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Mainstreaming Complementary and Alternative Medicine in the Face of Uncertainty

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MAINSTREAMING COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE FACE OF UNCERTAINTY

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What once appeared to be well-settled medical procedures have been called into question recently. New research suggests, for example, 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.[1] In fact, despite its countless wonders, modern medicine includes a variety of treatments and procedures that are of questionable efficacy. The Fen-Phen fiasco, the misuse and overuse of antibiotics, and the 100,000 deaths annually from the routine use of prescription drugs are other examples of this phenomenon.[2] Moreover, thousands of people die each year from cancer, heart disease and a host of other incurable diseases.[3]

Critical health insurance implications are associated with these facts. Although health insurance contract provisions vary, one principle is virtually universal – health insurers only reimburse their insureds for "medically necessary" treatments.[4] Insurers generally evaluate whether a treatment is medically necessary by looking to the customary practice within the medical community. Customary practice among medical doctors or physicians,[5] however, is often the result of trial and error. Doctors' prescription and treatment patterns are based frequently on their own clinical experiences – not on studies proving that the particular treatment is effective.[6] Studies for many treatments simply do not exist. Moreover, existing studies may reach conflicting results, like those regarding the effectiveness of mammograms and hormone replacement therapy. Thus, in many instances, medical knowledge may not accurately reflect

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[1] *See infra* notes 49-55 and accompanying text.

[2] *See infra* notes 56-63 and accompanying text.

[3] The costs associated with treating these and other diseases, as well as the costs associated with questionable or discredited treatments and procedures, are astronomical. For example, a look at one small microcosm of health care costs – those associated with environmentally induced diseases in children like cancer, lead poisoning, and asthma – is estimated at $48.8–64.8 billion annually. Philip J. Landrigan et. al, *Environmental Pollutants and Disease in American Children: Estimates of Morbidity, Mortality, and Costs for Lead Poisoning, Asthma, Cancer, and Developmental Disabilities*, 110 ENVTL. HEALTH PERSP. 721 (2002), *at* http://ehp.niehs.nih.gov/members/2002/110p721-728landrigan/EHP110p721PDF.PDF.

[4] *See infra* notes 15-28 and accompanying text.

[5] The terms "medical doctor" and "physician" are used interchangeably in this article to refer to those who have a doctor of medicine (M.D.) or a doctor of osteopathy (D.O.) degree.

[6] *See infra* notes 41-43 and accompanying text.

whether treatments are medically necessary. Yet insurers almost always rely on medical doctors, to the exclusion of other health care providers, to assess medical necessity.

At the same time, there has been a growing acceptance of complementary and alternative medicine ("CAM").[7] For example, the National Institutes of Health ("NIH") has an entire center – the National Center for Complementary and Alternative Medicine ("NCCAM") – dedicated to studying CAM.[8] States also recognize the legitimacy of some forms of CAM by imposing educational and licensing requirements for CAM health care providers like acupuncturists and chiropractors, among others.[9] In addition, Americans spend billions of dollars each year on CAM, demonstrating that much of the public is convinced of its corresponding health benefits.[10] Indeed, some health insurers have begun to provide limited coverage of specific CAM treatments.[11] Nonetheless, most CAM expenditures are not covered by health insurance. As a result, CAM is largely limited to those who can afford it.

Given the fact that some conventional medical treatments are of questionable efficacy, it is inappropriate for health insurers to deny coverage for CAM treatments because their effectiveness is also uncertain at times. It is virtually impossible, given the current state of medical knowledge, to apply the medical necessity test rationally, consistently, or with true integrity. The time has come for a paradigm shift in health insurance coverage to level the playing field between licensed CAM and conventional health care providers.

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[7] The terms "conventional care" or "conventional treatments" are used in this article to include customary care provided by medical doctors including, but not limited to, surgery and conventional pharmaceutical drug therapies. The widely embraced term, "complementary and alternative medicine" ("CAM") refers to a broad range of disciplines that have not yet been accepted as part of conventional medical practice. Examples include homeopathy, chiropractic, acupuncture, naturopathy, nutritional therapy, massage therapy, reiki, aromatherapy, and herbal medicine. The National Center for Complementary and Alternative Medicine ("NCCAM"), a center within the National Institutes of Health ("NIH"), provides the following definition: "Complementary and alternative medicine . . . is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine." NCCAM, *What Is Complementary and Alternative Medicine (CAM)?*, http://nccam.nih.gov/health/whatiscam (last modified Feb. 5, 2004); *see also* Kenneth R. Pelletier & John Astin, *Integration and Reimbursement of Complementary and Alternative Medicine by Managed Care and Insurance Providers: 2000 Update and Cohort Analysis*, 8 ALTERNATIVE THERAPIES IN HEALTH & MED. 38 (2002) ("Complementary and alternative medicine (CAM) [are] 'medical interventions not taught widely at US Medical schools or generally available at US hospitals.' Among the most commonly used practices are nutritional supplements, herbal therapy, chiropractic, mind-body techniques such as mindfulness, meditation, massage and acupuncture.").

[8] *See infra* note 91 and accompanying text.

[9] Recognition of CAM disciplines varies from state to state. *See infra* notes 146-50 and accompanying text.

[10] *See infra* notes 87-89 and accompanying text.

[11] *See infra* notes 122-29 and accompanying text.

Part I of this article provides an overview of the medical necessity test, and[12] examines the decision-making process pursuant to the test, including who makes coverage determinations and what criteria are used in making them. Part I also sets forth examples of conventional treatments that insurers routinely cover despite their questionable efficacy from a medical necessity perspective. Part II explores CAM disciplines and describes how they differ from conventional medicine. Part III discusses the legal challenges CAM faces and explores the limited extent to which CAM is covered by health insurance and the failure of state laws to provide mandates for such coverage. Part III also examines the need for expanded state licensing laws for CAM providers and highlights state laws that are designed to keep CAM dollars in the pockets of conventional medical doctors instead. Part IV analyzes the inability of traditional methods of insurance decision-making to adequately determine whether CAM should also be covered, and sets forth a new paradigm for determining whether CAM should be covered by health insurers. Part IV proposes a shift from the current medical necessity test to a reasonable necessity standard. The term "medical" suggests decisions made solely by medical doctors. The reasonable necessity test, on the other hand, will encompass treatments that are necessary in the opinion of any licensed health care provider, including CAM providers. This would correct two problems. First, it would allow all licensed health care providers to determine what treatments are reasonably necessary. Second, it would acknowledge the limitations on the current state of knowledge and place more power back in the hands of health care providers, both conventional and CAM, rather than insurers, in making coverage determinations.

Insurers will undoubtedly claim that shifting to a reasonable necessity standard will be financially prohibitive, however, this is not necessarily true. Some patients may choose CAM treatments instead of conventional ones. For example, the patient with the arthritic knee may choose acupuncture over surgery if health insurance covers either choice. In that case, the cost to the insurer may well be less than if the patient chose conventional care. In other instances, patients may choose a combination of conventional and complementary care. Cancer patients who are undergoing toxic chemotherapy treatments, for example, may maintain their strength by combining conventional treatments with complementary ones like acupuncture, massage, nutritional therapy and the like. To the extent that the CAM treatments enhance well-being, cancer patients may be better able to complete conventional treatments without interruption, maximizing their potential benefits. In these cases, while the short-term costs of combining both types of treatments may increase, long-term health care costs could go down.

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[12] *See infra* notes 13-41 and accompanying text.

I. MEDICAL NECESSITY AND MEDICAL UNCERTAINTY

Health insurance coverage is generally a matter of state law.[13] State insurance laws may set forth certain mandates with respect to coverage, but much discretion remains with each insurance carrier.[14] Coverage varies then not only from state to state, but within a state from one insurance plan to another. There are, however, certain health insurance principles that are virtually universal in the United States. One such principle is that health insurance coverage is generally limited to those treatments that are "medically necessary."[15]

The definition of medical necessity can vary from one state to another. Moreover, it may vary from one insurance plan to another. Some state statutes explicitly define medical necessity. Although state statutory definitions are not uniform, a common statutory definition restricts medically necessary treatments to those that are "consistent with generally accepted standards of medical practice."[16] Other states do not explicitly define medical necessity. Instead, they

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[13] The states' police power to regulate the health, safety and welfare of their citizens encompasses health care. *See* Jacobson v. Massachusetts, 197 U.S. 11, 38 (1905); Dent v. West Virginia, 129 U.S. 114, 128 (1889).

Health insurance comes in many forms. While private insurance is generally governed by state law, self-insured employers – those employers who assume the risk of insuring their employees directly – escape state insurance regulations under the Employee Retirement Income Security Act of 1974 (ERISA). 29 U.S.C. §§ 1002-1466 (1975 & Supp. 1985). ERISA "supersedes" any state law that "relates to" an employee benefit plan. 29 U.S.C. 1144(a). Even though ERISA, via what is commonly referred to as the savings clause, 29 U.S.C. 1144(b)(2)(A), does not preempt state laws that regulate insurance, self-insured employers are not considered insurers for purposes of ERISA. Therefore, rules governing employer self-insured employee benefit plans are governed by ERISA itself rather than by the savings clause.

While this article focuses on private health insurance, there are also many government-based forms of health insurance. Medicare, which covers many elderly and disabled, and Medicaid, a state/federal partnership that covers individuals who meet certain income and other eligibility requirements are, perhaps, the two best-known public health coverage programs. Other public health programs include State Children's Health Insurance Program ("SCHIP") and Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"). *See generally* BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, & PROBLEMS ch's 11, 12 (2d ed. 2000). This article does not address the problem of the more than forty million Americans who are uninsured.

[14] *See* Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 728-29 (1985).

[15] *See* Katskee v. Blue Cross/Blue Shield of Nebraska, 515 N.W.2d 645 (1994); *see also* Mark A. Hall & Gerald F. Anderson, *Models of Rationing: Health Insurers' Assessment of Medical Necessity* 140 U. PA L. REV. 1637 (1992); Wendy K. Mariner, *Patients' Rights After Health Care Reform: Who Decides What is Medically Necessary?*, 84 AM. J. PUB. HEALTH 1515, 1516 (1994); E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REF. 939, 1010 (1999); Sara Rosenbaum et al., *Who Should Determine When Health Care is Medically Necessary?*, 340 N. ENG. J. MED. 229 (1999).

[16] *See* ME. REV. STAT. ANN. tit. 24-A, § 4301-A (10-A) (West 2001). The Maine statute goes on to specify that medically necessary must be "representative of the 'best practices'" in the medical profession. *Id.*; *see also* 16 DEL. CODE ANN. tit. 16, § 9119(a) (2004), *available at* http://www.delcode.state.de.us/title16/c091/index.htm#P226_20036 ("'[M]edical necessity' means the providing of covered health care services or products that a prudent physician would provide

permit individual health insurers to define it.[17] A typical insurer definition of medical necessity is illustrated by the Blue Cross/Blue Shield of Nebraska policy in *Katskee v. Blue Cross/Blue Shield of Nebraska*,[18] as those "services, procedures, drugs, supplies or Durable Medical Equipment . . . [that are c]onsistent with the standards of good medical practice in the medical community of the State of Nebraska."[19]

As is evident from these definitions, reliance on the custom and practice of the medical community is key in determining what treatments are medically necessary. Therefore, the procedures that will be deemed medically necessary are those that physicians routinely adopt in their practices.[20] Traditionally, physicians determined what treatments were medically necessary based upon their clinical observations and discussions with their patients.[21] After examining the patient, obtaining his or her medical history and any other necessary information, the doctor would prescribe a course of treatment. In the past, the doctor's treatment decisions were implemented without question from the health insurer.[22]

. . . in a manner that is [i]n accordance with generally accepted standards of medical practice."); GA. CODE ANN. § 33-20A-31(5) (2002) ("'Medical necessity' . . . means care based upon generally accepted medical practices."); MASS. GEN. LAWS ch. 176O, § 1 (2003) ("'Medical necessity' or 'medically necessary' health care services are [those] consistent with generally accepted principles of professional medical practice."); R.I. GEN. LAWS §23-17.12-2(14) (2002) ("Medical necessity . . . means the standard of care which is based upon generally accepted medical practices."); VA. CODE ANN. § 38.2-5800 (Michie 1998) ("'Medical necessity' . . . means appropriate and necessary health care services . . . according to generally accepted principles of good medical practice."); 47 D.C. Reg. 229 § 6099.1 (2000) ("[M]edically necessary care means the care which, in the opinion of the treating physician, is reasonably necessary."). *See generally* MASS. GEN. LAWS ch. 6A, § 16D (2000) (medically necessary services are "health care services that are consistent with generally accepted principles of professional medical practice.").

[17] See for example, N.H. REV. STAT. ANN. § 420J:7-a(I) (2002), which allows the insurance companies to define medical necessity. They must, however, submit their definition with the state insurance department. *See also* FLA. STAT. ch. 641.54(4) (2004) ("The organization shall . . . determine whether health care services are 'medically necessary.'"); MINN. STAT. § 62L.02(d)(21) (2002) ("'Medical necessity' means the appropriate and necessary medical and hospital services eligible for payment under a health benefit plan as determined by a health carrier.").

[18] 515 N.W.2d 645 (Neb. 1994).

[19] *Id.* at 648–49.

[20] *See supra* note 16 and accompanying text. *But see* ARIZ. ADMIN. CODE R9-22-101 (2002) ("'Medically necessary' means a covered service provided by a physician or other licensed practitioner of the healing arts."); HAW. REV. STAT. § 432E-1.4(b) (2001) ("A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider [and] is approved by the health plan's medical director or physician designee.").

[21] *See* Hall & Anderson, *supra* note 15, at 1650. Although "medical necessity" clauses are written into most health insurance policies today, this was not always the case. Until the 1960s, insurers did not question physicians' treatment decisions and routinely paid for anything the doctor deemed necessary without questioning that judgment. *Id.* at 1644-45; *see also* Rosenbaum, *supra* note 15, at 229 ("From the 1950s through the late 1970s, physicians' medical opinions largely dictated coverage and were rarely challenged by insurers.").

[22] Rosenbaum, *supra* note 15, at 229.

Today's health insurance policies, however, typically specify that the *insurer* is to determine the medical necessity of the treatment or procedure.[23] Thus, unless the treatment is mandated by the state,[24] health insurers have a great deal of discretion in making reimbursement decisions. Since health insurers are not in a position to evaluate patients clinically, they look to the custom and practice in the medical community to decide whether a treatment is medically necessary.[25] Nurses are typically hired by insurance companies and are authorized to make initial approvals for treatments that the companies deem usual and customary.[26] Denials of treatment, however, are made by physicians. In disputed cases, the insurer's medical director generally makes the final coverage decision, typically a medical doctor. Medical directors use a variety of resources to make medical necessity determinations. For example, they may consult medical journals, Medicare policies, and other external sources. They may also consult experts in the field. One study has shown, though, that insurers use "information generated by the trade associations representing the health plans and undefined practice guidelines" more than " information from national experts, government documents and NIH consensus conferences."[27] Regardless of the specific sources used in a given case, the medical director is ultimately focused on the customary practice of other conventional medical doctors.[28]

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[23] *See* Hall & Anderson, *supra* note 15, at 1644-45. All states have begun to protect patients rights by mandating appeals procedures for adverse decisions. *See* FURROW, *supra* note 13 at 593.

[24] Robert Tillman, *Paying for Alternative Medicine: The Role of Health Insurers*, 583 ANNALS AM. ACA. POL. & SOC. SCI. 64, 68 (2002) (insurers are mandated by states to reimburse specific treatments).

[25] *See* Hughes v. Blue Cross, 263 Cal. Rptr. 850, 857 (Cal Ct. App. 1989) ("[G]ood faith demands a construction of medical necessity consistent with community medical standards that will minimize the patient's uncertainty of coverage in accepting his physician's recommended treatment."); *see also* Rosenbaum, *supra* note 15, at 229. "[I]nsurance contracts typically use clinically derived professional standards of care as the basis for determinations of medical necessity and coverage." *Id.* (citations omitted). If the insurer's decision is consistent with custom and practice, courts are likely to uphold their decisions. Conversely, if the insurer's decision does not comport with custom and practice, courts are likely to overrule it.

[26] Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, HEALTH AFF., Jan.-Feb. 2001, at 200.

[27] Rosebaum, *supra* note 15, at 231. *Cf.* Singer & Bergthold, *supra* note 26.

[28] *See* Singer & Bergthold, *supra* note 26, at 201. In a recent study, medical directors in HMOs reported they approved an average of 94% of treatment requests. *Id.* In the current managed care climate, not only do insurers determine whether a treatment or procedure is medically necessary, but they do so prospectively rather than retrospectively as they did in the past. As the name suggests, prospective review requires insurer approval prior to treatment. Thus, if the insurer denies coverage, the health care provider may refuse to provide the patient with the recommended treatment, potentially threatening the patient's health and well-being. *See, e.g.,* Lubeznick v. HealthChicago, Inc. 644 N.E.2d 777 (Ill. App. Ct. 1994) (plaintiff sought injunction against medical center ordering it to treat her without providing a $100,000 deposit and later took a voluntary nonsuit against the medical center). With retrospective review, even if the insurer denied that the treatment was medically necessary, the patient already had received the benefit of the disputed procedure. *See* Wickline v. State, 239 Cal. Rptr. 810, 812 (Cal. Ct. App. 1986) ("A

An outgrowth of the medical necessity test is the general refusal of insurers to pay for experimental treatments.[29] Since experimental treatments by definition fall outside the parameter of what is usual and customary, they do not meet the definition of medical necessity. In fact, experimental treatments are expressly excluded in the typical health insurance contract.[30] Therefore, insurers virtually always deny coverage for such treatments.[31] Of course, whether or not a treatment is still experimental is often highly debated.[32] Every procedure has to begin somewhere. The point at which it shifts from being new and experimental to usual and customary, is unclear. Thus, distinguishing between experimental and non-experimental treatments is not a matter of black and white but often involves varying shades of grey.[33]

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mistaken conclusion about medical necessity following retrospective review will result in the wrongful withholding of payment. An erroneous decision in a prospective review review process, on the other hand, in practical consequences, results in the withholding of necessary care, potentially leading to a patient's permanent disability or death."). Thus, the medical necessity determination is arguably more critical now than it was under the former retrospective approach.

[29] *See* Jones v. Laborers Health & Welfare Trust Fund, 906 F.2d 480, 481 (9th Cir. 1990) (insurance company refused to pay for hypothermia treatment used to treat breast cancer due to its experimental nature); *see also* Sweeney v. Gerber Prod. Co. Med. Benefits Plan, 728 F. Supp. 594 (D. Neb. 1989) (plaintiff received high dose chemotherapy with an autologous bone marrow transplant for refractory breast cancer after she had no response to standardized treatments and theinsurer denied reimbursement because autologous bone marrow transplants were not recognized in the medical field as appropriate treatment for breast cancer and therefore were considered experimental). *See generally* Paul J. Molino, *Reimbursement Disputes Involving Experimental Medical Treatment*, 24 J. HEALTH & HOSP. L. 239 (1991).

[30] *Lubeznik*, 644 N.E.2d at 777 (insurance policy excluded "[e]xperimental medical, surgical, or other procedures as determined by the [insurer]").

[31] *See also* Frank P. James, *The Experimental Treatment Exclusion Clause: A Tool for Silent Rationing of Health Care?*, 12 J. LEGAL MED. 359 (1991); J. Gregory Lahr, *What is the Method to Their "Madness?" Experimental Treatment Exclusions in Health Insurance Policies*,13 J. CONTEMP. HEALTH L. & POL'Y 613 (1997). *But see* Hall & Anderson, *supra* note 15, at 1655-57 (explaining that courts often rule in favor of the insured, finding that procedures are not experimental even when the facts suggest otherwise, in order to give the patient a chance at being cured).

[32] *See* Pirozzi v. Blue Cross & Blue Shield of Virginia, 741 F. Supp. 586 (E.D. Va 1990). Pirozzi, like *Sweeney*, 728 F. Supp. 594, involved high-dose chemotherapy with an autologous bone marrow transplant for the treatment of breast cancer. 741 F. Supp. 586. The court in *Pirozzi*, however, found that the autologous bone marrow transplant was state of the art treatment for metastatic breast cancer and therefore the treatment was not experimental, as the insurance company had argued. *Id.*; *see also* Kekis v. Blue Cross & Blue Shield of Utica-Watertown, 815 F. Supp. 571 (N.D.N.Y. 1993) (granting a preliminary injunction requiring defendant insurance company to pay for plaintiff's autologous bone marrow transplant which was recommended as treatment for ductal invasive breast cancer, rejecting insurer's claim that the treatment was experimental); Melody L. Harness, *What is "Experimental" Medical Treatment? A Legislative Definition is Needed*, 44 CLEV. ST. L. REV. 67 (1996); Elaine Reckner Sammon, *"Experimental Treatment": Legislating Against Unfair Deals*, 27 HOFSTRA L. REV. 143, 145-150 (1998).

[33] Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361 (2002).

Insurers should not have unbridled discretion in determining whether a treatment is medically necessary, medically unnecessary, or experimental. As profit-making business ventures, there is an inherent conflict of interest between them and their insureds.[34] Perhaps for this reason, the U.S. Supreme Court explained in *Pegram v. Herdrich*[35] that "eligibility decisions cannot be untangled from physicians' judgments about reasonable medical treatment."[36]

In addition to the inherent conflict of interest from a business perspective, there is another shortcoming of the medical necessity test. Its focus is on what is usual and customary among conventional *medical doctors*, to the exclusion of other health care providers. No account is taken of customary practice among CAM health care providers.[37] Nor are non-medical research sources typically consulted.[38] Insurers justify these practices on the theory that many CAM treatments have not been proven effective. The same is true, however, of many conventional medical treatments. Despite the existence of randomized clinical trials, many customary conventional treatments remain unproven.[39] As the Congressional Budget Office acknowledged:

> [P]atients have little knowledge upon which to judge the benefits of a new technology. But even physicians cannot always be fully informed about all the new treatments and technologies, especially given the rapid pace of complex medical advances. *More important, good statistical information concerning the effectiveness of many treatments – even common treatments – is simply not available.*[40]

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[34] Hall & Anderson, *supra* note 15, at 1666. In noting some of the objections that have been raised to insurers making medical necessity decisions, Hall and Anderson frame the issue succinctly: "[C]an insurers be trusted to make decisions in their subscribers' best interest? . . . [B]y virtue of their proprietary interest in the premiums they have already collected, insurers have a conflict of interest that precludes them from making a neutral, unbiased decision." *Id.*

[35] 530 U.S. 211 (2000).

[36] *Id.* at 229.

[37] Joseph A. Barrette, *The Alternative Medical Practice Act: Does it Adequately Protect the Right of Physicians to Use Complementary and Alternative Medicine?*, 77 ST. JOHN'S L. REV. 75, 78 (2003) ("[T]he differing views underlying organized medicine and unorthodox healthcare have led to a dilemma for legal decision makers. This professional rivalry has historically led courts, legislators, and administrative bodies to examine CAM practices through the perspective of conventional medicine.") (citations omitted).

[38] *Id.*

[39] Not only is there a great deal of doubt about the efficacy of many standard medical treatments, but it is also estimated that medical interventions result in many "adverse events." HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990). The Harvard study estimated that there were 98,609 adverse events in New York in 1984. *Id.*

[40] CONGRESSIONAL BUDGET OFFICE, ECONOMIC IMPLICATIONS OF RISING HEALTH CARE COSTS (1992) (emphasis added); *see also* Lucian L. Leape, *Unnecessary Surgery*, 13 ANN. REV. PUB. HEALTH 363, 374 (1992); Morreim, *supra* note 15, at 990 ("Uncertainties . . . permeate medicine."); Kevin Patterson, *What Doctors Don't Know (Almost Everything)*, N.Y. TIMES, May 5, 2002, at 74

Since many conventional medical treatments have not been scrutinized for efficacy, the focus on customary practice as the guide for health insurance decision-making is understandable. Yet 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.[41] One common example involves the frequency of caesarean sections. The variation in frequency is not just from one part of the country to another, but from one doctor to another within the same hospital.[42] Similar variations surround the use of heart bypass surgery.[43]

Not only do doctors' treatment patterns vary based on the preferences of the individual physicians, but disparities also occur due to conflicting opinions about the safety and efficacy of certain treatments. It is easy to identify conventional medical procedures that lost favor either because they were proven to be ineffective[44] or dangerous.[45] The nineteenth century practice of bloodletting, for example, which involved draining blood from sick patients, was later determined to hasten death rather than postpone or avoid it.[46] More recent conventional

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("[C]onclusions doctors reach from clinical experience and day to day observation of patients are often not reliable. The vast majority of medical therapies, it is now clear, have never been evaluated by systemic study and are used simply because doctors have always believed they work.").

[41] CONGRESSIONAL BUDGET OFFICE, *supra* note 40 (stating that "[d]octors preferences for particular procedures – rather than science – appear to determine how they are used, a situation that leads to significant variations in the patterns and costs of medical care around the country."); *see also* Hall & Anderson, *supra* note 15, at 1652 ("During the 1980's a number of . . . studies found wide variations in hospital admission rates across geographic areas that could not be explained by demography, health status, economic status, or other relevant factors. The general consensus of the researchers was that much of the variation in medical practice could only be explained by a discretionary "medical practice factor.'") (citations omitted).

[42] *See* Benjamin P. Sachs, *Is the Rising Rate of Cesarean Sections a Result of More Defensive Medicine?*, *in* 2 MEDICAL PROFESSIONAL LIABILITY AND THE DELIVERY OF OBSTETRICAL CARE: AN INTERDISCIPLINARY REVIEW 29-31 (Victoria P. Rostow & Roger J. Bulger eds., 1989).

[43] *See* Morreim *supra* note 15, at 992 (stating that "ample evidence suggests that . . . cardiac bypass surgery. . . should not be routinely used over more conservative medication based approaches."); *see also* Gina Kolata, *Heart Pump and Brain Injury: A Riddle Deepens With Time*, N.Y. TIMES, May 13, 2003, at F1. The article discusses the confusion in the medical community about whether a heart pump that is used during heart bypass surgery sometimes leads to patients experiencing confusion or forgetfulness following their surgery. *See id.* Some have argued that bypass surgery should be performed without the pump. *Id.* Kolata continues, "converts, to off-pump surgery and skeptics of it say the field faces a huge problem, one that is in a sense emblematic of modern medicine: the practice seemed to be reasonable and took hold before anyone could conduct a controlled randomized clinical trial on its merits." *Id.* Kolata goes on to analogize this to the hormone replacement therapy flip-flop. *Id.*

[44] *See infra* note 49 and accompanying text (discussing the recent controversy surrounding the efficacy of mammograms).

[45] *See infra* notes 62-63 and accompanying text (describing the Fen-Phen fiasco) and notes 50-55 (discussing the safety and efficacy of hormone replacement therapy).

[46] *See* Patterson, *supra* note 40.

treatments have also been discredited or questioned. For example, the New England Journal of Medicine reported in 1999 that providing blood transfusions to seriously ill patients – essentially the opposite of bloodletting – might be equally ineffective and possibly dangerous.[47] And there are now indications that in some instances arthroscopic knee surgery may be ineffective.[48]

The recent controversy surrounding the effectiveness of routine mammograms is another classic example of the level of uncertainty that continues to permeate medicine, even in areas that once appeared to be settled. An October 2001 article in *The Lancet* reported that "there is no reliable evidence that screening for breast cancer reduces mortality."[49] This controversy was publicized years after doctors assured women that yearly mammograms after the age of forty would help reduce the risk of death from breast cancer.

The now questionable use of hormone replacement therapy for menopausal women is another recent example of this phenomenon. After observational studies suggested that hormone replacement therapy provided a number of health benefits such as protecting against heart disease,[50] maintaining bone density, and minimizing hot flashes, randomized clinical studies have failed to find such benefits.[51] Not only are the benefits of hormone replacement therapy questionable, but the risks associated with it are significant and it poses a significant risk of adverse side effects.[52] Thus, estrogen replacement therapy for menopausal women now appears to be worse than ineffective and downright dangerous. In fact, a recent hormone replacement study was halted midstream because it was determined that the risks, including an increased "risk of invasive breast cancer," and of "heart attacks, blood clots, and strokes" outweighed its benefits.[53] One physician who developed breast cancer after taking hormone

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[47] *See* Paul C. Hebert et al., *A Multicenter, Randomized, Controlled Clinical Trial of Transfusion Requirements in Critical Care*, 340 NEW ENG. J. MED. 409 (1999).

[48] Jerome Groopman, *Do You Know Where That Cartilage Came From?*, N.Y. TIMES, May 17, 2003, at 17A (stating that "[a] recent study in the New England Journal of Medicine showed no significant difference between patients who underwent arthroscopic [knee] surgery to remove diseased cartilage, and those who only thought they had.").

[49] Ole Olsen & Peter C. Gotzsche, *Systemic Review of Screening for Breast Cancer with Mammography*, LANCET, Oct. 2001, at 1340-42, *available at* http://image.thelancet.com/lancet/extra/fullreport.pdf; *see also* News Release, National Cancer Institute, NCI Statement on Mammography Screening (Jan. 31, 2002), *available at* http://www.cancer.gov/newscenter/mammstatement31jan02 (recommending that women in their forties and fifties continue to be screened despite the findings in Lancet, and committing to engage in further research in an effort to clarify this issue).

[50] *See* Gina Kolata, *In Public Health Definitive Data Can Be Elusive*, N.Y. TIMES, Apr. 23, 2002, at F1, F4.

[51] *See* Gina Kolata, *Study Is Halted Over Rise Seen in Cancer Risk*, N.Y. TIMES, July 9, 2002, at A1.

[52] *See* Kolata, *supra* note 50, at F4 ("'It is mind-boggling to give 20 million American women a drug with major side effects without definitive proof that it works.'") (quoting Dr. Deborah Grady, a professor of Medicine and Epidemiology at the University of California-San Francisco).

[53] Kolata, *supra* note 51, at A1; Gina Kolata & Melody Petersen, *Hormone Replacement Study a Shock to the Medical System*, N.Y. TIMES, July 10, 2002, at A1. Almost one year after the hormone

therapy believes that "hormone replacement therapy may be remembered as one of the terrible medical mistakes of the 20th century."[54] Therefore, the six million or more women who have been taking the hormones must now determine whether to continue the treatment.[55]

Even basic treatments that have proven beneficial, like antibiotics for the treatment of bacterial infections, have had unforeseen adverse consequences. Bacteria have evolved as fast as or perhaps faster than antibiotics, creating a risk of drug resistant infections.[56] One reason for this appears to be the overuse and misuse of antibiotics. From a comparative perspective, antibiotics are not used as extensively elsewhere as they are in the United States. For example, in some countries, ear infections are not treated with antibiotics unless they persist for more than three days.[57] Since many ear infections go away on their own accord within that time period, far fewer antibiotics are used in a number of foreign countries. In the United States, antibiotics are also administered extensively to nonhuman farm animals, which is done in an effort to promote growth and profitability.[58] Thus, consuming an ordinary chicken dinner involves the ingestion of antibiotic remnants. We now know that the overuse and misuse of antibiotics has caused a major public health threat.[59] As one commentator concluded, "[t]he connection between [animal] growth promoters and antibiotic resistance in both the animals and in human consumers [is] clear."[60]

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study was halted, "new findings . . . paint[ed] an even more ominous picture of the hormones' role in . . . [breast cancer]." Denise Grady, *Study Finds New Risks in Hormone Therapy*, N.Y. TIMES, June 25, 2003, at 12.

[54] Anne A. Gershon, M.D., *Letter to the Editor*, N.Y. TIMES, June 29, 2003, at 12.

[55] Kolata & Peterson, *supra* note 53. Doctor Robert Wilson, the doctor who originally espoused the use of hormone therapy reportedly was paid to lecture to women's groups by Wyeth, the drug company that makes Premarin, one of the hormone replacement drugs. *Id.* at A16. Controversy also surrounds the use of growth hormones for children. *See* Barry B. Bercu, *The Growing Conundrum: Growth Hormone Treatment of the Non-Growth Hormone Deficient Child*, 276 J. AM. MED. ASS'N 567 (1996).

[56] LAURIE GARRETT, BETRAYAL OF TRUST: THE COLLAPSE OF GLOBAL PUBLIC HEALTH 237-28 (2001).

[57] *Cf.* Morreim, *supra* note 15, at 991 (stating that "[a]ntibiotics have often been used with unnecessary frequency at unnecessary levels of potency, with the result that resistant organisms are increasingly a problem.").

[58] *See* GARRETT, *supra* note 56, at 463.

> The primary use of antibiotics in livestock was not for veterinary medicine; rather, for reasons not clearly understood, the drugs acted as growth promoters, and chickens, turkey, cows, pigs – all livestock – fed antibiotic-laced feed were 3 to 4 percent larger by adulthood than their untreated counterparts. This offered a powerful incentive for use of the drugs, for some farmers and ranchers, 4 percent could be the margin of their profits.

Id.

[59] *Id.* at 467-68 (stating that "[a]s early as 1969 . . . Great Britain . . . recommended a full stop ban on the use of therapeutically significant antibiotics as animal growth promoters on the grounds that resistance acquired by bacteria in those animals would spread to human beings. Sadly the report was largely ignored in the United States.") (citations omitted).

[60] *Id.* at 468.

Adverse reactions to routine prescription medicine constitute another potential health threat. Prescription medicines are estimated to kill "more than 100,000 people" annually.[61] The Fen-Phen fiasco is one example. It was discovered that this drug combination, which was prescribed for weight control, caused heart disease in otherwise healthy women,[62] leading the FDA to recall the drug combination.[63]

An emphasis on "evidence-based medicine" exists because of these examples and others. The underlying theory of evidence-based medicine is that the treatments doctors provide should be supported by legitimate medical studies. A number of problems exist, however, with attempting to rely solely upon evidence-based medicine. First, there simply are no studies to support many medical procedures.[64] Moreover, trying to rely solely upon evidence-based medicine overlooks the premise that medicine is not just a science, but an art. To try to impose a "one size fits all" generalized standard undermines the importance of clinical evaluation.[65] Doctors' intuition . . . play[s] a critical role in providing care.[66] If we accept that the healing arts genuinely involve "art," evidence-based medicine cannot be the be-all and end-all for treatment decisions or insurance coverage determinations.[67]

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[61] Sheryl Gay Stolberg, *Study Finds Fault in Tracing of Drug Reactions*, N.Y. TIMES, Dec. 15, 1999, at A19. Many of these deaths could be prevented. There are, however, flaws in the FDA system for tracking adverse reactions to prescription drugs. *Id.*

[62] Heidi M. Connolly et al., *Valvular Heart Disease Associated with Fenfluramine-Phentermine*, 337 NEW ENG. J. MED. 581 (1997); Eugene Mark et al., *Fatal Pulmonary Hypertension Associated with Short-Term Use of Fenfluramine and Phentermine*, 337 NEW ENG. J. MED. 602 (1997); Apryl A. Ference, Comment, *Rushing to Judgment on Fen-Phen and Redux: Were the FDA, Drug Manufacturers, and Doctors Too Quick to Respond to Americans' Infatuation With A Cure-All Diet Pill for Weight Loss?*, 9 ALB. L.J. SCI. & TECH. 77 (1998).

[63] Centers For Disease Control & Prevention, *Cardiac Valvulopathy Associated with Exposure to Fenfluramine or Dexenfluramine: U.S. Dept. of HHS Interim Public Health Recommendations*, 278 J. AM. MED. ASS'N 1729 (1997).

[64] Patterson, *supra* note 40. "'Scientific data cannot be expected to guide most medical decisions directly. . . . There are not enough randomized trials or epidemiological studies; there are virtually no studies on appropriate ordering of tests.'" *Id.* (quoting Dr. Nuala Kenny); *see also* Morreim, *supra* note 15, at 983-86; Rosenbaum, *supra* note 15, at 231 ("Many basic medical interventions have not been studied rigorously.").

[65] Rosenbaum, *supra* note 15, at 231.

[66] Thus, "when an experienced neonatology nurse doesn't like the look of an infant, . . . a pediatrician takes that very seriously, or quickly learns to, even if there is no fever or abnormal lab results. It sounds a little like magic, this art." Patterson, *supra* note 40.

[67] *Id.*

> The randomized clinical trial has become the gold standard but . . . it is a leap of faith to expand the results of a trial to a broad therapeutic principle. Clinicians recognize this instinctively. The best drug, the optimal dose and duration of therapy for a particular patient are not determined by a study involving a large population.

Id. Cf. Morreim, *supra* note 15, at 981-82.

> Decisions about insurance coverage that rely solely on broad standards derived from generalized evidence diminish the ability of clinicians to perform their roles because they lock in certain outcomes and effectively impose "one size fits all" values . . . At the extreme, physicians and patients are left with no discretion. The clinician's knowledge of the individual patient is rendered irrelevant.[68]

The foregoing discussion highlights that what is "medically necessary" is often unclear. Many uncertainties surround conventional medical treatments.[69] Thus, whether a conventional treatment is truly "medically necessary" in the sense that it is an effective regimen for that particular patient's condition is often unknown.[70] Yet no one is suggesting that insurers deny coverage for routine mammograms because of their questionable efficacy. Nor should they fail to reimburse patients for FDA-approved prescription drugs because of the potential adverse side effects or because of a minimal risk of an allergic reaction. Further, while antibiotics may be overused or misused we would not want to discontinue health insurance coverage for prescription antibiotics. Nonetheless, we must address the reality that the medical necessity test largely confines health insurance coverage to treatments that are in customary use by medical doctors, to the exclusion of all other health care providers, and despite the significant uncertainty that surrounds many conventional medical treatments.

Thus, while insurers routinely deny coverage for experimental treatments,[71] one could argue that medicine is, in many respects, one enormous ongoing experiment.[72] Conventional medicine has achieved so very many important advances in the twentieth century and will undoubtedly achieve even greater successes in the new millennium. Nonetheless, the perception that medicine has solved all the mysteries of human disease and suffering does not reflect present day reality.

Given the medical necessity requirement and the refusal of insurance companies to cover experimental or investigational treatments, where does this leave CAM? While some argue that many CAM treatments are also unproven,[73] that makes them similar to, rather than different from, the myriad unproven conventional, traditional treatments that insurers routinely cover. Therefore, refusing or strictly limiting coverage for CAM appears arbitrary.

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[68] Rosenbaum, *supra* note 15, at 230-31.

[69] *See supra* notes 42-63 and accompanying text.

[70] *Id.*; Morreim, *supra* note 15, at 1011 ("If health plans clearly owe their beneficiaries medically necessary care, . . . it is not at all clear what medical necessity means.").

[71] *See supra* notes 29-33 and accompanying text.

[72] Noah, *supra* note 33, at 362 ("To a greater or lesser extent, all medical interventions have an experimental quality to them.").

[73] Kathleen M. Boozang, *Is this Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567 (2000) (arguing that physicians should not offer unproven alternative therapies); Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185 (1998) (arguing that CAM is unproven in both safety and efficiency and that insurers should not cover CAM treatments).

II. COMPLEMENTARY AND ALTERNATIVE MEDICINE

Defining CAM is not easy. The National Institutes of Health define CAM in general terms as "a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine."[74] For purposes of this article, the varieties of CAM are too numerous to lump together. A sampling of CAM therapies includes chiropractic,[75] acupuncture,[76] massage therapy,[77] homeopathy,[78] reflexology,[79] iridology,[80] kinesiology,[81] nutritional therapy,[82] color therapy,[83] and reiki.[84] Each modality is unique, although there are often shared similarities.[85] Acupuncture and shiatsu massage, for example, both work on the meridian system in an effort to balance the patient's energy. Similarly, acupuncture is often combined with herbal

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[74] *See supra* note 7.

[75] "Chiropractic . . . focuses on the relationship between bodily structure (primarily that of the spine) and function. . . . [c]hiropractors use manipulative therapy as an integral treatment tool." NCCAM, *supra* note 7.

[76] *See infra* note 94 and accompanying text (discussing acupuncture).

[77] Massage therapy is a type of bodywork that includes Swedish massage, shiatsu, thai massage, reflexology, and reiki.

[78] Homeopathy is a system of medicine based on the "Law of Similars." National Center for Homeopathy, *What is Homeopathy?*, *at* http://www.homeopathic.org/whatis.htm (last visited Mar. 30, 2004); *see also* Reflexology Association of America, *Terms and Publications*, http://www.reflexology-usa.org/def_pub.htm (defining homeopathy as a "holistic medical science developed over 200 years ago . . . [that] employs the use of minute doses of natural remedies that are created from herbal, mineral and animal substances.") (last updated Feb. 22, 2004).

[79] "Reflexology is the systematic, manual stimulation of the reflex maps located on the feet, hands and outer ears that resemble a shape of the human body." Reflexology Association of America, *supra* note 78.

[80] Iridology is the study of the iris of the eye to diagnose disease under the assumption that every organ in the body has a corresponding location within the iris. The Skeptics Dictionary, *Iridology*, http://skepdic.com/iridol.html (last visited Mar. 30, 2004).

[81] Kinesiology is the study of movement. American Academy of Kinesiology & Physical Education, *Historical Overview*, http://www.aakpe.org/aakpe1.htm (last updated Nov. 11, 1997).

[82] Although this article will not discuss nutritional therapy as part of the medical paradigm, it is another important source of health. The costs associated with organic fruits, vegetables and meats, not to mention the costs of nutritional supplements are all generally borne by the patient. This article does not suggest that health insurance should begin to pay for groceries from health food stores.

[83] Color therapy is also known as chromotherapy and is used by CAM practitioners to balance energy in areas of the body which are lacking. Phylameana Lila Desy, *Color Therapy – Chromotherapy*, http://healing.about.com/library/weekly/aa080699.htm?once=true& (last visited Mar. 30, 2004).

[84] Reiki is a method of natural healing based on the application of universal life force energy. David Heron, *What is Reiki*, http://reiki.7gen.com (last visited Mar. 30, 2004).

[85] CAM disciplines are generally holistic in nature and emphasize the mind, body and spirit connection. Essentially, the theory is that because all are connected, the health of each affects the health of the other two. *See* CAROLINE MYSS, ANATOMY OF THE SPRIT, THE SEVEN STAGES OF POWER AND HEALING (1996).

therapy, which, like nutritional therapy, relies on what the patient consumes to enhance biological well-being. And reflexology is a form of massage therapy.

The demand for CAM is huge and growing regardless of which definition is employed. Despite legal restrictions that render access to CAM more difficult,[86] CAM has undergone extraordinary growth in the past decade. One commentator describes this growth as a "quiet revolution."[87] A 1990 study concluded that one-third of the U.S. population had consulted CAM providers, and had spent $13.7 billion on CAM.[88] By 1997, a follow up study found that 42% of Americans had used CAM and had spent $27 billion in the process.[89] There are other signs as well not only of the growth of CAM, but of its growing acceptance in the United States.[90] The National Center for Complementary and Alternative Medicine ("NCCAM") for example, is devoted to studying complementary and alternative medicine.[91] The mission of the NCCAM is to "facilitate the evaluation of alternative treatment modalities."[92] The dedication of federal resources toward the study of CAM has helped to legitimize it, though uncertainty continues to surround the efficacy of many CAM treatments.

One reason for this continued uncertainty is that modern technology is not always capable of effectively measuring their efficacy. This is particularly true for those CAM disciplines that are based on balancing the patient's energy or *qi*.[93] Acupuncture, for example, which predates modern medicine, is based on

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[86] *See infra* notes 127-93 and accompanying text.

[87] Aimee Doyle, *Alternative Medicine and Medical Malpractice Emerging Issues*,22 J. LEGAL MED. 533 (2001).

[88] David M. Eisenberg et al., *Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use*, 328 NEW ENG. J. MED. 246 (1993).

[89] David M. Eisenberg et al., *Trends in Alternative Medicine Use 1990-1997: Results of a Follow-up National Survey*, 280 J. AM. MED. ASS'N. 1569 (1998); *see also* AARP, *Complementary and Alternative Medicine: The Road Less Traveled?*, *at* http://www.research.aarp.org/health/ib46_medicine.pdf (last visited Feb. 26, 2003).

[90] *See supra* notes 7-11 and accompanying text.

[91] *See* NCCAM, *About NCCAM*, http://www.nccam.nih.gov/about/aboutnccam/aboutnccam.pdf (last modified Feb. 5, 2004) (stating that "NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine (CAM) researchers, and disseminating authoritative information to the public and professionals.").

[92] U.S. Dep't of Health & Human Services, NIH, *NCCAM*, http://www.nih.gov/about/almanac/organization/NCCAM.htm (last visited Mar. 30, 2004). The NIH first initiated its study of alternative medicine in 1992 with the creation of the Office for the Study of Unconventional Medical Practices. *Id.* It was subsequently renamed the Office of Alternative Medicine and later Called the Office of Complementary and Alternative Medicine. *Id.* The name changes alone reflect the increasing acceptance of many forms of complementary care, making them not "unconventional" but merely complementary to conventional practices. *Id.*

[93] Acupuncture, kinesiology, reiki, and to some degree reflexology and massage therapy fall into this category. *See infra* notes 94-96 and accompanying text. Energy is sometimes referred to as "qi," "chi"or "prana" in some Eastern cultures. *See, e.g.*, TED J. KAPTCHUK, THE WEB THAT HAS NO WEAVER: UNDERSTANDING CHINESE MEDICINE 35 (1983) (stating that "[q]i is not . . . merely

balancing the patient's entire energy system.[94] Although this treatment physically places needles in the body, the purpose of the needles is to increase or balance the patient's energy, which in turn helps enhance the functioning of internal organs. Yoga, a form of exercise that is often encouraged for cancer patients, is also based on movements that balance or strengthen the energy field. The fact that conventional medicine has just begun to understand and measure energy medicine or energy anatomy[95] does not detract from its legitimacy. Conventional medicine has a limited understanding at best of how and why CAM energy treatments work. This makes perfect sense because conventional treatments are based on physical, rather than energetic, symptoms. Current technology is incapable of measuring shifts in a patient's energy.[96] Instead, we need trained CAM health providers to assess energetic changes. It is important to bear in mind though that the shortcoming is not necessarily on the part of the energy-based treatments, but on the ability of conventional medicine to evaluate them. Conventional medical technology is designed to measure physical rather than energetic changes.[97] Therefore, at present, the only way to measure the usefulness of CAM energy-based techniques is to follow patients' progress over time, which requires long-term, and presumably costly study.

Another factor that makes many CAM modalities difficult to measure from an efficacy perspective is that they are often specific to the individual. For example, if two patients visit an acupuncturist complaining of similar symptoms, the acupuncturist may treat each patient differently depending on what the acupuncturist believes to be the underlying cause of the symptoms in each case.[98] Thus, two different treatments may be used, each corresponding to the individual needs of the patient. If each recovers from his or her symptoms, one could attribute the success to acupuncture but not to a specific treatment within acupuncture. The idea that a randomized clinical trial can measure the worth of a

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vital energy, although the word is occasionally so translated. . . . [W]e can perhaps think of Qi as matter on the verge of becoming energy, or energy at the point of materializing.").

[94] KAPTCHUK, *supra* note 93, at 79 (stating that "[t]he basic idea behind acupuncture . . . is that the insertion of very fine needles into points along the Meridians can rebalance bodily disharmonies. . . The needles balance the Qi and the bodily organs."). Acupuncturists assess the level and flow of qi by engaging in pulse diagnosis. A number of CAM disciplines are based on the principle of balancing the flow of energy. *See supra* note 93 and accompanying text.

[95] KAPTCHUK, *supra* note 93; *see also* MYSS, *supra* note 85. Myss is perhaps the person who has been best able to educate the layperson about energy anatomy. Through her many writings and lectures, she has brought to an understandable level the theory behind energy anatomy. Although Caroline Myss' contemporary explanations of energy anatomy have helped many more people understand it, energy anatomy is not new.

[96] The sophistication of modern medical equipment is nonetheless astounding. For example, conventional medicine has machines for conducting magnetic resonance imaging ("MRI"), CT scans, mammography, and radiation therapy equipment, among others.

[97] *See* CAROLINE MYSS, ENERGY ANATOMY (Sounds True CD-ROM, 2002). Caroline Myss, who is well-known for her work on energy and health, predicts that the study of health and anatomy will one day begin with the study of energy anatomy before the study of physical anatomy. *Id.* at disc 7.

[98] KAPTCHUK, *supra* note 93, at 4-7.

specific treatment does not, therefore, easily apply in this context.[99] Finally, many forms of CAM are holistic in nature and incorporate mind, body, and spirit techniques. Therefore, an entire CAM modality may not easily lend itself to the traditional clinical trial.[100] To the extent that randomized clinical trials can be conducted, they will face the same time and financial constraints as those associated with conventional medical clinical trials.[101]

Despite the difficulties associated with measuring the efficacy of CAM treatments, several have been shown to be beneficial. According to the NIH, for example, "[r]esearch shows that acupuncture is beneficial in treating a variety of health conditions,"[102] including pain relief and nausea.[103] The NIH has also reported a consensus statement that "behavioral and relaxation interventions . . . are effective in the treatment of chronic pain and insomnia."[104] Moreover, the NIH reports that there is "strong evidence for the use of hypnosis in alleviating pain associated with cancer."[105] A study involving Co-enzyme Q10 "suggest[s] that it can slow disease progression in patients with early-stage Parkinson's disease. . . . [i]t is also a potent antioxidant."[106] Ongoing research is being

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[99] David G. Warren, Book Review, 18 J. LEGAL MED. 257, 261 (1997) (reviewing JULIE STONE & JOAN MATTHEWS, COMPLEMENTARY MEDICINE AND THE LAW (1996)); Boozang, *Western Medicine Opens the Door to Alternative Medicine*, *supra* note 73, at 207-08 (criticizing use of untested CAM treatments).

[100] Tillman, *supra* note 24, at 69 (stating that "'The acceptable double-blind approach to research, although appropriate for traditional allopathic research, is not appropriate for CAM procedures.' . . . Both sides of the debate agree that conventional, allopathic medicine and alternative medicine operate under different philosophical and epistemological assumptions.") (quoting Ingrid Lucis, *Testimony Before the White House Commission on Complementary and Alternative Medicine* (Oct. 16, 2000), *available at* http://govinfo.library.unt.edu/whccamp/meetings/transcript_10_06_00_afternoon.txt); *see also* Michael H. Cohen, *A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing*, 27 ARIZ. ST. L. J. 79, 85 (1995).

[101] *See supra* notes 64-68 and accompanying text.

[102] NCCAM, *Acupuncture*, Mar. 2002, *available at* http://nccam.nih.gov/health/acupuncture/acupuncture.pdf.

[103] *Id.* A non-Federal, non-advocate panel further concluded that,

> promising results have emerged . . . showing the efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, stroke, rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative.

Id. (citing NIH, *NIH Consensus Statement: Acupuncture*, Nov. 3-5, 1997, *available at* http://odp.od.nih.gov/consensus/cons/107/107_statement.htm); *see also* Cohen, *supra* note 100, at 96.

[104] NIH, *NIH Technology Assessment Conference Statement: Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia*, Oct. 16-18, 1995, *available at* http://consensus.nih.gov/ta/017/017_statement.htm.

[105] *Id.*

[106] Press Release, Nat'l Institute of Neurological Disorders and Stroke, Study Suggests Coenzyme Q10 Slows Functional Decline in Parkinson's Disease (Oct. 14, 2002), *available at*

conducted by the NCCAM to assess the efficacy of a variety of other CAM treatments.[107]

Physicians also recognize the legitimacy of some forms of CAM. Medical oncologists,[108] for example, routinely have literature in their offices on stress management, acupuncture, meditation, or yoga, among other things. In a survey of 572 physicians, "92% encouraged at least one unconventional therapy."[109] In fact, a number of major medical centers now have CAM units available for their patients.[110] Moreover, state statutory definitions of various CAM modalities often imply state recognition of their potential health benefits.[111] Even medical schools now offer courses on CAM.[112] Thus, it is time for the laws governing CAM, particularly those related to health insurance, to catch up.

III. LEGAL CHALLENGES TO MAINSTREAMING CAM

To 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.[113] Perhaps for this reason, among others,[114] some inroads have been made toward mainstreaming CAM. For example, most states recognize the legitimacy of at least some forms of CAM by imposing educational and licensing requirements on certain CAM practitioners.[115] Every state, for example, licenses chiropractors,[116] and more

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http://www.ninds.nih.gov/news_and_events/pressrelease_parkinsons_coenzymeq10_101402.htm. This study will be followed by a larger, definitive study. *Id.*

[107] *See* NIH, *Research*, http://nccam.nih.gov/research/ (last modified Mar. 3, 2004).

[108] A medical oncologist is a physician who specializes in treating cancer with medication.

[109] Cohen, *supra* note 100, at 106.

[110] In New York, New York-Presbyterian Hospital is among those that offer CAM services. New York-Presbyterian Hospital, *Complementary, Alternative, and Integrative Medicine*, http://wo-pub2.med.cornell.edu/cgi-bin/WebObjects/PublicA.woa/2/wa/viewService?servicesID=144&website=nyp&wosid=aGcrxTtpCfMQvlNP0EXRfw (last visited Mar. 30, 2004).

[111] Cohen, *supra* note 100, at 95-98.

[112] Deborah Daly, *Alternative Medicine Courses Taught at US Medical Schools: An Ongoing Listing*, 1 J. ALT. COMP. THER. 205 (1995); Barrette, *supra* note 37, at 77 (noting that 60% of American medical schools offer CAM training).

[113] *See supra* notes 42-63 and accompanying text.

[114] Patients often express feelings of well-being after visiting their CAM providers. The experience can be much richer than seeing the conventional physician who is often pressured because of lowered fees from managed care companies, to see so many patients per day that few receive the individual time and attention that they want.

[115] *See, e.g.*, ALA. CODE § 34-43-21 (2003) (requiring licensed massage therapists to complete sixteen hours of continuing education as a condition to renew their licenses); § 34-43-9 (requiring completion of a massage therapy program and providing specific number of hours that must be dedicated to certain areas); NEB. REV. STAT. § 71-1,348 (2003) (requiring an applicant for acupuncture license to have completed an acupuncture curriculum at a board-approved university or college, or school of acupuncture and 1,725 hours of entry-level acupuncture education); NEV. REV. STAT. 634A.167 (2003) (requiring every individual applying for a renewal of their oriental medicine license to comply with the board's continuing education requirements); N.J. STAT. ANN. § 45:2C-15 (West 2004) (creating standards for an acupuncturist's continuing education); § 45:2C-9

than half license acupuncturists.[117] As of the mid 1990s "twenty-three states [licensed] massage therapists."[118]

In 1995 Washington enacted a key piece of legislation mandating health insurance coverage for CAM providers.[119] This legislation, the Alternative Provider Statute, requires health plans to "[p]ermit every category of health care provider to provide health services or care for conditions included in the basic health plan."[120] The Alternative Provider Statute "forbids a carrier from excluding an entire category of licensed providers, for example, all chiropractors or naturopaths, from its policy."[121] Accordingly, all "providers who are licensed, registered, or certified by the state of Washington, including naturopaths, acupuncturists, licensed midwives, chiropractors, and massage therapists" are covered by Washington's Alternative Provider Statute.[122]

In addition to legislative efforts, insurance companies have begun initiatives that include CAM coverage.[123] Oxford, for example, began offering CAM

(requiring a bachelor's degree and a two year course of study, or the completion of a board approved tutorial program).

[116] *See, e.g.*, FLA. STAT. ANN. § 460.403(5)(West 2002) (defining a chiropractic physician as one who is licensed to practice chiropractic medicine in Florida); GA. CODE ANN. § 43-9-7 (2002) (requiring an individual desiring to practice chiropractic medicine in Georgia to be licensed); N.J. STAT. ANN § 45:9-41.5 (West 2004) (requiring that all individuals practicing chiropractic medicine in New Jersey be licensed); *see also* Boozang, *Western Medicine Opens the Door to Alternative Medicine*, *supra* note 73, at 196. Moreover, the U.S. Department of Education recognizes certain chiropractic colleges. *See* Chiropractic Colleges in the United States, http://www/fclb.org/directory/colleges.pdf (last visited Feb. 26, 2003).

[117] MICHAEL H. COHEN, COMPLEMENTARY AND ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES 43 (1998); *see also* American Ass'n of Oriental Medicine, http://www.aaom.org (last visited Mar. 30, 2004); NIH, *Research Report: Acupuncture, Check a Practitioner's Credentials*, http://www.nccam.nih.gov/health/acupuncture/#checkcredentials (stating that "[a]bout 40 States have established training standards for acupuncture certification, but States have varied requirements for obtaining a license to practice acupuncture.") (citation omitted).

[118] Tillman, *supra* note 24, at 71; *see also* Cohen, supra note 100, at 91-92 ("[A]bout a dozen [states] license naturopaths.").

[119] WASH. REV. CODE § 48.43.045(1) (2002); *see* N.Y. PUB. HEALTH LAW § 230(1) (McKinney 2004), *available at* http://assembly.state.ny.us/leg/?cl=91&a=8 (creating a board for professional medical conduct that consists of two doctors of osteopathy, who dedicate a "significant portion of their practice to the use of non-conventional medical treatments who may be nominated by New York state medical associations dedicated to the advancement of such treatments.").

[120] WASH. REV. CODE § 48.43.045(1).

[121] Wash. Physicians Serv. Ass'n v. Gregoire, 147 F.3d 1039, 1042-43 (9th Cir. 1998).

[122] Tillman, *supra* note 24, at 68. Washington also established the "first government-subsidized natural medicine clinic." Wash. Physicians Serv. Ass'n, 147 F.3d at 1042-43; *see also* Melanie K. Curtice, Comment, *Every Category of Provider: Hindsight is 20/20 Vision*, 21 SEATTLE U. L. REV. 317, 318 (1997).

[123] UnitedHealth Group offers "network-based complementary and alternative medicine benefit services for employers and insurers" which includes acupuncture, massage therapy, naturopathic medicine and nutritional supplements. UnitedHealth Group, *Products and Services*, http://www.unitedhealthgroup.com/global/prodserv.htm (last visited Mar. 30, 2004). Health Net Oregon became the first Oregon insurer in April 2000 to provide chiropractic treatment, acupuncture, naturopathic medicine and massage therapy as core benefits to all of its insured

coverage in 1997.[124] In a recent brochure, it uses that coverage to convince members of its dedication to providing the kinds of services they demand.[125] Other insurers have made similar initiatives.[126] In fact, insurers have begun to realize that cost savings may result from covering CAM.[127] Despite these inroads, significant challenges remain for patients who seek insured CAM treatments.

First, health insurance coverage is much more readily available for conventional medical treatments than it is for CAM.[128] "A nationwide survey of ten thousand adults conducted in 1997 and 1998, which asked respondents about their use of alternative medicine, and excluded chiropractic treatments from the definition of alternative medicine found that 72 percent of those visits . . . were paid for out of pocket . . . ."[129] One reason for the disparity in health insurance coverage between CAM and conventional care is that the legal system has failed

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members. *See* Press Release, Health Net, Health Net Oregon and Complementary Healthcare Plans to Provide First Member-Wide Core Benefit Offering of Complementary Health Care in Oregon (Apr. 26, 2000), *available at* http://www.healthnetoregon.com/news/releases/2000_04_26.asp. Additionally, Kaiser Permanente expanded their complementary and alternative care coverage to 540,000 members in the mid-Atlantic region beginning January 1, 2000. *See* Press Release, Kaiser Permanente, Kaiser Permanente Launches New Complementary and Alternative Healthcare Package for all Mid-Atlantic Members (Oct. 12, 1999), *available at* http://www.ashplans.com/NewsPress/content/Articles/1999/p_oct121999.asp. Kaiser Permanente's coverage will include chiropractors, acupuncturists and massage therapists. *Id.* A recent study in the northeast found that chiropractic services are covered by almost all health insurance companies, but less than half the insurers reimbursed for acupuncture and even fewer covered massage therapy. *Regional Survey Examines Health Insurance Coverage for Complementary and Alternative Health Care Services*, TODAY'S CHIROPRACTIC, Nov/Dec 2002.

[124] *See* Oxford Health Plans, *Frequently Asked Questions About Oxford's CAM Program*, *at* https://www.oxhp.com/altmed/program/oxford_faqs.html (last visited Mar. 30, 2004).

[125] *See* Oxford Health Plans, *Healthy Mind Healthy Body Your Oxford Guide to Living Well*, Fall 2003, *available at* https://www.oxhp.com/secure/materials/member/hmhb_current.pdf (last visited Mar. 27, 2003) ("At Oxford, we know there's more than one path to wellness. . . . We've . . . created a new feature that we call the CAM connection, which focuses on integrated approaches to healthcare. The CAM Connection presents dialogue between conventional and alternative medicine providers."). Oxford Health Insurance covers chiropractors, acupuncturists, naturopaths (in Connecticut only), yoga instructors, massage therapists, and nutritionists. *Id.*

[126] *See supra* text accompanying note 123; *see also* Barrette, *supra* note 37, at 76 (stating that "Kaiser Permonente, the largest HMO, . . . Western Life, Mutual of Omaha, and Blue Cross Blue Shield now offer some level of reimbursement for alternative therapies."); Doyle, *supra* note 87, at 539 n.33.

[127] *See* Barbara Whitaker, *Providing Alternatives*, CHICAGO TRIBUNE, Dec. 6, 1996, at C7 ("Managed care organizations are competing bitterly . . . .") (citing George Lundberg, former editor of J. AM. MED. ASS'N); *see also* Doyle, *supra* note 87.

[128] Tillman, *supra* note 24, at 64; *see also* Roland Sturm & Jurgen Unutzer, *State Legislation and the Use of Complementary and Alternative Medicine*, 37 INQUIRY 423 (2001); *infra* notes 129-30 and accompanying text.

[129] Tillman, *supra* note 24, at 65.

to address the inability of the medical necessity test to adequately incorporate CAM.[130]

The following hypothetical illustrates the practical shortcomings of relying on the medical necessity test. Heather was diagnosed with breast cancer.[131] Like many other cancer patients, Heather underwent the conventional cancer treatments – surgery, chemotherapy, and radiation. Although these therapies hold some promise for killing cancer cells,[132] they also take a toll on the rest of the body. Chemotherapy, for example, can cause a variety of side effects ranging from nausea to fatigue to hair loss to death.[133] Radiation also causes fatigue and weakens the body.[134] Therefore, it is logical for cancer patients like Heather to seek out other body strengthening therapies to help offset the side effects of these conventional cancer treatments.

Heather did just that; she now has an acupuncturist and a massage therapist. In addition, she takes Chinese herbs, vitamins and other supplements, and has drastically improved her diet.[135] The cost of these complementary treatments is approximately $400 per month,[136] 80-90% of which are not reimbursed by Heather's health insurer. Despite the implicit acknowledgement by many conventional medical practitioners of the usefulness of certain CAM therapies, such treatments are not covered.[137]

This is not unusual. While insurers have made advances in covering CAM treatments,[138] the advances do not go far enough. Heather's health insurer, for example, provides limited coverage for acupuncture treatments but only if she sees a "participating" acupuncturist; it provides no reimbursement for care

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[130] Of course, there are also historical reasons for the disparity. CAM has not always enjoyed the growth and acceptance that it is experiencing today. *See infra* note 167 and accompanying text.

[131] In 2000, 1.3 million people were diagnosed with cancer. *See* Press Release, Nat'l Cancer Institute, Annual Report Shows Overall Decline in U.S. Cancer Death Rates; Cancer Burden is Expected to Rise with an Aging Population (May 14, 2002), *available at* http://newscenter.cancer.gov/pressreleases/2002reportnation.html.

[132] Although there have been advances in the treatment of cancer, there is no absolute cure.

[133] Some common side effects include sore mouth, gums and throat; nerve and muscle problems; dry skin, kidney and bladder irritation and sexuality and fertility effects on reproductive organs. American Cancer Society, *What are Common Side Effects?*, http://www.cancer.org/docroot/MBC/content/MBC_2_2x_What_Are_Common_Side_Effects.asp?silearea=MBC (last revised Jan. 22, 2001).

[134] *See* Cancer Treatment Centers of America, *CTCA After Care Services: Fatigue and Weakness*, *at* http://www.cancercenter.com/aftercareservices/fatigue.cfm (last visited Mar. 30, 2004).

[135] This article addresses insurance coverage only for the professional services of CAM providers. It does not address insurance coverage for herbs and vitamins. Nor does it suggest that insurance coverage should be provided for organic products, which typically cost more than non-organic products.

[136] This figure does not include the increased food costs she incurs by purchasing mostly organic fruits and vegetables and free range antibiotic and hormone free meats.

[137] Oncologists' offices, for example, often have literature about various CAM modalities like acupuncture, yoga, and stress management techniques. *See supra* notes 108-09 and accompanying text.

[138] *See supra* notes 122-26 and accompanying text.

provided by "non-participating" acupuncturists.[139] Coverage for CAM treatments is not at all commensurate with the coverage Heather receives for conventional medical care, which is 70% of charges by non-participating physicians after meeting the annual deductible and all but minimal co-payments for participating physicians.

Heather's case demonstrates the current problem with the medical necessity test. Health insurers do not routinely accept the customary practice of licensed CAM providers as proof of medical necessity, but limit their inquiry to the customary practice of conventional medical doctors.[140] Typically, the conventional physician does not practice CAM. By making health insurance coverage determinations in this manner, health insurers arbitrarily exclude potentially beneficial CAM treatments simply because they are not customarily used by medical doctors. Thus, entire systems of health care may be excluded from coverage.

In Heather's case, the insurer is more progressive than some others. It pays for some CAM, but the coverage is unduly restrictive. The insurer will only reimburse acupuncture services provided by a participating acupuncturist. If Heather's acupuncturist is not a participating provider, the services are wholly excluded from coverage. Yet this acupuncturist may be the CAM provider whose range of services best satisfies Heather's needs. Thus, it becomes clear that while CAM struggles to permeate the mainstream of the health care system, it remains in large part on the periphery, and patients like Heather may be financially unable to receive beneficial CAM treatments.[141]

Thus, broader insurance coverage for CAM is needed so that the public will have greater access to it. Although some legislative advances have been made, Washington stands alone in the breadth of health insurance coverage that it mandates. Moreover, even Washington's Alternative Provider Statute is limited in scope. For example, as a state insurance regulation, it does not apply to employer self-insured ERISA plans.[142] Thus, the statute can be easily

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[139] In the world of managed care, which dominates today's health insurance market, participating health care providers are those who have an agreement with the managed care plan to provide service for a limited fee. That fee can be either a fixed or capitated fee per patient or a discounted fee for service. *See generally* John D. Blum, *Lawyering for a New Democracy: Leveraging Quality in Managed Care: Moving Advocated Back Into the Box*, 2002 WIS. L. REV. 603, 611-12.

[140] Medical doctors, of course, should not be expected to engage in treatment for which they lack training and understanding. Their lack of knowledge and understanding of what CAM is and how it can benefit patients, however, should not be at the patients' expense.

[141] Data suggests that those who seek CAM are generally well-educated and financially well-off, which is arguably due in part to the expense associated with unreimbursed CAM treatments. *See infra* notes 144-149; *see also* Sturm & Unutzer, *supra* note 128, at 423, 424 (noting that individuals were more likely to seek CAM treatments in states that mandate insurance coverage for two or more CAM modalities); Tillman, *supra* note 24, at 68.

[142] *See* Wash. Physicians Serv. Ass'n v. Gregoire, 147 F.3d 1039, 1043 (9th Cir. 1998) ("[I]f ABC Corporation were itself the health self-insurer for its employees, the Act would not apply at all."); *see also supra* note 13 for an overview of ERISA.

circumvented by large employers that decide to self-insure.[143] In fact, as of the early 1990s "40 percent of all insured employees [nationwide] were covered under health insurance plans that were self-insured and therefore were not subject to state oversight."[144] Despite its limitations, Washington's Alternative Provider Statute has gone further than any other in its effort to expand health insurance coverage for CAM providers.

In addition to the need for more expansive statutory changes, a shift is also required on the part of health insurers. Rather than confining their focus to the customary practice of conventional medical doctors, health insurers need to cover customary treatments by licensed CAM providers as well. While some health insurers have expanded their coverage of CAM in recent years, such coverage remains limited. Health insurance 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.[145] As one commentator explains:

> [T]he majority of . . . [CAM] treatments are paid for out of pocket rather than being reimbursed by third parties . . . [h]ealth insurance companies do provide such benefits when required by law through state mandates, and they do so voluntarily for certain forms of alternative medicine. *But in the absence of legal requirements and for the great majority of CAM treatments, insurers tend not to provide coverage.* . . . Alternative medicine has not been well integrated into the American system of health insurance.[146]

Sometimes coverage is provided pursuant to state mandates. This is generally true for chiropractic treatments.[147] However, state mandates for CAM are limited.[148] In fact, there are many CAM modalities that states do not recognize at all. While all states license chiropractors and most license acupuncturists, a significant number of states do not license acupuncturists, despite acupuncture's proven efficacy.[149] Moreover, no state licenses "practitioners of . . . biofeedback, herbal medicine or Tibetan medicine. . . . [and] [o]nly eleven states [license] practitioners of naturopathy."[150] A correlation

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[143] *See Wash. Physicians Serv. Ass'n*, 147 F.3d at 1043.

[144] Tillman, *supra* note 24, at 69. Thus, an argument can be made that even with the proposed shift from medical to reasonable necessity outlined in Part IV, additional changes will be needed to ensure greater access to CAM for employees covered by ERISA employee benefit plans.

[145] "A 1998 Mercer/Foster Higgins study found that 59 percent of point-of-service plans (POS) cover chiropractic, while about 45 percent of health maintenance organizations (HMO's) cover [chiropractic services.]" *See* AARP, *Complementary and Alternative Medicine: The Road Less Traveled?* 6, *at* http://www/research.aarp.org/health/ib46_medicine.pdf (last visited Mar. 30, 2004).

[146] Tillman, *supra* note 24, at 65, 67. Tillman goes on to explain that "coverage of homeopathic treatments was provided by only 4 to 11 percent of all plans; acupuncture, 9 to 19 percent; biofeedback, 4 to 10 percent; and massage therapy, 6 to 10 percent." *Id.* at 67.

[147] "By 1998, forty-two states required licensed insurers to provide some type of coverage for chiropractic treatments." *Id.* at 68.

[148] Sturm & Unutzer, *supra* note 128.

[149] *See supra* note 117 and accompanying text.

[150] Tillman *supra* note 24, at 71; *see also* Cohen, *supra* note 100, at 91-92.

exists between state recognition and licensing of CAM practitioners and health insurance coverage. "In a survey of eighteen insurance carriers, [it was] found that among those that did cover [CAM] services, reimbursement levels were based in part on whether the provider was licensed."[151]

Instead of expanding insurance coverage for CAM, state laws have focused primarily on giving conventional medical doctors a larger piece of the CAM pie. Rather than widen the health insurance umbrella to include licensed CAM practitioners, state laws have focused on permitting conventional medical doctors to include non-conventional treatments in their practices. While this flexibility may be useful, such legislation needs to go further and explicitly provide for health insurance coverage when CAM treatments are provided by specially trained and licensed CAM providers.

This is especially true since the laws designed to allow conventional medical doctors to incorporate non-conventional treatments do not always achieve the intended result. In 1994, for example, New York enacted The Alternative Medical Practice Act, which explicitly permits physicians to use "effective" "non-conventional" treatments.[152] While it might appear that this

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[151] Tillman, *supra* note 24, at 71 (referencing Kenneth Pelletier et al., *Current Trends in the Integration and Reimbursement of Complementary and Alternative Medicine by Managed Care, Insurance Carriers, and Hospital Providers*, 12 AM. J. HEALTH PROMOTION 112 (1997)). *Cf.* Peter J. Van Hemel, Comment, *A Way Out of the Maze: Federal Agency Preemption of State Licensing and Regulation of Complementary and Alternative Medicine Practitioners*, 27 AM. J. L. MED. 329, 333 (2001) (discussing three levels of licensure: mandatory licensure, title licensure (certification) and registration).

[152] N.Y. EDUC. LAW § 6527(4)(e) (McKinney 1994) ("This article shall not be construed to affect or prevent the following . . . [t]he physician's use of whatever medical care, conventional or non-conventional, which effectively treats human disease, pain, injury, deformity or physical condition."); *see* Ralph Moss, *A Major Victory for Choice: New York State Passes Alternative Medical Practice Act, Ralph Moss on Cancer*, CANCER CHRON'S, Sept. 24, 1994, *available at* http://www.ralphmoss.com/html/nys2.shtml. The Alternative Medical Practice Act recognizes the role of alternative medical treatments, allows two non-conventional practitioners to take positions on the State Board of Medical Conduct, and encourages greater involvement of these physicians in investigation of misconduct cases. *See also* ALASKA STAT. § 08.64.326(a)(8)(A) (Michie 2002) ("[The] board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional . . . in the absence of demonstrable physical harm to a patient."); COLO. REV. STAT. § 12-36-117(3)(a) (2002) ("The board shall not take disciplinary action against a licensee solely on the grounds that such licensee practices alternative medicine."); GA. CODE ANN. § 43-34-42.1 (2002) ("An individual shall have the right to be treated . . . with nonconventional medical treatment. . . . The treatment of patients incompliance with this Code . . . shall not by itself constitute unprofessional conduct."); MASS. GEN. LAWS ch.112, § 7 (2002) (stating that laws shall "not be held to discriminate against any particular school or system of medicine."); N.C. GEN. STAT. § 90-14(a)(6) (1993) (stating that the Board shall not revoke a physician's license "solely because of that person's practice of a therapy that is . . . nontraditional . . . unless . . . the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective."); OHIO REV. CODE ANN. § 4731.227 (Anderson 2001) (stating that a physician may "use alternative medical treatments" if the "treatment meets the standards enforced by the state medical board."); OKLA. STAT. tit. 59, §

legislation would give conventional physicians the flexibility to incorporate CAM into their practices, the bias against CAM treatments remains, and conventional medical doctors are often challenged by state boards when they incorporate such non-conventional treatments into their practices.[153] Furthermore, in New York, the statute has been construed in such a way as to undermine the apparent legislative intent.

For example, in *Gonzales v. New York State Department of Health*,[154] Dr. Gonzales treated cancer patients with nutritional therapy.[155] When he was brought before the Board for Professional Medical Conduct due to his use of non-conventional treatments, Dr. Gonzales made two arguments: first, that the proceeding against him reflected a bias against non-conventional treatments;[156] and second, that because the Alternative Medical Practice Act mandated that at least two of the eighteen Board members be non-conventional physicians, he was entitled to a hearing committee that consisted of at least one non-conventional physician.[157] The court rejected both arguments and agreed with the Board that alternative medicine involves a different treatment regime than conventional medicine.[158] Nonetheless, it held Dr. Gonzales "to the same standard of care to which all physicians in New York are held."[159] With respect to the second argument, the court concluded that the Act simply requires that there be two non-conventional physicians on the eighteen member Board of Professional Medical Conduct. None, however, need to be assigned to a specific case involving a physician who incorporates non-conventional methods into his or her practice.[160]

492(F), 493.1(M), 509.1(D)(2) (2003) (Section 509.1(D) states that the Board "shall not revoke the license of a person otherwise qualified to practice allopathic medicine . . . solely because the person's practice or a therapy is . . . nontraditional."); OR. REV. STAT. § 677.190(1)(b) (1995) ("[T]he use of an alternative medical treatment shall not by itself constitute unprofessional conduct."); 22 TEX. ADMIN. CODE § 200.1-200.3 (West 1998) ("A licensed physician shall not be found guilty of unprofessional conduct . . . solely on the basis of employing a health care method of integrative or complementary medicine, unless it can be demonstrated that such method has a safety risk for the patient that is unreasonably greater than the conventional treatment for the patient's medical condition."); WASH. REV. CODE § 18.130.180(4) (2002) ("The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed."). *Cf.* FLA. STAT. ANN. § 456.41 (West 2003) ("It is the intent of the legislature that citizens be able to make informed choices for any type of health care they deem to be . . . effective . . . including . . . prevailing of conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing of conventional treatment methods.").

[153] Vional Patel, *Understanding the Integration of Alternative Modalities into an Emerging Healthcare Model in the United States, in* ALTERNATIVE MEDICINE AND ETHICS 45, 65 (James M. Humber & Robert F. Almeder eds., 1998).

[154] 648 N.Y.S.2d 827 (N.Y. App. Div. 1996).

[155] *Id.* at 829.

[156] *Id.* at 830.

[157] *Id.*

[158] *Id.*

[159] 648 N.Y.S.2d at 830.

[160] The court also concluded that since Dr. Gonzales' hearing took place prior to the effective date of the Act, the Act did not apply to his case. *Id.*

In *Gant v. Novello*,[161] the court adhered to its *Gonzales* analysis, concluding that "[n]otwithstanding the difference in treatment regimes between nonconventional and conventional physicians, this Court has held that all physicians who are licensed to practice in New York may be held to the same standards of care."[162] Relying on *Metzler v. New York State Board for Professional Medical Conduct*,[163] a case predating the Alternative Medical Practice Act, the court concluded 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."[164]

Combined, these three New York cases – *Gonzales*, *Gant*, and *Metzler* – suggest that the Alternative Medical Practice Act has had little if any impact. While *Metzler* arose prior to the Act, *Gonzales* arose during the time the Act became effective, and *Gant* after the Act took effect, the analysis in all three cases is identical. Therefore the failure, particularly of the court in *Gant*, to adjust its analysis based on the Act, undermines the Act completely.[165]

Despite legislation intended to help mainstream CAM into the general health care market, cases like these present an ongoing deterrent. The case law "'mirrors biomedicine's historical view of holistic practice as deviant, suspect, or "on the fringe."'"[166] Moreover, even if New York's Alternative Medical Practice Act effectively protects physicians who provide non-conventional treatments, it does not provide or even address the issue of non-physician CAM providers who employ the same non-conventional treatments.[167] The legislature condones the

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[161] 754 N.Y.S.2d 746 (N.Y. App. Div.. 2003).

[162] *Id.* at 749.

[163] 610 N.Y.S.2d 334 (N.Y. App. Div. 1994). Doctor Metzler was a physician who included homeopathy in his medical practice. He was charged with gross negligence because of his use of homeopathy. *Id.* at 334.

[164] *Id.* at 335.

[165] Cases in other jurisdictions reflect similar bias against physicians who incorporate CAM into their practices. In *In re Guess*, 393 S.E.2d 833, 837 (N.C. 1990), the Board of Medical Examiners charged Dr. Guess with unprofessional conduct pursuant to a state statute that defined unprofessional conduct as the departure from "standards of acceptable and prevailing medical practice." *Id.* at 836. At the time, Dr. Guess was the only medical doctor in the state of North Carolina who practiced homeopathy. *Id.* at 837. Thus, that practice did not represent "prevailing medical practice." *Id.* at 838. There was no evidence that Dr. Guess had ever harmed a patient with homeopathic treatments and to the contrary, there was some evidence that Dr. Guess had helped some of his patients with such treatments. *Id.* at 835. Nonetheless, the court upheld the Boards' disciplinary action. *Id.* at 840. The court concluded that unless Dr. Guess discontinued the homeopathic treatments, he would lose his license to practice medicine. *Id.* at 835. Although Dr. Guess argued that he should have the right to select his practice methods, the court disagreed. *Id.* at 839. It concluded that "'there is no right to practice medicine which is not subordinate to the police power of the states.'" *Id.* (quoting Lambert v. Yellowsley, 272 U.S. 581, 596 (1926)). Another North Carolina case similarly concluded that "there exists no protected privacy right to practice unorthodox medical treatment, here acupuncture." Majebe v. N.C. Bd. of Med. Exam'rs, 416 S.E.2d 404, 407 (N.C. 1992) (referring to *In re* Guess, 393 S.E.2d 833 (N.C. 1990)).

[166] Barrette, *supra* note 37, at 78 (quoting COHEN, *supra* note 117, at 23).

[167] N.Y. PUB. HEALTH LAW § 230 (McKinney 2004).

expansion of physicians into the CAM market, continuing the long-standing history of preserving the health care market for physicians.[168] No attempt is made to increase access to CAM treatments via non-physician CAM providers. New York's legislation simply expands upon the kinds of treatments that *physicians* can use,[169] and does not eliminate the problem of bias against physicians who include CAM in their practices, such as the bias experienced by Dr's Gonzales and Gant.[170] Moreover, the New York statute explicitly limits physicians to non-conventional treatments that are "effective."[171] As discussed above, distinguishing effective from ineffective treatments is often a guessing game,[172] but this is true of both conventional and non-conventional treatments. Just as we are unable to measure the efficacy of many forms of conventional care, we have not yet developed the ability to measure the effectiveness of many forms of CAM.[173]

Another shortcoming of the Alternative Medical Practice Act is that it does not require health insurance coverage for CAM treatments provided by non-physicians. In fact, it does not address health insurance at all.[174] The end result is that while health insurers may defer to a physician's treatment decision, whether conventional or otherwise, their limited coverage of non-physician CAM providers remains unchanged by this legislation. The physician's CAM training, however, is likely to be much more limited than his or her CAM provider counterpart.[175] The legislature needs to directly address and correct for the lack

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[168] The partial integration of CAM into the mainstream health care system follows on the heels of 150 years of strong opposition, and in some cases, hostility to CAM. Moreover, physicians continue their efforts, as they have historically, to do everything within their power to limit the ability of CAM providers to practice. For example, physicians tried to eliminate the entire practice of chiropractic. Wilk v. Am. Med. Ass'n, 895 F.2d 352 (7th Cir. 1990) (holding that the American Medical Association violated Sherman Act by conducting illegal boycott directed at chiropractors); *see also* Lori B. Andrews, *The Shadow Health Care System: Regulation of Alternative Care Providers*, 32 HOUS. L. REV. 1273, 1288-89 (1996); Barrette, *supra* note 37, at 85 ("Conventional medicine practitioners, mostly through the American Medical Association have attempted to discredit the practices of midwives, homeopaths, chiropractors, acupuncturists and naturopaths.") (citations omitted). *Cf.* Hoffman v. Regence Blue Shield, 991 P.2d 77, 78 (Wash. 2000) (plaintiffs contended that Regence violated the Alternative Provider Statute by denying coverage for services provided by complementary care providers), *rev'd on other grounds*, Wash. Indep. Tele. Ass'n v. Wash. Util. & Trans. Comm'n, 64 P.3d 606 (Wash. 2003).

[169] N.Y. EDUC. LAW § 6527(4)(e) (McKinney 2003); *see supra* note 151 and accompanying text.

[170] *See generally In re* Guess, 393 S.E.2d 833 (N.C. 1990).

[171] *See* N.Y. EDUC. LAW § 6527(4)(e).

[172] *See supra* notes 42-63 and accompanying text.

[173] *See supra* notes 93-97 and accompanying text (discussing energy anatomy).

[174] While it does not directly address insurance, the Act and others like it arguably address insurance indirectly by recognizing nonconventional treatments as legitimate and therefore potentially medically necessary.

[175] For example, New York law permits the Education Department to establish separate rules and regulations for the "certification of physicians and dentists as acupuncturists." N.Y. EDUC. LAW § 8216(3). The regulations promulgated pursuant to section 8216(3) require physicians wishing such certification to undergo a total of two hundred hours of instruction and one hundred hours of

of equity in health insurance coverage, which is currently based solely on the professional degree of the health care provider who renders the treatment. Paradoxically, health insurers may refuse to cover the acupuncture treatments provided by the licensed CAM acupuncturist who has completed years of acupuncture training because the acupuncturist is not a licensed physician, but approve coverage for the same treatment provided by a physician counterpart who has received fewer hours of acupuncture training.[176] The same limitation exists in other states.[177]

Let us take another look at Heather's case.[178] Assume that her acupuncturist is a graduate of a licensed acupuncture school, which required several years of training. The acupuncturist is not, however, a medical doctor. Thus, Heather's insurer will not cover her acupuncture treatments if the acupuncturist is not a participating provider. If, instead, Heather is treated by a physician who has undergone more limited acupuncture training and been certified to administer acupuncture treatments, she will be covered to the extent that other physician-provided treatments are covered.[179] Regardless of who she sees for treatment, a physician or a non-physician, New York has recognized acupuncture as a legitimate form of health care both by setting forth educational and licensing requirements for acupuncturists, and by allowing medical doctors to obtain acupuncture certification.[180] Ironically, however, it facilitates patient choice to undergo that care only to the extent that a lesser-trained physician provides treatment. Heather may be unable to afford the fully trained and licensed, non-physician acupuncturist.

Who benefits from this situation? Physicians benefit because the many dollars spent on acupuncture will tend to be concentrated in their hands. Patients like Heather may have no choice but to seek care from the lesser qualified physician/acupuncturist. Thus, while recognizing the benefits of CAM,

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supervised experience. N.Y. State Educ. Dept., Office of the Professions, *Regulations of the Commissioner, § 60.1 Professional Study of Medicine, available at* http://www.op.nysed.gov/part60.htm (last visited Mar. 14, 2004). Assuming a forty-hour work week, a physician could be certified to practice acupuncture in less than eight weeks. *Id.* A non-physician acupuncturist, on the other hand, must complete "a course of formal study," which typically takes three years. N.Y. EDUC. LAW § 8214(2). The candidate must also undergo satisfactory experiential training, § 8214(3), and pass an examination. *Id.* § 8214(4). Moreover, licensed acupuncturists must "advise each patient as to the importance of consulting with a licensed physician regarding the patient's condition." *Id.* § 8211(1)(b).

[176] This may be true for several reasons. Health insurers are more likely to refuse coverage when a state does not license acupuncture or other CAM disciplines. In fact they provide the broadest coverage when there is a state mandate. Sturm & Unutzer, *supra* note 128, at 427 ("Insurance mandates are associated with significantly higher levels of insurance coverage of CAM."). In addition, since physicians are licensed in every state and covered by health insurance in varying degrees in each state as well, a physician can incorporate CAM as part of the patient's office visit. Insurance is then provided as it would be for any other office visit.

[177] *Id.*

[178] *See supra* notes 131-37 and accompanying text.

[179] An insurer could, of course, argue that the treatment is not necessary regardless of who is providing it.

[180] N.Y. EDUC. LAW §§ 8216(3), 8214(2).

legislation like the New York statute retains much of the power for physicians. Insurers also stand to benefit. If Heather manages to pay the more fully trained and arguably more capable, non-physician CAM acupuncturist out of pocket, bearing the full financial brunt of her choice, the insurer pays nothing at all. For many who cannot afford the out of pocket expense, however, this may mean little choice at all. Thus, the medical necessity test, with its focus on medical doctors, continues to work in a manner that limits choice.

In addition to the medical necessity test, CAM's ability to level the playing field with conventional medicine is hampered by scope of practice statutes that define the practice of medicine (which can only be performed by licensed physicians) so broadly that any other health care providers risk being charged with practicing medicine without a license.[181] A typical definition, for example, states that the practice of medicine "includes doing, undertaking, professing to do and attempting any of the following: (1) [d]iagnosing, healing, treating, preventing, prescribing for, or removing any physical, mental, or emotional ailment, or supposed ailment of an individual."[182] Because virtually every health care provider will engage in one or more activities that come within the practice of medicine definition, those who are not physicians risk being charged with practicing medicine without a license unless they are separately licensed for their specific discipline. [183] CAM providers, along with other health care providers such as nurses and podiatrists, are typically licensed separately under their own scope of practice statutes.[184] As long as they confine their procedures and

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[181] "Since the practice of medicine is broadly defined, physicians are provided with the broadest scope of practice among health care providers." Barrette, *supra* note 37, at 80.

[182] MD. CODE ANN., HEALTH OCC. § 14-101(k)(2) (2003); 63 PA. CONS. STAT. ANN. § 422.2 (West 2003) (stating that the practice of medicine is defined as "the art and science of which the objectives are the cure of diseases and the preservation of the health of man, including practice of the healing art with or without drugs."); *see also* MO. REV. STAT. § 334.010 (2003); N.J. STAT. ANN. § 45:9-5.1 (West 2002) (stating that where the practice of medicine and surgery is defined as "any method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition."); N.Y. EDUC. LAW § 6521 (McKinney 2003) (stating that the "practice of medicine is defined as diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition."); VA. CODE ANN. § 54 1-2900 (Michie 2002). The New York courts have found that the fact that the definition of the practice of medicine is overbroad does not render it unconstitutional. *See* People v. Amber, 349 N.Y.S.2d 604 (N.Y. App. Div. 1973). The practice of medicine is also sometimes referred to as the "healing arts."

[183] Every state requires that physicians be licensed before they can practice medicine. *See, e.g.*, Pinkard v. Commonwealth, 100 S.E. 821 (Va. 1920)(holding that the defendant was properly convicted of illegally practicing medicine where he announced to the public his ability to diagnose diseases, provide treatments, and prescribe remedies for patients, but was not licensed under Virginia law as a physician); CONN. GEN. STAT. § 20-9 (2001) (stating that no person can diagnose, treat, operate, etc unless licensed under § 20-10.); N.J. STAT. ANN. § 45:9-6 (West 2002) (indicating persons practicing in New Jersey shall apply to the Board of Medical Examiners for licensure to be able to practice); TEX. OCC. CODE ANN. § 155.001 (Vernon 2002) (stating that an individual cannot practice medicine in Texas unless licensed under Texas law).

[184] *See, e.g.*, FLA. STAT. ANN. § 457.105(1) (West 2002) (stating that Florida requires that any individual who wants to practice acupuncture must be licensed in addition to taking a board-

treatments to those authorized under their respective scope of practice provisions, these non-physician health care providers are theoretically protected from being charged with practicing medicine without a license.[185]

Nonetheless, the broad statutory scope of practice definitions governing the practice of medicine protect 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.[186] Not surprisingly, scope of practice provisions for non-physicians are narrowly tailored.[187] In addition, the ambiguity and overlap in scope of practice statutes sometimes results in challenges to one's practice.[188]

Moreover, while some CAM providers are licensed, many are not. States may refuse to recognize certain CAM disciplines through their licensing mechanism.[189] Unlicensed providers, therefore, risk being charged with

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approved course of study.); VA. CODE ANN. § 54.1-2956.9 (Michie 2002) (stating that it is unlawful for a person to practice or hold himself out as an acupuncturist unless licensed by the Board of Acupuncturists).

[185] When a state recognizes CAM providers such as acupuncturists, the acupuncturists will not be charged with practicing medicine without a license as long as they are practicing within their own scope of practice. An acupuncturist, for example, may be statutorily permitted to engage in the following activities: stimulation of certain points, normalizing psychological functions, and modifying the perception of pain by insertion of needles. *See* MD. CODE ANN., HEALTH OCC. § 14-101(i) (defining acupuncture as "to stimulate a certain point or points on or near the surface of the human body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control."); *see also* N.Y. EDUC. LAW § 6551(1) (defining the practice of the profession of chiropractic as "detecting and correcting by manual or mechanical means structural imbalance, distortion, or subluxations in the human body"); N.C. GEN. STAT. § 90-451 (2002) (defining acupuncture as "the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body based upon acupuncture diagnosis as a primary mode of therapy."); VA. CODE ANN. § 54.1-2900 (defining acupuncture as " the stimulation of certain points on or near the surface of the body by the insertion of needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain ailments or conditions of the body and includes the techniques of electro acupuncture, cupping and moxibustion.").

[186] *See, e.g.*, State Bd. of Nursing & State Bd. of Healing Arts v. Ruebke, 913 P.2d 142 (Kan. 1996) (holding that lay midwife was practicing nursing and medicine without a license.). *Cf.* Hunter v. State, 676 A.2d 968 (Md. 1996); Leggett v. Tenn. Bd. of Nursing, 612 S.W.2d 476 (Tenn. Ct. App. 1980).

[187] *See supra* note 182; *see also* Cohen, *supra* note 100, at 85 ("Nonmedical health care professionals . . . have limited licensure. . . . [t]o avoid charges of practicing medicine unlawfully, these nonmedical healing professionals must . . . limit the scope of their activities to the statutorily defined conduct.").

[188] Foster v. Ga. Bd. of Chiropractic Exam'rs, 359 S.E.2d 877 (Ga. 1987) (licensed chiropractor who dispensed nutritional substances charged with exceeding his scope of practice); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. 1983) (nurses, concerned that they would be charged with unauthorized practice of medicine, sought declaratory judgment and injunction that the nursing scope of practice included and protected their activities).

[189] *See supra* notes 115-18, 148-49 and accompanying text.

practicing medicine without a license.[190] In fact, a number of cases have found CAM providers whose disciplines have not been recognized by the states guilty of practicing medicine without a license.[191] This protects licensed physicians' territory from encroachment by unlicensed health care providers.[192] Even acupuncture, which has been recognized by NIH as effectively providing a variety of health benefits,[193] is not a licensed discipline in all states.[194] Thus, despite progress toward mainstreaming CAM into the general health care market, ongoing deterrents remain.

IV. REASONABLE NECESSITY — A NEW PARADIGM

As discussed above, medical knowledge has not evolved to the point of being able to determine accurately what treatments are medically necessary in many cases.[195] Uncertainties clearly surround the efficacy of both conventional medical and CAM treatments. The medical necessity test seems to overlook some uncertainties associated with conventional medicine while highlighting those connected with CAM. As long as medical necessity is defined by the treatment standards of medical doctors to the exclusion of other health care providers,[196] the test is faulty. A new reimbursement standard is needed. That new standard should be one of *reasonable* necessity rather than medical necessity.

At first glance this might seem to be simply a change in semantics.[197] However, there are important differences between the medical necessity and reasonable necessity tests. The new reasonable necessity standard represents a genuine substantive shift in the manner in which health insurance coverage decisions should be made. All licensed health care providers, not just conventional medical doctors, would have equal ability to recommend reasonably necessary procedures. Therefore, "reasonably necessary" procedures and treatments would include those that are customarily used by physicians and CAM providers.

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[190] *See generally* Mitchell v. Clayton, 995 F.2d 772 (7th Cir. 1993); State v. Miller, 542 N.W.2d 241 (Iowa 1995); State v. Hinze, 441 N.W.2d 593 (Neb. 1989); Majebe v. Bd. of Med. Exam'rs, 416 S.E.2d 404 (N.C. App. Ct. 1992); Stetina v. State, 513 N.E.2d 1234 (Ind. App. 1987). *But see* OKLA. STAT. tit. 59 § 492(F) (2003) (stating that "[n]othing in the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act shall prohibit services rendered by any person not licensed by the Board and practicing any nonallopathic healing practice.").

[191] *See supra* notes 181-87 and accompanying text.

[192] *See supra* note 185.

[193] *See supra* note 103 and accompanying text.

[194] *See supra* note 117 and accompanying text.

[195] *See supra* notes 42-63 and accompanying text.

[196] *See supra* note 20 and accompanying text.

[197] In fact, there would be similarities between the medical necessity and reasonable necessity standards. For example, like medical necessity, insurers would undoubtedly continue to look to the community practice as one factor in determining whether a treatment is reasonably necessary.

Currently, procedures ordered by medical doctors are much more likely to be covered by health insurance than those performed by other CAM providers.[198] Under the reasonable necessity standard, all *licensed* health care providers would be on an equal footing. If a licensed health care provider – whether a licensed acupuncturist, massage therapist, or other licensed health care provider – treats the patient within the scope of the license, the treatment would be presumed reasonable to the same extent as if the treatment were provided by a conventional medical doctor.[199] Licensed CAM providers have the legitimacy of having satisfied state educational and licensing standards and should not be treated as second-class providers by insurers. Treating all licensed health care providers equally will expand the ability of patients to choose health care providers and treatments of their choice, whether conventional or otherwise. Washington's Alternative Provider Statute, which requires every health plan to permit "every category of provider" to render care for conditions included in the basic health plan services,"[200] is an important step in this direction. Mainstreaming CAM will be furthered if other states follow Washington's lead.

While not the primary focus of this article, other legal changes are needed in order fully mainstream CAM. First, ERISA plans must also implement a reasonable necessity standard. Otherwise, even if state laws and health insurers embrace the reasonable necessity standard, many individuals will continue to be excluded if employer-sponsored ERISA plans do not also embrace the new standard.[201] Second, state laws must not be manipulated to simply protect

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[198] When CAM treatments are provided by conventional medical doctors, the doctors can use standard diagnosis codes to increase the chance that the treatment will be covered. *See* Sturm & Unutzer, *supra* note 128, at 424 ("[I]f CAM services provided by a physician were at least partially reimbursable by insurance (because of billing using standard visit codes and diagnoses), demand for CAM could increase."). In addition, some states "explicitly limit the practice of acupuncture to licensed physicians." *Id.*

[199] As noted above, states vary in terms of the various CAM disciplines that they recognize with educational and licensing requirements. *See supra* notes 115-18, 148-49 and accompanying text; *In re* Guess, 393 S.E.2d at 836 (N.C. 1990) ("Reliance must be placed upon the assurance given by [one's] license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications."). Moreover, reasonable necessity should be defined by states rather than by profit motivated insurers. Such definitions should be sufficiently flexible that the ultimate decision whether a procedure is or is not reasonably necessary can be made primarily between the health care providers and their patients.

[200] WASH. REV. CODE § 48.43.045 (1997); *see also* Wash. Physicians Serv. Ass'n v. Gregoire, 147 F.3d 1039, 1042 (9th Cir. 1998).

[201] Since section 514(b)(2)(a) saves from preemption any state laws regulating insurance, 29 U.S.C. 1144(b)(2)(A), any state laws which mandate a shift from medical to reasonable necessity would arguably be state laws that regulate insurance and would be saved from ERISA preemption. *Id.* Such a widespread change in the way health insurers make coverage decisions is "specifically directed" toward the insurance industry. Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 50 (1987); *see also Wash. Physicians Serv. Ass'n*, 147 F.3d 1039. *See generally* Ky. Ass'n of Health Plans v. Miller, 538 U.S. 329 (2003) (holding that a law regulates insurance if it is "specifically directed toward entities engaged in insurance," and "substantially affect[s] the risk pooling arrangement between the insurer and the insured."). Self-insured employers are not insurers for purposes of the

physicians who expand their practices to include CAM. Some insurers only cover CAM treatments when administered by conventional medical doctors.[202] While this protects the medical profession, medical doctors are not necessarily best at administering CAM. Instead, states need to license CAM providers on a wider scale and protect their right to practice fully through their scope of practice provisions. Moreover, narrowing the definition of the practice of medicine would facilitate the integration of CAM into the health care system. This would also help to limit the risk of CAM providers being charged with practicing medicine without a license.

At least one commentator has suggested that health insurance coverage should not include CAM.[203] Several rationales underlie this position. First, is the suggestion that CAM is unsafe.[204] A second argument is that even if it is safe, CAM should not be covered by health insurance because it has not been proven effective. Therefore, it does not satisfy the medical necessity standard typically used by insurers to make coverage determinations.[205] A third argument is that CAM can be adequately handled by free market forces.[206] None of these arguments are persuasive.

Turning first to the issue of safety, there are a myriad of choices when it comes to CAM.[207] In terms of health insurance coverage, it is appropriate to limit coverage to those CAM disciplines that states implicitly recognize as legitimate by setting forth appropriate educational and licensing requirements for specific CAM providers. Once a state recognizes a particular discipline by setting forth such requirements, health insurers should also be required to recognize their legitimacy. More than half the states, for example, license acupuncturists.[208] When practiced by a competent licensed provider, acupuncture is at least as safe as conventional treatment. Acupuncture involves the insertion of small needles and thus arguably has the potential to be unsafe if, for example, the needles are not properly sterilized or are improperly inserted.[209] The same, however, can be said of conventional treatments that require the use of needles. Whether the issue involves acupuncture needles or needles used by conventional

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preemption and savings clause. Therefore, self-insured employee benefit plans are governed by ERISA rather than by state insurance regulations.

[202] *See supra* notes 172, 194.

[203] *See, e.g.*, Boozang, *Is this Alternative Medicine?*, *supra* note 73.

[204] *Id.* at 588; *see also* Boozang, *Western Medicine Opens the Door*, *supra* note 73, at 206 ("That which is simply unproven *should not be provided.*").

[205] Boozang, *Is this Alternative Medicine?*, *supra* note 73, at 588.

[206] *Id.* at 570.

[207] *See supra* notes 74-85 and accompanying text.

[208] *See supra* note 117. Unfortunately, a significant number still do not.

[209] Obviously, like any other type of needle, acupuncture needles must be sterilized to minimize any chance of infection. However, Boozang argues that "acupuncture is . . . potentially risky: needles that are not properly sterilized can transmit infections; needles can break; and can puncture lungs or blood vessels." Boozang, *Is this Alternative Medicine?*, *supra* note 73, at 588. These statements are true of both conventional and acupuncture needles. The key to any good health care is to find competent health care professionals who follow proper sterilization and sanitary procedures.

medical doctors to draw blood or inject medication, they must all be properly sterilized and inserted. Conventional medical doctors use millions upon millions of needles each year. Obviously, it is critical that the health care provider – whether a CAM provider or a conventional medical doctor – be competent and carefully selected. This is true regardless of the treatment at issue.

The argument that CAM has not been proven effective is also overly simplistic. First, CAM is not homogeneous. It includes a diverse range of treatments. Some forms of complementary care, like acupuncture, are generally acknowledged as effective.[210] In addition, chiropractors are licensed in every state, suggesting state recognition of the efficacy of chiropractic treatments.[211] Others, like reiki, color therapy, kinesiology, reflexology, yoga, iridology, and naturopathy while growing in popularity, require further study. The same is true of massage therapy and homeopathy. To group all CAM together and suggest that none is worthy of heath insurance coverage is a gross generalization that does a disservice to patients seeking CAM treatments.[212] Instead, a distinction should be drawn between those CAM modalities that states recognize and those they do not. For the former, health insurance should be available if the licensed CAM provider deems the treatment to be reasonably necessary.

The absence of double blind studies does not render CAM any less effective than many conventional medical treatments. Although "[t]he randomized clinical trial is widely accepted as the gold standard for measuring effectiveness,"[213] the time has come to consider other means for determining efficacy for at least two reasons. First, as noted above, this "gold standard" has not removed the element of doubt even about the efficacy of conventional medical treatments.[214] Second, we currently lack the technology to measure the efficacy of some forms of CAM.[215] Limitations on the capability of current technology should not be a basis for denying health insurance coverage to patients who need it.

The market force argument – that patients who wish to receive CAM can pay for it themselves – is unrealistic. It ignores the fact that many patients cannot afford the CAM they seek. Health care fees of CAM providers often exceed an individual's ability to pay out of pocket.[216] CAM provider fees can be as high as or higher than fees charged by conventional medical doctors. To assume that those in need of such services can afford to pay for them out of pocket is naïve. This is particularly true for cancer patients who may regularly seek access to CAM providers in order to help offset the toxic effects of chemotherapy and radiation treatments. Similarly, patients with other chronic conditions may also seek CAM on an ongoing basis. In these cases in particular, the costs associated

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[210] *See supra* notes 103 and accompanying text.
[211] *See supra* notes 116 and accompanying text.
[212] *See* Andrews, *supra* note 168, at 1288-89.
[213] Lucian L. Leape, *Unnecessary Surgery*, 13 ANN. REV. PUB. HEALTH 363, 378 (1992).
[214] *See supra* notes 42-63 and accompanying text.
[215] *See supra* notes 93-97 and accompanying text.
[216] Eisenberg, *supra* note 88, at 248.

with CAM can be prohibitive. For these patients, access to CAM "depends on third-party payment."[217]

Insurers are likely to embrace the foregoing arguments and will undoubtedly add a few of their own for not expanding coverage for CAM. Insurers may suggest, for example, that the status quo be maintained because "reasonable" is too uncertain a term.[218] Clearly it is a term that is subject to interpretation. Yet the reasonableness standard, as every first-year law student quickly discovers, is used extensively throughout the law.[219] The reasonableness standard, like the medical necessity test, is subject to case-by-case interpretation.[220] The lack of a bright line is not sufficient justification for rejecting the reasonable necessity test.

The insurance industry is also likely to resist the reasonable necessity test on the grounds that it would be too expensive. This is not necessarily true.[221] The reasonable necessity test would allow patients to avail themselves of CAM treatments that may enhance their strength and well-being. In addition, the reasonable necessity test may enable conventional treatments to work more effectively, and may reduce the level of required conventional treatments as a result.[222]

As an example, one of the adverse side effects of chemotherapy is that it lowers the blood count.[223] Therefore, before each treatment, the patient must have his or her blood tested to ensure that the blood count is sufficiently high.[224] Conventional health care providers traditionally advised that there was nothing the patient could do to control the blood count. Their belief was that it would simply go up and down at its own pace.[225] Some CAM providers, however,

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[217] COHEN, *supra* note 117, at 97.

[218] *See* Barette, *supra* note 37 and accompanying text.

[219] Tort law's reasonable person standard is perhaps the most common "reasonable" standard and the one that first-year law students become intimately familiar with. *See* RESTATEMENT (SECOND) OF TORTS §§ 282, 283, 291 (1965).

[220] *Id.*

[221] While it may be assumed that a shift to reasonable necessity, where a variety of health care providers can order many diverse treatments, will be financially prohibitive, this is not necessarily the case. In the long run costs may actually decrease. CAM treatments may cost less to administer than many high tech conventional treatments. *See also* Andrews, *supra* note 168, at 1285 (suggesting that CAM costs are lower because treatments are less costly. In addition there may be fewer needless procedures and fewer drugs.).

[222] *Id.*

[223] "Chemotherapy treatments destroy some of the bone marrow cells so fewer blood cells are produced." American Cancer Society, *How Will Chemotherapy Affect My Blood Count?*, http://www.cancer.org/docroot/MBC/content/MBC_2_2X_How_Will_Chemotherapy_Affect_My_Blood_Cell_Count.asp?sitearea=MBC (last revised Jan. 22, 2001).

[224] *Id.* "Your doctor will check your blood cell count often during your treatment." *Id.* If the blood count falls too low, the "doctor may postpone treatment [or] give . . . a lower dose of chemotherapy." *Id.*

[225] The American Cancer Society web site, though, suggests that blood transfusions or a growth factor may be prescribed. *Id.* It appears that these mechanisms are resorted to only as a last resort.

believe that there are herbs that can help keep blood counts within their normal range.[226] An acupuncturist, nutritionist, or herbalist, for example, may prescribe an herb called Don Quai to help boost the blood count.[227]

Revisiting Heather's case illustrates how the reasonable necessity test could work. Assume that Heather had a cancer recurrence and was undergoing a chemotherapy regimen that involved the drug Taxol. After the initial Taxol treatment, Heather returned twice, only to discover on both occasions that her blood count was too low for her to be treated. Obviously Taxol cannot help kill cancer cells if it cannot be administered to the patient. Heather may be unaware of CAM treatments that could help keep her blood count high enough to continue treatments uninterrupted. She may also be unable to afford those CAM treatments even if she becomes aware of them.

If we examine Heather's story under both the medical necessity and the reasonable necessity paradigms, we see that her story is basically an illustration of the medical necessity paradigm. She probably had little if any health insurance coverage for CAM.[228] It is also likely that she had little awareness of how such CAM treatments might benefit her. Whether it is a lack of financial ability or a lack of education and awareness, or a combination of both, Heather has arguably not been well served by the medical necessity test if, in fact, there are CAM treatments – whether Don Quai or something else – that could have increased her blood count and allowed her to complete her chemotherapy treatments uninterrupted.[229]

Under the reasonable necessity test, on the other hand, Heather would be able to take advantage of reasonable treatments ordered by any licensed health care provider. Under this paradigm, she is more likely to seek out CAM[230] and to become aware of the diversity of treatment options that exist. Let us assume that Heather received acupuncture treatments and that she took Don Quai and was able to complete her chemotherapy treatments without interruption.[231] Presumably, her prognosis would improve, she would feel better, and she may

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As discussed below, there may be other effective tools for maintaining the blood count that are less invasive. *See infra* note 227.

[226] PHYLLIS A. BALCH & JAMES F. BALCH, PRESCRIPTION FOR NUTRITIONAL HEALING 95 (3d ed. 2000).

[227] Don Quai is a root that "improves the blood." *Id.*

[228] *See supra* notes 127-29 and accompanying text (discussing the lack of adequate health insurance for CAM).

[229] Medical doctors, especially oncologists, need to educate themselves on how CAM can complement conventional chemotherapy. They would then be able to guide Heather to an appropriate CAM provider but without sufficient health insurance coverage, such care may not be available as a practical matter.

[230] *See supra* note 140 and accompanying text.

[231] This is not to suggest that Don Quai will eliminate the problem of low blood counts associated with chemotherapy. This is an illustration of how expanded treatment options can potentially benefit patients without being financially prohibitive for insurers. Even if the costs are comparable, the quality of Heather's life would be much improved. Her emotional and mental well-being, and presumably her physical well-being as well, are furthered by being able to complete her conventional treatments as initially planned.

incur fewer days of hospitalization. Thus, the financial cost to the insurer under the reasonable necessity test, could be less than it would be under the medical necessity test.

Because conventional medicine and CAM have been kept separate, neither knows much about the benefits the other has to offer. Thus, the chemotherapy nurse believes blood counts are something over which we have no control.[232] The acupuncturist is frustrated that conventional medicine does not reach out and educate itself better about other disciplines that, in conjunction with conventional treatments, could produce powerful benefits.[233]

In the case of cancer patients in particular, there are at least two good reasons to cover at least some forms of CAM. Cancer is a disease for which, by and large, there is no known cure. Despite chemotherapy and radiation, doctors are unable to predict who will and will not survive.[234] We do know, however, that chemotherapy and radiation have adverse as well as beneficial effects on the human body.[235] If CAM treatments can help counterbalance the toxic effects of conventional cancer treatments by enhancing physical comfort and a feeling of well-being, they are particularly important to include in the overall treatment plan when one is undergoing chemotherapy or radiation treatments. Acupuncture and massage therapy, for example, make the patient feel much more relaxed and comfortable after treatment, which in turn can provide a psychological boost.[236] It is well documented that a person's psychological outlook can be a critical component in the recovery process.[237]

V. CONCLUSION

While uncertainty permeates much of both conventional medicine and CAM, conventional medicine enjoys a decided advantage over CAM with respect to health insurance coverage. Conventional medical treatments are routinely covered by health insurers because they are the customary treatments of medical doctors – the only health care providers health insurers generally look to in making coverage determinations. Since customary CAM procedures are not taken into account under the medical necessity test, CAM is often not covered by health insurance. A paradigm shift from medical necessity to reasonable necessity recognizes the uncertainty that encompasses all health care disciplines and establishes equity among licensed health care professionals. In addition,

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[232] American Cancer Society, *supra* note 223.

[233] This example admittedly has many assumptions and unknowns. It is an illustration of how the reasonable necessity test can be quite workable both from the patient perspective and from the perspective of the insurer.

[234] There are statistical odds, of course, but doctors cannot say, in any individual case, whether a patient will respond well to the conventional chemotherapy and radiation treatments, whether the patient will have a recurrence, or a miraculous cure.

[235] *See supra* note 132 and accompanying text.

[236] KAPTCHUK, *supra* note 93, at 79.

[237] The mind, body, spirit connection discussed above in note 85 and accompanying text is premised on the need for health in all three areas.

state legislatures should be cautioned against making legal changes designed solely to permit medical doctors to expand into the CAM market without giving separately trained CAM providers the benefit of insurance coverage. Finally, a shift in scope of practice laws could facilitate the ability of CAM health care providers to practice unimpeded. From the licensing of CAM providers to the NCCAM to the billions of dollars spent on CAM, it is clear that CAM should be legally mainstreamed into the U.S. health care system. Greater health insurance coverage for CAM will give consumers greater freedom to select health care providers of their choice. That choice has the potential to enhance the nation's well-being.