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COMPLEMENTARY & ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES

MICHAEL H. COHEN (Johns Hopkins University Press, Baltimore, Maryland, 1998), 180 pages, $45.

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INTRODUCTION

The rapid rise in visibility of complementary medicine (also called alternative, integrative, or unconventional medicine) over the past decade is an understandable response to the evolution of biomedicine in this country. At the turn of the last century, medicine was a poorly regulated enterprise. Many physicians received their education from "diploma mill" medical schools, followed by a brief period of preceptorship with clinicians of variable quality. The trainee was unleashed on society carrying with him or her the biases and shortcomings of limited education and misconceptions regarding patient care passed from one generation of physicians to the next. Moreover, efforts to improve the quality of care were thwarted by the for-profit nature of many schools and the lack of scientific bases for many of their endeavors.

In this environment, attempts to qualify providers of health care centered on state medical society certification and/or graduation from an approved medical school. These regulatory mechanisms often failed, especially because the quality of medical school education was variable. Abraham Flexner's famous 1910 report[1] condemned the existing educational system for physicians and led to the closing of many second-tier facilities. By the end of the first World War, the remaining medical schools had partnered with universities. This merging of allopathic medicine into science departments around the country resulted in rapid standardization of the educational process and facilitated the expeditious maturation of biomedicine.

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[1] A. FLEXNER, MEDICAL EDUCATION IN THE UNITED STATES AND CANADA (Carnegie Foundation for the Advancement of Teaching 1910).

Conventional medicine benefitted, especially in the public's eye, from this close affiliation with science and by continually working wonders. Antibiotics were developed, which reproducibly killed bacteria with predictable reversal of infectious ailments. Even when resistant strains appeared, newer antibiotics appeared to meet the challenge. Insulin was discovered to arise from islet cells of the pancreas and was used to treat diabetes. Mechanical support of the heart was developed through concerted efforts of physicians and bioengineers. The initial pumps, created by the meticulous engineer and aviator Charles Lindbergh, made possible my specialty, surgery of the heart. Medicine cured polio, eradicated small pox, and made it possible to keep 22-week-old fetuses alive—to name just a few of its many miracles.

The continued progress of biomedicine made alternative approaches appear limited and possibly represent the work of charlatans; but the advance of mainstream medicine had its price. With standardization came the risk of stagnation. Allopathic practitioners understandably felt superior to healers who had not run the conventional gauntlet of medical school admission and education. Alternative paradigms to explain bodily function and disease treatment were seen as attempts of less advanced societies to grapple with the mysteries of the body, which we now are able to comprehend more thoroughly and accurately with modern biomedicine. In particular, the organ-based approach to healing focused on the culprit disease within a particular organ that was often demonstrated at autopsy to be responsible for the patient's ailment. Physicians began to specialize in treating a particular organ or system, with few interested in generalist practice, which was less lucrative and generally seen as less intellectually challenging.

As the baton was passed to newer generations of physicians, the model of a body composed of independent organs, which could be studied independently of each other and of the mind, became accepted. Confidence that science-based medicine would continue to close the gaps in our understanding of the human body allowed us to ignore alternative approaches. Yet, as biomedicine improved, our limitations in fully grasping the complexities of the human body and the subtleties of its functioning became clearer. We could understand, for instance, how the eye detects shape, light, and movement; but we still could not explain how the mind knew that the figure perceived was one's grandmother. Moreover, we could not fathom the subject's psychophysiologic responses to this perception. Patients and physicians hoped that biomedicine would provide a rational and complete basis for understanding the body; yet, despite the magnificent advances, we are still far from a comprehensive paradigm. More importantly, better understanding of disease processes, such as myocardial infarctions, forced us to address the pathophysiology rather than solely the anatomy of disease. In this transition, the impact of the mind on bodily functions became clearer and a rationale for addressing these sometimes "nonscientific" approaches became more defensible.

In fact, medical clinicians long have realized that the organ-based model of biomedicine is limited. After completing the intense boot camp of medical school, many of us have realized that patients—perhaps because they had not read the medical texts we did—unobligingly presented with symptom complexes that did not fit neatly into the frame of our formal education. The art of medical practice, as opposed to the scientific understanding of biochemical phenomena affecting bodily processes, requires us to remember that our medical school education was based on a model of how the body functions independent of the mind. We have to learn to take account of the patient's consciousness and will in the healing process if we are going to mature from troubleshooting medical technicians to true healers. In so doing, we become practitioners of complementary medicine. Fueling physicians' growing interest in complementary medicine is the public's embrace of many of its practices. As proof, an estimated $27 billion was spent for these therapies in 1997.[2]

EXPLORING THE ALTERNATIVES FOR ALTERNATIVE MEDICINE

The growing popularity of complementary medicine mandates a better understanding of legal obstacles to the use of unconventional healing modalities. A useful aid to such understanding is Michael Cohen's new text, *Complementary & Alternative Medicine: Legal Boundaries and Regulatory Perspectives*.[3] In it, Cohen, an Associate Professor at California's Chapman University School of Law, eloquently describes the interlocking levels of control state and federal governments exercise over the art of medicine. The work is illustrated by case examples that bring alive the current status of such controls and highlight the dilemmas both faced and posed by our legal system.

Although others will find Professor Cohen's book interesting, it is of particular value to four main groups: physicians and institutions interested in integrating complementary modalities into their practices; complementary medicine practitioners, who must understand the licensure process and scope of practice arguments; insurance companies that need to deal with vicarious liability and medical necessity issues; and patients who desire to understand their rights to access alternative treatments and to cope with the medical paternalism which, for good or bad, strongly influences current legal structures surrounding medicine.

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[2] Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay, & Kessler, *Trends in Alternative Medicine Use in the United States, 1990-1997*, 280 J.A.M.A. 1569 (1998).

[3] Editor's note: Professor Cohen's work appears to be the first book-length treatment of these regulatory issues in the United States. For an overview of a book detailing the legal status of alternative medicine in the United Kingdom, see Professor David Warren's review of J. Stone & J. Matthews, *Complementary Medicine and the Law* (1996), at 18 J. LEGAL MED. 257 (1997). For a passionate and personal look at complementary medicine, see *Healing from the Heart* (1998), by Dr. Mehmet Oz, author of this essay.

To make his argument that the current approach to regulating the healing arts can be improved, Professor Cohen places the biomedical system in an appropriate historical context and leaves the reader with the profound insight that the discussion surrounding the practice of medicine has been reduced to too simple a level, namely: "Does a randomized study show that a therapy works?" For a scientist, this debate is of paramount importance. From a legal perspective, however, outcomes analysis does not, and probably should not, determine if a therapy can be offered. As a case in point, Professor Cohen reviews the often-cited case of *In re Guess*,[4] in which a well-respected physician had his license revoked for offering unconventional therapies. Even though no patients testified against Dr. Guess and he was generally successful in his therapeutic endeavors, the North Carolina supreme court ruled that the state's medical board was justified in its action because his activities deviated from the norm. The legal argument trumped the efficacy argument, even though Dr. Guess' approach was not shown to cause any more harm than conventional treatments. Interestingly, after the *Guess* ruling, North Carolina amended its medical practice law to provide that a practitioner should not lose or be denied a medical license solely because of that "person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable and prevailing medical practices unless, by competent evidence, the [Medical] Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective."[5]

The fundamental conflict in these cases is between the state's well-intentioned, but perhaps overly paternalistic, desire to protect its citizens, especially the uninformed, and the individual's rights of privacy and personal liberty, two core elements of American jurisprudence.[6] Where does the proper balance lie, and on whom should the burden of proof rest when access to a desired modality of care is in question? The authority to regulate the healing arts inheres in the states' "police power," as the Supreme Court declared in its landmark 1889 decision in *Dent v. State of West Virginia*. This authority allows a state to "prescribe all such regulations as in its judgment will secure or tend to secure . . . [the public] against the consequences of ignorance and incapacity, as well as of deception and fraud."[7]

Because the states can regulate all aspects of medical practice, decisions often rest on individual state medical practice acts, which generally define

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[4] 393 S.E.2d 833 (N.C. 1990).

[5] B. Furrow, T. Greaney, S. Johnson, T. Jost, & R. Schwartz, Health Law 90 n.2 (3d ed. 1997).

[6] The term "right of privacy" is conspicuously absent in more recent federal constitutional analysis, replaced by reference to the "liberty interest" protected under the 14th amendment's due process clause. *See, e.g.*, Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 839 (1992); Roe v. Wade, 410 U.S. 113, 152-53 (1973).

[7] Dent v. West Virginia, 129 U.S. 114, 122 (1889), *cited in* M. Cohen, Complementary & Alternative Medicine: Legal Boundaries and Regulatory Perspectives 24 (1998).

the practice of medicine as the diagnosing, preventing, treating, and curing of disease. This approach has a predictable bias toward biomedicine, leaving precious little room for alternative medicine, especially because states have applied the definition of medical practice quite broadly.

In *Stetina v. State*,[8] for instance, an Indiana appeals court forbid a nutritionist who practiced iridology[9] from practicing medicine without a license, arguing that the state's medical practice act was intended to protect not only "against the well-intentioned but unskilled practices of health care professionals . . . [but also] against those well-intentioned and skilled practices which simply exceed the scope of acceptable health care."[10] In arguing that *Stetina* defines the scope of the medical practice act too broadly, Professor Cohen contends that the law should be interpreted within the context of "disease care within the biomedical model, not wellness care within the holistic healing model."[11]

A rational mechanism for bringing alternative medicine practitioners within the fold of legally allowable healers is occupational licensure.[12] This approach, which Professor Cohen suggests and I endorse, would help to foster a culture of professionalism, which has both financial and social implications, and insulate holistic practitioners from medical practice laws. A minimal level of professional competence would be assured, other professionals would be prevented from gaining control over the field, and a recognized basis for professional opportunities, including hospital privileges and insurance reimbursement, would be established. If such protection is not garnered, then courts will remain unable to identify alternative practitioners as belonging to a recognized branch of the healing arts[13] and will have to apply conventional medical standards for quality of care and scope of practice.[14]

As Professor Cohen explains, the three main options for establishing governmental control of complementary medicine practitioners are mandatory licensure, permissive certification (title licensure), and mandatory registration.[15]

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[8] 513 N.E.2d 1234 (Ind. App. 1987), *cited in* M. COHEN, *supra* note 7, at 30.

[9] Iridology is the examination of the patient's eyes (iris) to help assess the condition of his or her health.

[10] *Stetina*, 513 N.E.2d at 1238.

[11] M. COHEN, *supra* note 7, at 32.

[12] "Occupational licensure," as is traditionally applied to plumbers, electricians, and the like, is legally similar to "professional licensure," applied to physicians, attorneys, and their ilk. The difference lies primarily in the extent and complexity of the education, testing, character verification, and other licensing criteria required. *Id.* at 33; B. BLEDSTEIN, THE CULTURE OF PROFESSIONALISM: THE MIDDLE CLASS AND THE DEVELOPMENT OF HIGHER EDUCATION IN AMERICA 80-81 (1976).

[13] Studdert, Eisenberg, Miller, Curto, Kaptchuk, & Brennan, *Medical Malpractice Implications of Alternative Medicine*, 280 J.A.M.A. 1610 (1998).

[14] *See, e.g.*, Metzler v. New York State Bd. for Prof. Med. Conduct, 610 N.Y.S.2d 334 (N.Y. App. 1994).

[15] Under a licensure approach, the prospective practitioner cannot practice without first complying with the state's prescribed educational and other requirements. Under certification, the practitioner can practice but may not use a defined professional title without meeting the requirements of the certifying body. That body could be professional or governmental; in the present context a governmental certifying mechanism

These approaches provide progressively less strict barriers to practitioner inclusion and can create a versatile mechanism, which can be tailored to the diverse array of alternative therapies. Disciplines such as acupuncture, for which a complex and standardized body of knowledge exists, would seem to call for mandatory licensure. At the opposite end of the spectrum, many holistic practices, such as "energy medicine,"[16] would be better served by a simple registration process, which allows the specialty some latitude to grow and develop. The degree of invasiveness and the riskiness of the practice in question bear importantly on deciding what kind of control is best and how stringently it should be applied. Of course, an unconventional therapy, harmless in itself, nevertheless may pose a risk if it deters a patient from pursuing conventional treatment that might be helpful.[17]

Once an alternative medicine practice has been licensed, scope of practice regulations will protect its practitioners from claims that they are practicing medicine outside of their allowed scope. Turf battles can be expected; ambiguous and shifting boundaries among practice areas often lead to scope of practice disputes. Professor Cohen illustrates this issue using the example of chiropractic because its conflicts with biomedicine's approach are frequent and of long standing. In *State v. Beno*,[18] the Michigan Supreme Court held that a chiropractor cannot provide advice on an extremity injury because this falls outside the statute of the chiropractic license and constitutes the practice of medicine. The fine line becomes even finer in cases such as *Foster v. Georgia Board of Chiropractic Examiners*,[19] in which a licensed chiropractor was sanctioned for dispensing vitamins and food supplements to a patient. The chiropractor argued that because the preparations he recommended and sold were legally available to a purchaser without a prescription, his dietary and vitamin recommendations stood on the same footing as simple advice to "get more exercise" or "eat a better balanced diet," neither of which would constitute practicing medicine. The court ruled that, in the context involved, the chiropractor's recommendations constituted the prescribing of drugs in violation of the Georgia Chiropractic Practices Act.

Professor Cohen highlights the wide variety of rules governing scope of practice among the states and points out that the lines dividing complementary

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is contemplated. Under registration, the least restrictive alternative, the would-be practitioner has only to register with the state that he or she intends to engage in the defined activity. Information provided through the certification process allows the state to monitor the practitioner's activities and helps assure accountability.

[16] "Energy medicine" is a healing modality involving subtle or very low intensity nonmaterial stimuli. Examples include homeopathy, electromagnetic therapies, acupuncture, and therapeutic touch. Energy therapies are particularly challenging to the dominant biomedical paradigm and generally defy conventional scientific explanation. Rubik, *Energy Medicine and the Unifying Concept of Information*, 1 ALT. THERAPIES IN HEALTH & MED. 34 (1995).

[17] *See* Rutherford v. United States, 442 U.S. 544, 556 (1979).

[18] 373 N.W.2d 544 (Mich. 1985).

[19] 359 S.E.2d 877 (Ga. 1987).

care from medical diagnosis and treatment are inevitably blurred, both conceptually and legislatively. He counsels that providers of services should have their patients "acknowledge in writing that the provider does not have an MD degree and does not diagnose and treat disease."[20] His analysis also suggests that an expanding scope of practice can create interprofessional conflicts and may be better managed by avoidance of mandatory licensure.

Yet another mechanism of legal regulation is malpractice litigation, based upon both direct and vicarious liability. Because malpractice claims are based, generally speaking, on failure to conform to the professional standard of care, use of complementary practices not taught in medical schools or preparations, which are not FDA-approved, understandably poses a legal risk. Although off-label use of therapies is common, if biomedical approaches to a specific ailment are the norm, deviating from these therapies can be grounds for malpractice. As an example, Professor Cohen highlights the risks of chelation therapy,[21] an unconventional alternative to coronary artery bypass surgery, which is a conventional biomedical therapy of proven effectiveness. The best defense for these activities is rigorous biomedical research, with institutional review board approval, as indicated. This has been our approach at Columbia-Presbyterian Medical Center and Columbia University. An academic approach is particularly important for an institution participating in these practices as it is exposed thereby to vicarious liability—and, perhaps, direct liability as well—and may be understood as sanctioning all activities occurring within its facility.

An interesting paradox will soon occur, I suspect, when a physician dismisses a complementary therapy and is then sued for providing substandard medicine because his patient was not informed of all the treatment options available for the ailment involved, including unconventional ones. Because telling the patient about all reasonably feasible treatment alternatives has long been part of the physician's informed consent obligation, it would be an ironic recognition of the acceptance of complementary medicine if *not* informing a patient of an "alternative alternative" is held to violate informed consent laws. Professor Cohen makes the interesting observation that perhaps the requirement of informed consent should be understood to apply only to biomedicine. "Such an approach encourages the use of holistic modalities in a nonreductionistic manner," such as the nourishment of vital energy rather than treatment of a biomedically defined pathology.[22]

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[20] M. COHEN, *supra* note 7, at 54.

[21] Chelation therapy involves giving intravenous injections of chemicals intended to react with harmful metals that accumulate in, and deter passage of, blood within the body. Once dissolved by the chemical reaction, the harmful metals pass out through the patient's kidneys. The main danger is that excessive amounts of such substances may enter the kidneys too rapidly, causing renal poisoning, kidney failure and, possibly, death. United States v. Evers, 453 F. Supp. 1141, 1143 (M.D. Ala. 1978).

[22] M. COHEN, *supra* note 7, at 62.

One "benefit" of a poorly defined profession is the difficulty of proving that its standard of care has not been met. As a result of this and the more personal relationship that many complementary practitioners have with their patients, very few suits are brought against such practitioners. Increasing acceptance and integration of complementary medicine will change this dynamic. To date, most suits against complementary practitioners have involved claims of negligent nonreferral and misrepresentation. These actions usually are dependent on overlap with biomedical specialities and often require proof of an intent to defraud rather than simply the making of an untrue or unsupportable therapeutic claim. These suits sometimes include insurance fraud claims, yet the definition of fraud in this context requires the plaintiff to prove *scienter*, the defendant's knowledge of falsity and intent to deceive. The allowance of fraud in this context must be carefully examined and constrained, because the term "fraud," like "quackery," historically has been used as an epithet to indict biomedicine's rivals. Thus, if the court believes a provider projected a cure and honestly believed that projection, then he or she could be liable for negligence but not for fraud.

Even if improved access to complementary medicine is brought about by cultural integration of these practices and legal changes to facilitate the process, the eventual use of new modes of care still can be limited or blocked by third-party reimbursement rules. This barrier is felt keenly in biomedicine these days as innovative techniques, such as the use of left ventricular assist devices, can be shown in peer-reviewed journals to save lives,[23] receive FDA approval, and yet still be denied reimbursement on the ground that they are "experimental" therapy. As Professor Cohen highlights, "insurers and courts may find that notions of what is experimental often are culturally and politically determined and will vary as biomedicine edges toward a health care system that safely integrates previously suspect or marginalized disciplines."[24] These arguments become most acute when terminal patients seek alternative therapies because biomedicine offers no further hope. In *Dallis v. Aetna Life Insurance Co.*,[25] a federal court in Georgia refused to grant summary judgment in favor of an insurer's defense that an innovative "immunoaugmentative" therapy for cancer was not medically necessary because the patient had not responded to conventional cancer treatment and because the definition of medical necessity was inherently ambiguous.[26]

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[23] Oz, Argenziano, Catanese, Gardockiu, Goldstein, Ashton, Gelijns, Rose, & Levin, *Bridge Experience with Long-Term Implantable Left Ventricular Assist Devices: Are They an Alternative to Transplantation?*, 95(7) Circulation 1844 (1997).

[24] M. Cohen, *supra* note 7, at 102.

[25] 574 F. Supp. 547 (N.D. Ga. 1983), *aff'd*, 768 F.2d 1303 (11th Cir. 1985).

[26] Although the contract in question spoke in terms of medical necessity, the insurer's argument against necessity was basically that the therapy was unproven and, thus, experimental.

CHOOSING THE RIGHT PATH

My main reservation about Professor Cohen's commendable effort to gain greater parity for alternative medicine is that he might be too successful too soon. Many alternative approaches will not deserve equal respect and treatment until their fields are better defined and policed from within. In addition, weakening the rules protecting the practice of medicine could erode the public's confidence in the entire healing profession. Biomedicine deserves the respect it has earned over this century and only worthy competitors should be allowed on the same playing field. Orderly conflict of views is an inherently healthy process, especially as society's opinion of complementary medicine evolves. In Professor Cohen's defense, only a more tolerant legal environment for complementary medicine will allow patients the increased range of choice necessary to allow this dialogue.

As a practicing surgeon at an academic medical center who strongly favors greater development of complementary medicine and its integration with traditional medicine, I see at least three important areas for improvement in our rules governing complementary medicine. First, a claim of "fraud" in this therapeutic context should require a tightly defined level of culpability to prevent its being used as a tool to harass. In particular, deliberate intent to deceive should be required.

Second, all complementary practitioners should identify the regulatory approach that best suits their interests and work aggressively toward its establishment. Once a healing approach has achieved a reputable professional organization structure, standards of care will become evident and legal support for its activities becomes more feasible. Scope of practice issues are difficult to address without this advance. From a practical perspective, government regulation of some sort is important in allowing individuals to police their colleagues and ensure that the group's reputation and consumer confidence are maintained. In the long run, an anarchic, *laissez faire* approach will prove detrimental.

Third, malpractice in alternative medicine practices should primarily be defined as the act of dissuading patients from seeking conventional medical care and/or knowingly misleading consumers about one's treatment approaches. Informed consent, the full and fair disclosure of all material information, is probably the best prophylaxis in areas as to which the law lacks confident knowledge or settled standards of practice. Obvious negligence in the performance of alternative techniques, such as the use of dirty needles during acupuncture, would, of course, remain actionable.

In conclusion, Professor Cohen's own stated purpose for addressing the legal boundaries framing alternative medicine best explains the role that law

should play during the rapid evolution of our approach to healing. As he puts it:

> Rather than mirror present biomedical resistance to complementary medicine, legal rules can enhance integration by protecting the best interests of the patient. The legal paradigm should provide a place of reconciliation and synthesis, recognizing the evolving process by which the various communities of professional healing practitioners are coming to terms.[27]

[27] M. COHEN, *supra* note 7, at 118.