer, *Note, A Chimera In Every Sense: Standard of Care for Physicians Practicing Complementary and Alternative Medicine*, 2 *Ind. Health L. Rev.* 225, 225 (2005) [hereinafter Kallmyer, *A Chimera In Every Sense*] (“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”).

\(^{137}\) Schneider v. Revici, 817 F.2d 987, 990 (2d. Cir. 1987).

\(^{138}\) Bulen, *Informed Consent*, at 335.


\(^{140}\) Bulen, *Informed Consent*, at 335. See also Schneider, 817 F.2d at 995 (affirming the right of patient choice for CAM treatments). *But see Metzler v. N.Y. State Bd. for Prof’l Med. Conduct*, 503 A.2d 617, 619 (1994) (“it is well settled that a patient’s consent, 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”).
legal duty to provide for safe and effective medical care.141 Doctors who perform or oversee CAM treatments should pay close attention to informed consent, particularly when a CAM treatment is unproven or involves known risks. Physicians should be completely honest with patients about the benefits and risks of each approach to facilitate informed patient choice. Failure to inform patients of the risks and benefits of CAM could render physicians liable under a negligence theory, just as it would for conventional medical treatments.142 Doctors who provide referrals for CAM treatments have much less risk of breaching malpractice standards, as “[l]iability for referral only occurs in the situation where the decision to refer to another practitioner is in itself negligent or the physician is directly supervising that other practitioner.”143 Therefore, doctors who provide referrals are at low risk of malpractice liability. Even when making referrals, however, doctors ought to “inform patients of risks associated with concurrent CAM use, particularly adverse drug events and perioperative complications.”144 Through patient communication and the use of comprehensive informed consent forms, doctors can go a long way towards protecting themselves legally, and their patients medically.

**Standard of care**

The role of the standard of care is to provide “a minimum level of acceptable medical service.”145 The objective portion of this standard is often “generally accepted medical practices.”146 The subjective portion of the standard considers more individualized criteria, such as “the expertise of and means available to the physician-defendant,” as well as the health of the patient.147 Based on varying levels of expertise, including but not limited to medical school, the standard of care reasonably expected of a nonphysician CAM practitioner may vary substantially from that expected of a conventional physician. Determining the appropriate standard for physician CAM practitioners may be far more complex. Specifically, should “the physician who integrates homeopathy be held to the standard of care of the physician or the homeopath?”148 This is of particular concern when the treatment does

141 Kallmyer, A Chimera In Every Sense, at 246.
142 Bulen, Informed Consent, at 331.
143 Knoll, The Reawakening, at 362.
144 Bulen, Informed Consent, at 338.
145 Kallmyer, A Chimera In Every Sense, at 249.
not neatly fall into the category of conventional medicine or homeopathy, but somewhere in between.

A standard of care based upon conventional practice could potentially eviscerate CAM—by definition, CAM falls outside of conventional practice. Holding a physician performing acupuncture to a physician’s standard of care could establish a per se violation of the standard of care, even if it would not for a nonphysician acupuncturist performing the same procedure. To preserve the ability of physicians to engage in medically safe CAM, a new standard must be adopted or created. One approach would be to expand the understanding of “generally accepted medical practices” to include CAM. Specifically, courts could examine whether physician-defendants represented themselves as physicians, CAM practitioners, or integrated medical practitioners, and apply elements of the standard of ordinary skill in that art. A physician practicing acupuncture thus would be held to the acupuncturist standard of care, provided she represented herself as an acupuncturist when providing that particular treatment. Conversely, “a CAM provider claiming to possess advanced medical skill risks subjecting himself not only to ordinary tort claims but also to criminal charges for the unauthorized practice of medicine.” Although this variable standard would be a substantial improvement over the traditional conventional practice standard, it is not without its shortcomings. Determining which aspects of an integrated treatment were performed in persona physician could prove impossible.

Alternately, courts could shift to a more subjective reasonableness standard, as a substantial minority of courts has begun to do. The major drawback to such a standard is that its subjectivity can leave practitioners unclear on their potential for legal liability. This subjectivity also can prove to be something of a strength, however, by allowing a fact-specific inquiry to ensure results that are more equitable. Given the somewhat transitory nature of CAM’s relationship to conventional medicine, this standard should allow courts enough flexibility to separate legitimate unconventional medical practices from charlatanry.

149 Matter of Metzler, 610 N.Y.S.2d at 334.
151 Kallmyer, A Chimera In Every Sense, at 250.
152 Regardless of the standard of care, the doctrine of assumption of risk could create a strong defense for CAM practitioners, physician and nonphysician alike, either through the use of an informed consent form, or through a patient’s actions. E.g., a patient combining conventional medicine with certain alternative treatments after being informed by her or his physician of the dangers of combining the two treatments. Vlasis, The Doctor is Out, at 514.
**Should there be a duty to integrate CAM?**

Where states license CAM modalities, two related duties should arise. The first is a duty to inform. In circumstances where a reasonable patient may elect an alternative course of treatment, a patient should be informed of those alternatives. This is, and ought to be, an integral part of the doctrine of informed consent. Patients who provide consent without an awareness of reasonable alternatives are insufficiently informed to give informed consent. The second is a duty to refer. The duty to refer is an inherent part of the duty of due care, and means “a physician’s duty to act within the standard of care would necessitate referring a patient where the physician cannot provide that standard.” Unfortunately, at present, courts have declined to extend the duty to inform and refer to include CAM treatments, including those with a likelihood of effectiveness comparable to conventional medicine treatments.

Numerous patients have described being told by physicians that conventional treatment offers little or no hope for their condition, particularly devastating news when the prognosis is terminal or involves lifelong chronic pain. In many of these cases, patients report that they remained uninformed of potentially effective CAM treatments targeted at their conditions. This may lead patients to pursue physically invasive options, like surgery for chronic back pain, without considering a less invasive alternative. Other patients may give up hope of seeking a cure and suffer needlessly. Although physicians may have been entirely unaware of CAM treatment possibilities in the past, the injection of information about CAM into medical school courses and conventional medical journals makes this less true than before. Nevertheless, factors persist in deterring even informed physicians from recommending, or even acknowledging, successful CAM treatments. Conventional physicians may be opposed to CAM based on any of the arguments described earlier in this article. As noted, physicians “are increasingly in competition with CAM providers, thus perhaps tainting their recommendation with conflict of interest.” Finally, the legal system systemically discourages such disclosures. Specifically, while legal threats loom against physicians who encourage or administer CAM therapies, “no court has

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153 Knoll, The Reawakening, at n. 244.
154 Id. at 362.
156 E. Haavi Morreim, A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science, 31 J.L. MED. & ETHICS 222 (2003) [herein Morreim, A Dose of Our Own Medicine].
held that a physician has an obligation to refer to a CAM practitioner.”\textsuperscript{157} For risk-averse physicians, the choice is clear.

Regulators might argue that these legal disincentives protect patients from making bad decisions about their own health. At its most basic level, “the policy debate over CAM presents a clash between free market principles and consumer protection.”\textsuperscript{158} The consumers in question generally do not need or desire governmental protection, however. They are seeking information.\textsuperscript{159} A disproportionate number of CAM users are well educated. The most likely CAM users are “50-somethings who have graduate degrees, are relatively well off financially, live in the West and have quit smoking.”\textsuperscript{160} Some “55.4% of those [surveyed] with a masters, doctorate or professional degree used some form of CAM.”\textsuperscript{161} Not only do these patients not require governmental paternalism, but a surprising number also have a greater understanding and background in the field than do regulators. What patients possess in intelligence and capacity for self-determination, however, they often lack in specific information about treatments.

The most appropriate role for government is to ensure that health-care decisions confronting a patient, often some of the most personal decisions an individual can make, are truly the patient’s to make. This can best be accomplished by establishing clear and coherent duties to inform and refer, or more specifically, by extending the existing duties to the realm of CAM. Presently, physicians “have a duty to refer a patient to a specialist when required. Failure to do so would be a deviation from the standard of care, and if that was the proximate cause of injury, liability in medical malpractice.”\textsuperscript{162} Extending this duty to require referral for licensed CAM treatments with proven efficacy would reverse many systemic biases within the regulatory structure, and patients would be the ultimate beneficiaries. As physicians began to give referrals for physical therapists and counselors, for example, patients’ overall health improved.\textsuperscript{163} The medical duty of care should

\textsuperscript{157} Knoll, The Reawakening, at 362.


\textsuperscript{159} Michael S. Goldstein, The Persistence and Resurgence of Medical Pluralism, 29 J. HEALTH POL’Y & L. 925, 934 (2004) (explaining how CAM has grown in the wake of the “various rights movements (civil, women’s, gay, children’s, patient’s, etc.)” with a strong tendency towards self-empowerment) [herein Goldstein, Persistence].


\textsuperscript{162} Knoll, The Reawakening, at 361.

\textsuperscript{163} Cf. Debbie Ehrmann-Feldman et al., Physician Referral to Physical Therapy in a Cohort of Workers Compensated for Low Back Pain, 76 PHYSICAL THERAPY 150–56 (Feb. 1996); Janet
be focused on providing the best available medicine to patients, even when that treatment comes in unusual forms. Medical malpractice claims should be used to penalize those who do something wrong, not those who do something novel.

Conventional medicine, for all of its advantages, has certain limitations. Acknowledging these limitations and informing patients of the available options puts the power back in the hands of the patient. Tricky calculations may arise between medical options: choosing between a high-risk procedure with a greater chance of success, and a less risky, less effective alternative, for example. Doctors are the most qualified to provide the information necessary to make that decision, but the decision must ultimately remain the patient’s. Failure to inform patients of their options, or to explain what those options mean, is a failure in the duty of care owed the patient in a conventional medical context. It is time for courts and policymakers to extend that implicit duty to refer to include effective licensed CAM treatments.

Third-party reimbursement

Perhaps the most important area of institutional opposition to CAM has been third-party reimbursement. As Dr. Mary Hardy of Cedars Sinai Medical Center in Los Angeles has said, “Integrative medicine can be viable in a small practice where patients pay as they go, but it’s still hard to succeed on a larger scale.” The third-party reimbursement system is strongly biased against holistic care, “from Medicare down to the smallest private health plan.” Medicare, for example, “provides very limited coverage for CAM,” as only “manual manipulation by chiropractors for subluxation of the spine and religious nonmedical health care (e.g., Christian Science nursing care) are covered.” Acupuncture is covered by Medicare, but only if provided by a physician, rather than a trained acupuncturist. Because reimbursement is often unavailable, CAM remains “largely limited to those who can afford it,” leaving less economically privileged patients with few or no alternatives.

K. Freburger, An Analysis of the Relationship Between the Utilization of Physical Therapy Services and Outcomes of Care for Patients After Total Hip Arthroplasty, 80 PHYSICAL THERAPY 448–58 (May 2000).

164 Knoll, The Reawakening, at n.244 (citing Keir v. United States, 853 F.2d 398, 413 (M.D. Tenn. 1988)).


166 Boozang, Potential Pitfalls.

167 Boozang, Potential Pitfalls.

to conventional care. In a survey conducted nationwide in 1997 and 1998, seventy-two percent of non-chiropractic CAM visits were paid for out of pocket. Although insurance coverage has expanded somewhat since then, a large gap in coverage for CAM remains, and “access often has been limited to those with higher discretionary income.” The ironic result of this gap in coverage is that in their effort to cut costs, insurers often end up paying for more expensive conventional coverage, even when that coverage is less desirable or effective. In addition to stunting the development of CAM as a field of medicine, the disparities in reimbursement re-segregate integrative care because policies often cover only conventional portions of the integrative treatment. For both CAM and integrative medicine to succeed on a large scale, the crisis in third-party reimbursement must be resolved.

One of the critical problems in obtaining third-party reimbursement for CAM is overcoming institutional bias inherent to the medical necessity test. “Although health insurance contract provisions vary, one principle is virtually universal—health insurers only reimburse their insureds for ‘medically necessary’ treatments.” Medical necessity is generally determined by looking to “customary practice within the medical community.” The medical community, in this formulation, often is very narrowly construed. Some insurance policies explicitly restrict coverage to licensed physicians, refusing coverage for chiropractors. In practice, “insurers almost always rely on medical doctors, to the exclusion of other health care providers, to assess medical necessity.” Because CAM, by definition, is not part of the customary practice of conventional medical doctors, the medical necessity test, in its present state, has the practical effect of denying reimbursement for innovative treatments, even those treatments with a strong basis in clinical trials.


170 Atwell, Mainstreaming, at 612 (quoting Robert Tillman, Paying for Alternative Medicine: The Role of Health Insurers, 583 ANNALS AM. ACAD. POL. & SOC. SCI. 64, 65 (2002)).

171 WHITE HOUSE FINAL REPORT, at 88.

172 Atwell, Mainstreaming, at 593.

173 Id.


176 See Boozang, Potential Pitfalls (“Many definitions of, or criteria for determining, medical necessity reference generally accepted standards within the medical community. If a service or procedure is still considered complementary or alternative, by definition, it would not be within generally accepted standards within the medical community.”).
That the medical necessity test is not as scientific as its title suggests can be gleaned from the incongruous results it produces. While “[t]he nation’s insurers spend $30 billion a year on bypass and angioplasty for cardiovascular disease,” a mere “40 of them cover the lifestyle-based program developed by Dr. Dean Ornish—despite repeated demonstrations that it is safe, effective and vastly less expensive than surgery.”\footnote{Cowley, \textit{Integrative Care}. See also Goldstein, \textit{Persistence}, at 935 (“participation in Dean Ornish’s program of dietary change, stress management, and exercise is quite a bit cheaper than offering bypass surgery to a patient with heart disease (Turner 1995; Ornish 1998; White House Commission 2002: 110).”). For recent clinical trials showing the effectiveness of the Ornish Diet in cardiovascular health, see Yunsheng Ma et al., \textit{A Dietary Quality Comparison of Popular Weight-Loss Plans}, 107 \textit{J. Am. Diet Ass’n} 1786–91 (2007).}

This disparity becomes more striking in light of the fact that although angioplasty had been “performed in hundreds of thousands of patients,” it was never subjected to a single “randomized clinical trial demonstrating efficacy” prior to 1992.\footnote{Morreim, \textit{A Dose of Our Own Medicine}, at 223 (quoting J.E. Dalen, \“Conventional\” and \“Unconventional\” Medicine, 158 \textit{ARCHIVES INTERNAL MED.} 2179, 2180 (1998).} Likewise, although coronary artery bypass “was first performed in 1964, its efficacy was not scientifically evaluated until 1977.”\footnote{E. Haavi Morreim, \textit{Alternative Health Care: Limits of Science and Boundaries of Access, in Medicine and Social Justice: Essays on the Distribution of Health Care} 319, 324 (Rosamond Rhodes et al., eds., 2002)}

Thus, relying on an outmoded model of conventional medicine, insurers pay more for less effective treatments. Despite “an ever-growing body of research confirm[ing] the benefits of acupuncture,” the majority of insurers do not cover acupuncture.\footnote{Ronald Reimer, \textit{Acupuncture Becoming More Mainstream in Western Medicine}, MED. EDGE, Dec. 26, 2008, available at www.mayoclinic.org/medical-edge-newspaper-2008/dec-26b.html [hereinafter Reimer, \textit{Acupuncture Becoming More Mainstream in Western Medicine}].} For over a decade, the NIH has found acupuncture “a reasonable alternative for treating chemotherapy-induced nausea, dental pain, headaches, temporomandibular joint dysfunction (TMJ), fibromyalgia, and depression.”\footnote{Reimer, \textit{Acupuncture Becoming More Mainstream in Western Medicine}.} Providing reimbursement for this alternative would mean that “acupuncture can help reduce health care costs when fewer pain medications are needed and patients can be discharged more quickly from the hospital.”\footnote{Bulen, \textit{Informed Consent}, at 354–356.} It is neither in the insurer’s nor the patient’s long-term interest to refuse coverage of such practical, demonstrably effective alternatives to costly conventional treatment.

Insurers do seem to be recognizing the potential of CAM, albeit slowly.\footnote{Id.} Larger HMOs in particular “have been willing to accommodate themselves to various forms of CAM that offer the potential of cost...
savings” as a remedy to “shrinking profits … fierce competition, skyrocketing pharmaceutical costs and a sagging public image.” Specifically, HMOs see CAM as a cost-effective way to win new (healthy) enrollees by setting themselves apart from the competition. Smaller providers, as well as Medicare, have launched small integrative medicine pilot programs. This progress is promising, hinting at the long-term self-sustainability of CAM modalities as legal barriers are dismantled. Unfortunately, the integration of CAM into the reimbursement structure has been a piecemeal and disjointed process. “[I]nsurance coverage for CAM is often treated as an ‘extra.’ If covered at all, it is usually considered a bonus and is not covered to the same extent as conventional care.” Often, insurers charge extra for CAM coverage, despite the long-term savings it promises.

Policymakers can do much to address the disparities in CAM access and repair the broken reimbursement structure. To date, “the legal system has failed to address the inability of the medical necessity test to adequately incorporate CAM.” By requiring insurers to include licensed CAM healthcare providers in their consideration of “customary practice,” states would go a long way toward removing barriers to integrative medicine. The objection to this change likely will be that too much of CAM is based on small-scale clinical trials or anecdotal evidence, but in this regard, CAM is no worse than conventional medicine. Insurers routinely pay for mammograms, despite the fact that “there is no reliable evidence that screening for breast cancer reduces mortality.” Even if practitioners persist in what turn out to be ineffective modalities, CAM has the distinct benefits of being both cheaper and safer, on average, than conventional medicine.

A second, complementary solution is for states to require insurers to cover specific CAM modalities. While market demand has introduced a few CAM modalities into healthcare policies, others remain largely on the periphery. Although “in the absence of legal requirements and for the great majority of CAM treatments, insurers tend not to provide coverage,” “[h]ealth insurance companies do provide such benefits

184 Goldstein, Persistence, at 935.
186 Atwell, Mainstreaming, at 615.
187 Id. at 612.
188 Id. at 601 (noting that “it is important to be mindful that treatments become customary for a variety of reasons, not all of which relate to their effectiveness. In fact, doctors generally dictate which procedures will be used and under what circumstances, based on their individual training and experience.”).
when required by law through state mandates.” Washington State serves as a model. The state passed a law requiring “health plans to cover alternative medicine provided by licensed providers for conditions otherwise covered by the plan,” and requiring reimbursement for such alternative care, “whether provided by medical doctors and registered nurses, or licensed alternative practitioners, which, in the State of Washington, includes providers of ‘acupuncture, massage therapy, naturopathy, chiropractic services, and a variety of other ‘alternative’ medical treatments.’” An NIH study on the effects of the law found that although a substantial number of people use CAM insurance benefits, “the effect on insurance expenditures was modest.” In other words, Washington’s model of healthcare coverage produces a lot of benefit for very little cost.

Because “[p]atient access to medical treatment, conventional or CAM, often depends on third-party payment,” addressing the systemic barriers that even the most effective conventional and alternative medicines face is urgent. The “inclusion of CAM in insurance schemes” is necessary “to expand patients’ treatment options and put a new focus on holistic practice.”

**Conclusion**

Although complementary and alternative medical treatments offer many unique benefits, including effective, relatively inexpensive care for hard-to-treat chronic conditions and some of the most threatening diseases, it is hindered in large part by a regulatory system rooted in professional favoritism and statutory language from nearly a century ago. The regulatory structure is in dire need of repair. CAM practitioners face obstacles on all sides, from medical licensing restrictions to

190 Id. at 615 (quoting Robert Tillman, Paying for Alternative Medicine: The Role of Health Insurers, 583 ANNALS AM. ACADE. POL. & SOC. SCI. 64, 67 (2002)). It should be noted that a growing number of employers are self-insured, particularly large employers, as a result of the Employee Retirement Income Security Act (ERISA). Employer “health benefit plans that purchase coverage from insurance companies are subject to regulation directly at the federal level and indirectly at the state level, while self-insured plans are regulated exclusively at the federal level,” placing them outside of the reach of state mandates. William Pierron and Paul Fronstin, ERISA Pre-emption: Implications for Health Reform and Coverage, EBRI Issue Brief No. 314 (February 2008), Employee Benefit Research Institute, available at http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf.

191 WASH. REV. CODE § 48.43.045.


195 Id.
malpractice suits. The health and welfare of millions of patients suffer from this failure to integrate medicine, such as by herbal/pharmaceutical interactions; the failure of physicians to refer patients to appropriate CAM treatments; and the lack of third-party reimbursement to make CAM affordable. By taking a serious look at the promise and potential posed by CAM, as well as the risks, and updating the law accordingly, the health and welfare of Americans can be greatly enhanced.
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