

Virtual Mentor
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FROM THE EDITOR

Physician Responsibilities in a World of CAM

In 2009 the family of 13-year-old Daniel Hauser, who was diagnosed with Hodgkin lymphoma, refused chemotherapy in favor of “alternative medicines,” despite a predicted 90-percent chance of cure with chemo. As members of the Nemenhah Band, a religious organization that advocates natural healing based in Native American tradition, they believed that dietary changes, sweat lodge visits, and herbal supplements would prove superior to chemotherapy, and thus declined it. Physicians brought the case to court, and after ruling that Daniel had been “medically neglected,” the judge ordered that he proceed with infusions. In a last-ditch effort to avoid this, he and his mother fled their home state of Minnesota, but within a week reluctantly returned, daunted by the potential legal consequences [1]. Daniel received his chemotherapy and is now in full remission, but the Hausers remain firmly convinced that he would have been better off without it.

To what was the Hauser family referring when they spoke of “alternative medicines” and “natural healing?” Complementary and alternative medicine, or CAM, is any healing practice that falls outside the sphere of conventional allopathic medicine, or “that which has not been shown consistently to be effective” by peer-reviewed, appropriately controlled studies [2]. These methods are instead based on spiritual teachings, cultural traditions, or recently conceived approaches to health [3], and remain scientifically unvalidated. For this reason, many in the scientific community criticize such practices, asserting as Richard Dawkins has done that “there is no alternative medicine. There is only medicine that works and medicine that doesn’t work” [4].

While it is true that Daniel Hauser’s story represents an extreme on the spectrum of CAM use, it is no doubt a reminder that unconditional belief in CAM efficacy can encourage a rejection of evidence-based lifesaving care. It is also true that some alternative medicine supplements, including those that interact with prescribed drugs in unforeseen ways or those that themselves contain toxic chemicals, have the potential to directly inflict bodily harm. Yet CAM is immensely popular in the United States, and most patients use methods like acupuncture, chiropractics, herbal supplements, and homeopathy concurrent with evidence-based treatments, without ever experiencing adverse effects.

So the question remains—how can physicians approach CAM ethically? Should we support its use, reject it outright, or individually tailor our judgment to specific types of CAM and the particular patients using it? And what of academic and intellectual integrity? As scientists do we have a responsibility to actively discourage unproven

medical modalities, and if so, how do we determine what qualifies as legitimate evidence in the first place? Perhaps most importantly, how can we effectively and compassionately manage patients seeking alternative therapies, without compromising honesty, a value central to the practice of medicine?

When addressing the importance of honesty, or truth telling, we must consider that the reported success of some alternative therapies is due to placebo effect. Thus, at the heart of the debate over CAM ethics is the question of whether placebo use is itself ethically justified, since the very nature of placebos requires that patients be deceived about their function. Many argue that if a placebo decreases a patient's perceived level of pain, then it is in essence "effective" and is therefore acceptable. Proponents of this rationale no doubt value the possibility of improved symptoms, or patient beneficence, over patient autonomy (which requires that the patient be fully and honestly informed). After all, the end result does matter, and recent national surveys have revealed that roughly half of internists and rheumatologists prescribe placebos regularly for this reason [5]. But this side of the argument fails to address the larger picture—that the adoption of any kind of systematic deception in medicine has the potential to erode patients' trust in physicians—a consequence that could be devastating to the physician-patient relationship, and therefore to patient care overall.

This issue of *Virtual Mentor* seeks to examine all of these questions in depth, since the widespread use of complementary and alternative medicine has rendered it a topic with which almost every physician must contend, regardless of his or her specialty. We cannot ignore its importance to patients, whether or not we agree with its use. But what is it about CAM or its practitioners that makes it so appealing? Why do millions of people—38 percent of U.S. adults [6]—choose to use alternative therapies when evidence-based-medicine has been so effective; providing vaccines, antibiotics, state-of-the-art surgical techniques, and a vastly longer and improved quality of life? What is allopathic medicine lacking that drives patients to pursue other options? It is often observed that homeopaths, naturopaths, chiropractors, hypnotists, and practitioners of traditional Chinese medicine provide far more caring attention to patients. Unlike the typical busy, matter-of-fact, and overworked physician, who spouts baffling medical jargon and then scoots off to the next patient in his or her conveyer-belt practice, CAM practitioners often work in soothing environments tailored to patient comfort, use understandable language, and provide the time necessary to establish a warm therapeutic relationship. Such care is also patient centered, which grants them a sense of control over their own health. For terminal oncology patients in particular, this can provide optimism and empowerment in what often feels like an overwhelmingly futile situation [7]. But does this interaction actually help such patients or does it take advantage of their vulnerability by offering a false sense of hope?

Although some physicians do feel that allopathic and alternative medicine are mutually beneficial, the deep divide between the approaches more often than not pits advocates of truth, reason, and cold hard science against a multi-billion dollar industry that gives patients precisely what they want to feel and hear. This

fascinating struggle unfurls in this issue of *Virtual Mentor*, with passionate contributions from both avid skeptics and proponents of CAM, including physicians, attorneys, PhDs, and CAM practitioners. It is my hope that these discussions not only provide an intriguing glimpse into the controversy surrounding complementary and alternative medicine, but also help to inform those in the medical community about how to approach CAM philosophically and in daily clinical practice.

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CLINICAL CASE

When Patients Choose CAM over EBM—How to Negotiate Treatment

Commentary by Michael J. Fisch, MD, MPH, and Richard T. Lee, MD

Mr. Crowley visited his primary care physician after experiencing several months of fever, night sweats, nonspecific back pain, and “lumps in his shoulders and chest.” After a meticulous workup, including a biopsy that revealed Reed-Sternberg cells, he was promptly referred to Dr. Randolph, an experienced and reputable oncologist. After Mr. Crowley was seated in his office, Dr. Randolph pulled up his own chair, leaned forward, and explained that Mr. Crowley had classic stage I Hodgkin lymphoma. He added that the survival rate was generally 90 percent or better with chemotherapy, which made the prognosis a good one—most patients who entered remission lived normal, healthy lives.

Dr. Randolph could see that Mr. Crowley, an active and previously healthy man in his 50s, was upset. He said he would go home to consider his options before proceeding, so Dr. Randolph scheduled an appointment for one week later to finalize the treatment course. At his return visit, it was clear Mr. Crowley had come to a decision. After taking a deep breath, he began, “Doctor, I know that you think chemotherapy is best for me, but I think I want to try a macrobiotic diet instead. Chemo will only introduce its own harmful chemicals, and that really seems like the last thing I need right now. At the very least, I want to attempt a few months of macrobiotic cleanses before I even think about chemotherapy.”

At this point Dr. Randolph began to speak more firmly: “I understand where you’re coming from—chemo is a frightening and unpleasant prospect. But without it, the risk of death rises to 95 percent. Even delaying treatment could be detrimental, resulting in rapid tumor growth, which may happen if you follow the regimen you suggest.”

Mr. Crowley shook his head. “I’m sorry, but I need a second opinion, from someone who is...more open-minded about alternative therapies.”

Dr. Randolph considered the situation. He had heard anecdotes about the benefits of macrobiotic diets but knew there was no scientific evidence that they could treat cancer successfully. He cared about patient autonomy—and Mr. Crowley was clearly a competent adult—but was he really informed enough scientifically to make a proper decision? Perhaps negotiating a treatment plan that included a macrobiotic cleanse was necessary, but was it ethical?

Commentary

Because of the widespread use of complementary and alternative medicine (CAM) in the United States and abroad, physicians in this day and age must be able to address the topic with patients [1, 2]. Let's dissect this case vignette and think about a framework as well as an attitude and approach that would allow Dr. Randolph to help Mr. Crowley receive the best possible health care outcome under the circumstances. Provided below is a concise summary of what happened between Mr. Crowley and Dr. Randolph:

- Dr. Randolph broke the serious news about the diagnosis of lymphoma and stated a planned course of action, in response to which Mr. Crowley became upset and decided to think about alternative options;
- Mr. Crowley announced his decision to try another treatment approach before chemotherapy;
- Dr. Randolph responded by naming and acknowledging the emotion involved, expressing doubt about Mr. Crowley's decision, and stating his concerns about increasing the risk of cancer progression and death;
- Mr. Crowley perceived Dr. Randolph's objection to alternative therapy as close-minded and stated his intention to seek an expert opinion from a different kind of health care professional.

How could Dr. Randolph have approached Mr. Crowley's care in a way that might have achieved a different outcome? First, he would bring to the visit the attributes of a mindful practitioner, paying attention to his own physical and mental processes with presence, humility, courage, open-mindedness, and curiosity [3]. He would choose a level of intensity in his voice and body language fitting to the visit, which in this case would demonstrate his calmness and focus. He would also be aware of an appropriate framework for the physician-patient relationship. Multiple models of the physician-patient relationship have been described and examined over the past few decades, ranging from paternalistic models at one extreme to independent-choice models on the other end of the spectrum [4, 5]. Dr. Randolph favors an enhanced-autonomy model [5] that is patient-centered and dialogue-based and features shared decision making. Such a model emphasizes the physician's role as an expert guide who is actively and personally invested in, as well as jointly responsible for, the course of treatment that he or she and the patient plan together.

Using skills mastered for communicating serious news [6], Dr. Randolph would begin by asking Mr. Crowley about his perception of the illness. He would ask for permission to talk about the news. He might suggest that the main questions that need to be answered are [7]: "What is happening to me? What is going to happen to me? What can be done to help me?" If Mr. Crowley agrees that these are the key questions and invites answers, then Dr. Randolph would provide a straightforward explanation of the news. If there seems to be anger in response to the news, he would name the emotion and explore it further. Dr. Randolph knows that effective communication, finding common ground with the patient, and treating the patient as

an individual are key elements in crafting a compassionate patient-physician relationship—a therapeutic alliance [8].

Imagine that Mr. Crowley insists on doing the macrobiotic cleanses. Dr. Randolph, maintaining the attitude and intensity that he decided on before the initial visit, would remain calm and curious. He should also employ “toughness”: the ability to maintain his attitude and approach in the face of adversity. (From his perspective, his patient’s decision falls into that category.) In an attempt to defuse his patient’s oppositional attitude, he could ask Mr. Crowley questions in a nonjudgmental tone about the basis of the decision. He could assert his credibility on this topic by defining a macrobiotic diet, discussing the role of toxins and energy imbalance in regard to cancer development and treatment, and emphasizing the role of chemotherapy and its associated risks and benefits in this disease context. Dr. Randolph’s choice of words and his nonverbal behaviors would reflect that he respects Mr. Crowley’s background and beliefs and his individual concerns and decision-making processes.

A key question to explore is what underlies the choice of the macrobiotic approach. Is it the idea of “doing everything possible” or a desire to prioritize “natural” approaches? Perhaps Mr. Crowley is driven by fear from a past experience or maybe by a family member’s beliefs or experience. Overall, thorough and respectful assessment of Mr. Crowley’s beliefs and understanding will help assess if he is open to discussion about his medical decision and, if so, how best to approach the conversation.

The belief of many patients that CAM therapies offer nontoxic and effective options is frequently based on nonscientific data. For patients without a medical background, it can be very difficult to distinguish between therapies supported by clinical research and those endorsed by anecdotal evidence or tradition. Not all patients know that most therapies advertised as cancer cures have not undergone human clinical trials, whereas there is clearly data to recommend, for example, chemotherapy for stage I Hodgkin lymphoma. Some patients find the pharmaceutical industry suspect and believe it to be overwhelmingly profit-motivated; they may not realize that other information may come from sources with similar or more direct conflicts of interest. Discussing the specific source of the information patients are using will help evaluate its worth and create a better environment for informed decision making.

This discussion also requires the physician to be, to some degree, knowledgeable about the topics involved. Dr. Randolph would do well to admit, if it were true, that he is not completely familiar with the details about macrobiotic cleanses. An empathic approach goes a long way, and the patient will be able to sense the physician’s sincere compassion. Dr. Randolph could thus honestly express his worries about the implications of delaying chemotherapy without downplaying his concern for the patient and the patient’s explicit goal of achieving cure with the fewest possible side effects. If needed, he could use a “time out” and set up an early

follow-up visit to give himself some time to think through these issues carefully and, if necessary, learn more about macrobiotic diets.

Dr. Randolph might acknowledge, at some point, that he is not on the same page as Mr. Crowley and propose some way forward using negotiation skills. Dismissal of Mr. Crowley's views could easily result in a broken relationship, leaving Mr. Crowley too uncomfortable to return for further care. Instead, respectful acknowledgement of Mr. Crowley's views and a willingness to work with him, at least to monitor his health, will leave Mr. Crowley the option to return for further discussion and care. Depending on his level of commitment to the macrobiotic diet, a time-limited trial of 4-8 weeks would be reasonable, as long as Mr. Crowley was fully informed that this approach could allow the disease to progress and perhaps lower the chances of curing it. If, after a trial period, there were clear signs of disease progression, Mr. Crowley could then feel comfortable reconsidering Dr. Randolph's recommendation of chemotherapy. Regardless of the patient's eventual choice, Dr. Randolph could emphasize his desire to stay closely connected to Mr. Crowley [9] and help him in any possible way, thereby maintaining a therapeutic alliance.

A macrobiotic diet entails recommendations for certain foods and cooking methods. Unfortunately, no clinical trials have been performed to identify the risks and benefits associated with this approach. The current medical understanding of this diet is that the likelihood of any favorable impact on the course of Hodgkin lymphoma is extremely low. Referring Mr. Crowley to a colleague with additional knowledge about CAM could help satisfy the patient's desire to explore all avenues with expert care. If such a consultant is not available, referral to a licensed dietician might be helpful.

Physicians are commonly confronted with dilemmas like the one described in this vignette. In this case, it is not clear whether Mr. Crowley reacted badly because of the news he had received or because of the way Dr. Randolph handled the encounter itself. The basis for the patient's treatment decision appears to have been multifactorial.

Conflict between patients and physicians most often involves disagreement about the goals of care or the family's role in decision-making processes [10]. There is very little high-quality evidence about how to approach the subject of CAM with patients, but there is a wealth of information and expert opinion from the literature in oncology about general principles of effective patient-physician communication [11]. Respecting patient autonomy sometimes entails adult patients' making what we, in allopathic medicine, view as poor decisions—even at the risk of death [12]. Despite this, we continue to play an active role in caring for these patients. Physicians like Dr. Randolph would be well served to continue advocating for their patients' health and unequivocally supporting competent adult patients, such as Mr. Crowley, in their right to accept or decline chemotherapy for a highly curable disease such as stage I Hodgkin lymphoma.

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CLINICAL CASE

“CAM” Education in Medical Schools—A Critical Opportunity Missed

Commentary by Kimball C. Atwood, MD

Sophia was a second-year medical student at a highly regarded institution, and the day’s classes were dedicated to introducing complementary and alternative medicine (CAM). During the day, students rotated through different rooms to observe presentations about biofeedback hypnosis, holistic chiropractics, traditional Chinese medicine, yoga, and energy medicine.

Sophia was intrigued but expected a critical overview of CAM—published papers that would lend credence to these practices, or the perspective of physicians who deal with the patients seeking them. She was surprised to find that this was not how it was presented. CAM practitioners were given an unrestricted platform to promote their methods and neither they nor the medical school faculty provided disclaimers. The biofeedback hypnotist insisted that his therapies were “as effective as any science.” And the Chinese medicine practitioner said, “When the flow of qi is disrupted it can cause diseases like cancer. Acupuncture adjusts this flow.”

Afterwards, as her classmates were spilling into the hallway, Sophia spotted one of her friends and pulled him aside. “Hey, Michael, what do you think of that session? Wasn’t it kind of...unsettling?”

“What do you mean?” He asked.

“I mean... ‘qi?’ Seriously? I can’t believe they would teach this kind of thing here.”

“I get that you’re a skeptic, but I would appreciate it if you wouldn’t belittle Chinese medicine. Qi is widely accepted as legitimate. Of course, it’s a concept that I wouldn’t expect anyone who hasn’t grown up in the culture to appreciate. But 5,000 years of Chinese history—which is hard to argue against—lends credibility to traditional Chinese medicine. For example, red yeast rice has been used by the Chinese for 1,200 years, and guess what—now Western medicine uses it to treat high cholesterol in patients who can’t take statins. So keep an open mind before you disregard an entire school of thought.”

“Michael, I’m sorry if I sounded disrespectful; that really wasn’t my intention. And you’re right—red yeast rice is a perfect example of how a traditional medicine can successfully become part of an established modern therapy. But it only did so with the support of valid evidence—through appropriately peer-reviewed, controlled, and randomized clinical trials.”

“But Sophia, who are you to decide what constitutes ‘evidence?’ Many of these medical therapies are holistic and represent a way of life. It’s impossible to subject that kind of complexity to controlled trials.”

“Perhaps. But if they can’t be tested scientifically, then these ‘ways of life’ shouldn’t be actively promoted. Evidence is important, and the only way to get as close to it as possible is via the scientific method. It is the only tool available to us that systematically removes emotion and bias. Without it claims like those made by CAM practitioners cannot be objectively evaluated. I’m not saying that alternative remedies don’t have value, but to equate them with peer-reviewed, evidence-based therapies is misleading and potentially lethal.”

Michael chewed on his bottom lip. He understood what Sophia was getting at, but he still felt there were many therapies that could not truly be tested by evidence-based medicine. Should we simply discourage all of those practices? Did strict science really have a monopoly on truth? Or were there other legitimate forms of evidence?

Commentary

The clinical case illustrates a problem common to “complementary and alternative medicine” (CAM) courses in U.S. medical schools: they are uncritical and promotional [1-3]. This is unfortunate because the topic offers an ideal opportunity to discuss scientific skepticism, other critical thinking skills, accurate information, the history of medicine, medical practice ethics, human studies ethics, and linguistic integrity—all of which are basic to professionalism and excellence in modern medicine.

History, Language, and Integrity in Medical Education

Such courses are frequently based on the American Medical Student Association’s (AMSA) *Education Development for Complementary and Alternative Medicine (EDCAM) initiative: A National Curriculum For Medical Students* [4]. The EDCAM project was funded in 2002 by the National Center for Complementary and Alternative Medicine (NCCAM), which, concurrently, funded CAM teaching programs at several medical schools [5, 6]. From the EDCAM “Background and Overview”:

One hundred years ago...doctors and healers co-existing in the practice of medicine [were] more focused on clinical outcome than mechanism of action.

Over the past century...the mechanism of action of a treatment has often overshadowed patient preferences, cultural issues, and the biopsychosocial model of patient care, which are more emphasized in older medical systems.

Complementary and alternative medicines (CAM) in the U.S. are defined by general terms of exclusion...

Their exclusion...has labeled them as “alternative.” In the UK, where they are used in combination with drug-based medicines, they are called “complementary.” Healers who treat the patient and the disease process as mind-body-spirit call their work “holistic.” Recently, MDs trained in allopathic medicine who want to bring in other modalities...use “integrative” medicine. Several misnomers also exist in the terminology. Traditional...is also used to refer to allopathic medicine by Americocentric persons. Western medicine is also a misnomer, as homeopathy, osteopathy, and native American medicines were developed in the West, but the term is used to refer to allopathic medicine [7].

To EDCAM, the place of “alternative medicine” in modern health care would seem to be a matter of politics: a struggle over power, dominance, centrism, privileging, and exclusion. Plausibility is apparently irrelevant (except insofar as plausibility is itself a form of privileging); modern treatments are drug-based rather than holistic; modern medicine devalues patient preferences, cultural issues, and the biopsychosocial model; biomedicine is more concerned with mechanisms of action than with clinical outcomes. Such postmodern deconstructions are not limited to the musings of EDCAM authors [8].

In reality, the emergence of modern medicine and its discarding of prescientific myths were the result of scientific discoveries [9]. Medical schools might use the topic of CAM to discuss how the numerical method of Pierre Louis led to the downfall of bloodletting, or how the bacteriology of Koch, Pasteur, and Lister combined with the clinical observations of Holmes, Semmelweis, Snow, and others to explain the contagions that had plagued humankind throughout history and to drastically reduce the dangers of surgery and childbirth.

When I was in medical school in the 1970s, it was common to hear students complain that basic sciences were irrelevant to medical practice. CAM offers an opportunity to demonstrate how truly relevant they are, because it was the discovery of such principles as chemical thermodynamics and Avogadro’s number and the development of the basic medical sciences, that refuted vitalism, homeopathy, humoral theory, miasma theory, the doctrine of signatures, and other prescientific myths that persist today as CAM beliefs.

The EDCAM passage is full of its own misnomers: “allopathic” was coined circa 1800 by Samuel Hahnemann, the inventor of homeopathy, to highlight the difference between his idea that “like cures like” and the approach of contemporary “regular” European medicine, which, as he saw it, “supressed symptoms by opposition.” The term was not accurate even at the time, and certainly does not describe modern medicine [10]. “Holistic healers” are largely innocent of human biology [11]. “Integrative” boasts properties that it did not create (“patient-centered” care, preventive medicine [12]) and makes a promise that it can’t keep: to “combine the best of conventional and complementary medicine” [13].

Modern medicine is “Western” only in the trivial sense that its historical roots were found in Europe and North America. It is distinguished by its reliance on science. The principles of biology, chemistry, anatomy, physiology, and pharmacology do not vary according to location, nor does the capacity of science to follow evidence wherever it may lead, whether to new discoveries or to discrediting long-held opinions. Many of those discoveries—statins, for example (see below)—have been made in non-Western settings. Modern medicine is thus universally applicable. It is no more Western, in any important medical or scientific way, than the physics of Einstein was Jewish.

The biopsychosocial model was first proposed not by “older medical systems,” but in 1977 by the academic psychiatrist George Engel, who thereby demonstrated that it is within the capacity of modern medicine to recognize the benefits of a holistic—in the accurate sense of the term—approach to medical care [14]. “Complementary” and “alternative” are themselves euphemisms, designed not by those who would exclude them but by their apologists, to distract from less flattering adjectives [15]. An honest term for most practices covered by the term CAM would be “implausible medical claims.”

Learned Skepticism: An Equal-Opportunity Belittler of Prescientific Myths

Logical fallacies, including the appeal to tradition (“Five thousand years of Chinese history”), are common in CAM advocacy. Astrology is far older than acupuncture, but astrology is not valid. Others fallacies illustrated in the case scenario are the *ad populum* (“qi is widely accepted as legitimate”), the straw man (Michael appears to accuse Sophia of belittling Chinese culture, people, or history when she was doing nothing of the sort), the argument from ignorance and the argument from authority (“a concept that I wouldn’t expect anyone who hasn’t grown up in the culture to appreciate”), special pleading (“It’s impossible to subject that kind of complexity to controlled trials”), the *ad hominem* (“who are you to decide what constitutes evidence?”), and the *tu quoque* (“keep an open mind before you disregard...”).

The medical school classroom should seek to foster a rigorous, skeptical habit of mind [16-18]. Qi cannot, by dint of its Chinese pedigree, claim immunity from scientific scrutiny. Nor is such scrutiny even concerned with that pedigree: what makes qi unworthy of being taken seriously in science or medicine is that it is undetectable, unmeasurable, and unfalsifiable. The same can be said for many other beliefs found in CAM, no matter their geographical or ethnic origins: the human energy field, craniosacral rhythms, chakras, the four humors, chiropractic subluxations, vitalism, psychokinesis, *similia similibus curantur*, water memory, homunculi represented on the eyes, ears, and feet, and more. A scientific dismissal of qi no more belittles Chinese culture or people than a dismissal of humoral theory belittles European culture or people.

The term “Chinese medicine” is itself misleading, because medicine in China today is, overwhelmingly, modern. Even prescientific Chinese medicine, as the term usually implies, was not one thing or even a few things; it was many, disparate ideas

and treatments—as would be expected for such a long history and such a large geographical area [19]. There was substantial foreign influence, particularly from India and Greece [20]. “Traditional Chinese medicine” is a term invented in the People’s Republic of China only a few decades ago [21]. It refers to a variety of ideas and practices that resemble some found in Chinese history, but that during the 1950s and ’60s were forced—not by science or logic but by governmental fiat—into an unprecedented, standardized collection.

Pharmacognosy, Statins, and Red Yeast Rice

That many useful drugs have been and will continue to be derived from natural sources, exactly as biology would predict, is widely known. This has little to do with the recent political phenomenon known as “CAM,” whose champions have, in fact, frustrated such endeavors [22]. Statins were found by a purposeful search in soil microbes for inhibitors of cholesterol synthesis, much as streptomycin had been discovered in a search for antibiotics three decades earlier [23, 24]. Statins were eventually found in several fungi; the fungus associated with red yeast rice was one, but not the first, and traditional medicinal uses of red yeast rice appear to have had no bearing on the discovery. The promotion of a supplement as an alternative to pharmaceutical-grade statins, however, is fraught with hazards common to crude preparations: widely varying doses of active ingredients, and adulteration with naturally occurring toxins [25].

There is evidence that red yeast rice extracts capable of lowering cholesterol levels may be tolerated by patients who have experienced statin-associated myalgias from single agents [26]. If so, it might be due to the dose of lovastatin (the major active ingredient) in such extracts being lower than the usual prescribed dose, which would be unremarkable. On the other hand, it may be that the variety of monacolins (statins) in red yeast rice can reduce cholesterol with fewer side effects, which would be an important discovery. All of this will need to be determined by scientific means. This is pharmacognosy, not CAM [27].

Science, Evidence-Based Medicine, and Skepticism

Sophia is correct that whatever specific value there may be in an untested treatment can only be demonstrated through scientific evaluation. There are not “other legitimate forms of evidence.” The preponderance of evidence shows that the effects of CAM treatments, with the exceptions of a few biological substances, are not distinguishable from those of placebos [28, 29].

Ironically, evidence-based medicine (EBM) has often given CAM more credibility than science warrants. Recent reviews by the Cochrane Collaboration have called for randomized controlled trials (RCTs) of treatments that other scientific evidence has long put to rest, such as laetrile, chelation for atherosclerotic cardiovascular disease, therapeutic touch, and homeopathy [30-34]. Studying these topics would present medical educators with opportunity to discuss concepts of general interest in medicine, including what constitutes scientific evidence, the EBM levels-of-evidence

scheme, the purpose of the RCT, frequentist vs. Bayesian inference, why people believe that ineffective treatments work, and human studies ethics [35-39].

Such a discussion might also consider parapsychology: the study of clairvoyance, ESP, psychokinesis (telekinesis), precognition, remote viewing, communicating with the dead, and more. The field is more associated with CAM than most medical faculty appreciate (therapeutic touch, Reiki, distant healing, applied kinesiology, and external qigong are examples of psychokinesis) and has been subjected to trials for far longer than have CAM methods [40, 41]. Parapsychology, like CAM, has at best yielded equivocal, inconsistent results; yet it persists as a *pathological science* [42].

The history of parapsychology demonstrates that academic researchers are often not up to the task of evaluating bizarre claims. In 1978 the magician James Randi, famous for having debunked psychic spoon bender Uri Geller on the Johnny Carson Show, arranged for a pair of teenage magicians, who were particularly adept at spoon bending, to pose as psychics and present themselves for testing at a parapsychology lab at Washington University in St. Louis. Over a 3-year period the two were easily able to convince their hosts, including a physics professor, that they possessed paranormal powers [43]. Prior to the hoax, Randi had written the physicist, offering advice on how to control for trickery, only to be ignored.

History is repeating itself. David Eisenberg, director of CAM research and education at Harvard, recounted his amazement at watching a “qigong master” direct his “external qi” to light a light bulb. Eisenberg called for studies in American laboratories and wrote, “the suggestion that Chinese medical authorities would consciously dupe the Western scientific community is absurd” [44]. Yet James Randi exposed similar qigong feats as conjuring tricks, and Eisenberg had himself been duped by demonstrations of “acupuncture anesthesia” [45, 46].

David Katz, Yale’s representative on the steering committee of the Consortium of Academic Health Centers for Integrative Medicine, told me that he keeps an open mind about “strange powers that are beyond our understanding” in part because he saw a mentalist perform fork bending [47, 48]. Dr. Katz was unaware that he had witnessed a magic trick. Psychologist Gary Schwartz of the University of Arizona, the principal investigator (PI) of the NCCAM-sponsored Center for Frontier Medicine in Biofield Science, claims to have demonstrated scientifically that mediums, including John Edward, can communicate with the dead [49-51]. Victor Sierpina, the PI of the NCCAM-funded Curriculum in Alternative Therapies at the University of Texas Medical Branch at Galveston, published a book review in the *Journal of the American Medical Association* touting “the scientific evidence of the effects of nonlocal mind”—psychokinesis—as a treatment for an auto crash victim [52].

All four of the schools just mentioned are recipients of numerous NCCAM educational or research grants [53]. Is it any wonder that students are scratching their heads?

Conclusion: Medical Practice Ethics and Educational Ethics

Few articles address the ethics of medical doctors' prescribing or referring patients for CAM. One article argues that when the evidence is sufficient, the physician should recommend CAM, citing treatments that are either not CAM ("relaxation training for improving anxiety and decreasing pain"; "psychotherapy, group therapy, relaxation, and imagery for improving the quality of life in patients with breast cancer") or are not adequately supported by evidence (acupuncture for the nausea of chemotherapy) [54].

Another article considers the "broad principles...acknowledged to underlie medical ethics: Autonomy, Nonmaleficence, Beneficence, and Justice." It concludes: "Yes, patients have needs that are not being served by mainstream medicine, but these needs do not include being subjected to bogus tests, claims, and treatments" [55].

Elsewhere I've discussed the relevant excerpts from two widely accepted medical practice ethics treatises, including the *AMA Code of Medical Ethics*, concluding:

[There is] an obligation to patients and an obligation to honesty and integrity, which in turn is either explicitly or implicitly linked to science...

[It is] unethical for physicians to offer implausible treatments, to refer patients to others for implausible treatments, or, if asked, to fail to inform patients of the implausible nature of such treatments.

[It is] unethical to administer a placebo without the patient's informed consent, or to mislead patients about the reasons that implausible treatments make some people feel better. Thus it is dishonest to recommend acupuncture or homeopathy in a disguised attempt to elicit a placebo effect [56].

Those points may be debatable, but they deserve discussion in any medical school CAM presentation.

From the *AMA Principles of Medical Ethics*:

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public [57].

The clinical case presented here, the AMSA EDCAM modules, and the preponderance of other evidence demonstrate that violating this principle is the norm for CAM education in American medical schools. Marcus and McCullough, the authors of the most recent article reporting this state of affairs, concluded:

The flawed curricula presented by integrative medicine programs constitute an educational failure on the part of health professions schools and AMSA....

By tolerating this situation, health professions schools are not meeting their ethical obligations to learners, patients, or society [1].

CAM offers an opportunity to discuss numerous issues that are both fascinating and fundamental to medical education and professionalism. That opportunity is being squandered.

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CLINICAL CASE

Herbal Supplements as Placebos

Commentary by Valerie (Val) Jones, MD

Yawning, Dr. Grey strolled into her office, smoothed her coat over the back of her chair, and switched on her computer. It was Monday morning at her internal medicine clinic, and as she scrolled through the patient list for the day her eyes paused at one in particular. Ms. Freidlander was scheduled to see her at 2:00 for GI pain...again. It was her third visit this month alone, and Dr. Grey tamped down the jolt of frustration that coursed through her.

Ms. Freidlander, a 40-year-old seamstress who was raising two children on her own, came in frequently with a variety of pains and symptoms. A few months before it had been back pain, but lately she had been visiting over and over again for abdominal discomfort and frequent diarrhea. Despite negative blood work, stool studies, and colonoscopy, she was convinced that something was terribly wrong, but Dr. Grey felt strongly that it was likely related to Ms. Freidlander's undiagnosed chronic anxiety.

Dr. Grey hesitated for a moment, recalling that Ms. Freidlander's back pain subsided after her chiropractor instructed her to begin herbal supplements. She was fairly certain that this success was due to the placebo effect, and wondered whether Ms. Freidlander's abdominal pain would respond similarly. She had read that roughly half of internists and rheumatologists prescribe placebos regularly; in the form of sugar pills, antibiotics, over-the-counter analgesics, vitamins, and supplements. She had never done so, however, and had always felt that it was a violation of informed patient autonomy. If and when patients find out about placebos, the discovery surely has the potential to erode their trust in all physicians.

It was clear, however, that what Ms. Freidlander was feeling constituted legitimate distress, and if there were a relatively safe method to eradicate it—any method—should it not be attempted? Another bottle of herbal supplements or vitamins could theoretically cease her discomfort with few to no side effects. Was that not worth trying?

Commentary

This case study describes a common scenario: a patient (Ms. Freidlander) with an undiagnosed mental health disorder seeks attention from multiple medical experts (Dr. Grey et al.). Upon finding no evidence of pathologic process, the experts wonder if they should offer the patient a placebo to trick her into feeling better

temporarily. In my opinion, this is a classic example of a patient's receiving substandard care in our broken health care system.

Perverse financial incentives have caused the American health care system to become overspecialized, resulting in fragmented care [1], overutilization of resources, and increased health care costs [2]. While the system is incredibly good at solving specific problems (e.g. major trauma), it is exceedingly bad at addressing complex biopsychosocial dilemmas. Patients like Ms. Freidlander end up seeking help in all the wrong places—without proper guidance from their frazzled health care professionals.

While I have the utmost sympathy for Dr. Grey's predicament (she is a gastroenterologist presented with a patient whose underlying disorder is outside of her field of expertise), I cannot condone her proposed solution: to offer a non-evidence-based "quick fix" for a long-standing problem. Dr. Grey believes Ms. Freidlander's relief from previous psychogenic complaints was short-lived. A more appropriate response would be to direct Ms. Freidlander to a more likely source of permanent relief—and that requires the correct diagnosis and an evidence-based treatment plan.

Finding The Root Cause of Ms. Freidlander's Problem

In addition to genetic predisposition and medical history, biopsychosocial factors—such as childhood neglect and emotional trauma, cultural beliefs about sickness, socioeconomic status, and social isolation or lack of social support—can exert negative influence on many aspects of one's health, including (a) mental health, e.g., anxiety and depression, (b) health behaviors, e.g., poor eating habits, sedentary lifestyle, smoking, and lack of self-care, (c) chronic medical disorders, and (d) adverse health outcomes, e.g., lowered quality of life, functional impairment, or a high symptom burden. And each of these behaviors and outcomes can affect each of the others. Depression, for example, can increase the likelihood that one will adopt coping mechanisms (overeating, smoking, or drinking) that will be harmful to one's physical health; persistent anxiety can cause physiological damage [3].

Mental health professionals and primary care physicians are trained to approach patients from a holistic perspective, understanding that their physical symptoms may be related to complex risk factors, chronic medical disorders, and health behaviors. A thorough review of Ms. Freidlander's medical and social history could reveal an abusive relationship, addiction disorder, sedentary lifestyle, social isolation, or severe stress (which can be related to finances, children, relatives, or any life event). Any number of these could be contributing to her discomfort—and they each require a different kind of intervention for long-term success.

For argument's sake, let's assume that Dr. Grey is correct in her conclusion that Ms. Freidlander suffers from an anxiety disorder and that her pain symptoms are manifestations of anxiety. We know that the goal of every physician is to provide the

very best evidence-based care for patients. The question then becomes—what does the evidence suggest might work best for this patient?

Evidence-Based Treatments For Anxiety

Talk therapy. A systematic review of 14 meta-analyses of the effects of psychotherapeutic interventions versus medical interventions (for the treatment of mental health disorders) consistently showed “talk therapy” to have a far larger effect than medical treatments [4]. Evidence suggests that talk therapy might be as much as 8.5 times more effective than medications (which are proven in clinical studies to be more effective than placebos) in the treatment of some mental health disorders.

Not only is talk therapy likely to be more effective for patients like Ms. Freidlander than herbal supplements intended as placebos, research has documented a consistent trend toward larger effect sizes at follow-up for patients undergoing psychodynamic therapy. It is postulated that the therapy sets in motion psychological processes that lead to ongoing change, even after therapy has ended.

Regular follow-up. There is mounting evidence that chronic conditions (such as anxiety disorders and diabetes) are most successfully managed with a team approach. Rushika Ferbandopulle and others have found that enhanced patient contact, follow-up, and regular communication can reduce emergency room visits, hospital admissions, and health care costs by as much as 25 percent [5].

Physical activity. Regular physical activity, especially aerobic exercise, is well known to reduce anxiety symptoms [6].

Dietary interventions. Evidence suggests that caffeine intake and ephedrine-related OTC herbal remedies can increase anxiety symptoms [7].

Sleep hygiene. Regular sleep is important in reducing anxiety symptoms. Poor sleep hygiene is associated with more chronic forms of anxiety [8].

Antidepressants. Although I believe that antidepressant medications should be a treatment of last resort, current guidelines for managing generalized anxiety disorder suggest that there is a role for medications, specifically serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, and nonsedating tricyclic antidepressants [9, 10].

Conclusion

Millions of patients like Ms. Freidlander and their physicians are using the health care system inappropriately to treat mental health needs. Proper diagnosis, beginning with a careful medical, social, and family history (including a review of health behaviors, risk factors, and basic lifestyle choices), is critical in helping them to find an evidence-based treatment plan. Ample evidence suggests that talk therapy,

consistent follow-up, physical activity, dietary changes, improved sleep hygiene, and antidepressant medications may improve symptoms of anxiety.

It is not appropriate to offer an untested treatment to a patient when there are proven options that have not yet been tried. Furthermore, when such a treatment requires intentionally misleading a patient about the efficacy of the placebo, patient autonomy is violated—a breach of medical ethics.

Dr. Grey's temptation to offer Ms. Freidlander a quick placebo "fix" for what Dr. Grey believes to be her long-standing and complex anxiety is bad medicine on many levels. First, it delays the patient from getting care that may help her. Second, it gives her the wrong impression that she has been definitively diagnosed, and with something most likely unrelated to the true cause of her symptoms. Third, it may result in increased health care costs as the patient continues down additional diagnostic "rabbit holes." And finally, Dr. Grey's behavior violates the trust of a patient who is relying on her honest judgment.

In the end, I believe that Dr. George Lundberg had it right: "There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking" [11]. Evidence is lacking for the use of placebos (herbal or otherwise) in this patient's case, and therefore they should not be offered.

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AMA Code of Medical Ethics' Opinions on Ethical Referral

Opinion 3.04 - Referral of Patients

A physician may refer a patient for diagnostic or therapeutic services to another physician, limited practitioner, or any other provider of health care services permitted by law to furnish such services, whenever he or she believes that this may benefit the patient. As in the case of referrals to physician-specialists, referrals to limited practitioners should be based on their individual competence and ability to perform the services needed by the patient. A physician should not so refer a patient unless the physician is confident that the services provided on referral will be performed competently and in accordance with accepted scientific standards and legal requirements.

Report issued prior to April 1977.

Opinion 3.041 - Chiropractic

It is ethical for a physician to associate professionally with chiropractors provided that the physician believes that such association is in the best interests of his or her patient. A physician may refer a patient for diagnostic or therapeutic services to a chiropractor permitted by law to furnish such services whenever the physician believes that this may benefit his or her patient. Physicians may also ethically teach in recognized schools of chiropractic.

Report issued March 1992.

Opinion 3.01 - Nonscientific Practitioners

It is unethical to engage in or to aid and abet in treatment which has no scientific basis and is dangerous, is calculated to deceive the patient by giving false hope, or which may cause the patient to delay in seeking proper care.

Physicians should also be mindful of state laws which prohibit a physician from aiding and abetting an unlicensed person in the practice of medicine, aiding or abetting a person with a limited license in providing services beyond the scope of his or her license, or undertaking the joint medical treatment of patients under the foregoing circumstances.

Physicians are otherwise free to accept or decline to serve anyone who seeks their services, regardless of who has recommended that the individual see the physician. Updated June 1996.

Related in VM

[Chiropractic's Fight for Legitimacy](#), June 2011

[Licensure of Complementary and Alternative Practitioners](#), June 2011

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JOURNAL DISCUSSION

Fairness in the Context of CAM

Hannah L. Kushnick

Vaught W. Complementary and alternative medicine: the physician's ethical obligations. In: Snyder L, ed. *Complementary and Alternative Medicine: Ethics, the Patient, and the Physician*. Totowa, NJ: Humana Press; 2007. Biomedical Ethics Review Series.

There are a few oft-voiced objections to learning about, testing, and keeping an open mind about CAM. As Wayne Vaught points out in his piece “Complementary and Alternative Medicine: The Physician’s Ethical Obligations,” they tend to revolve around several main generalizations: CAM providers are unscrupulous or ignorant and therefore unworthy of being treated with respect; CAM practices are dangerous because they are untested or not supported by high-quality evidence; CAM practices do not merit testing because they are inherently unscientific. Vaught addresses each of these with aplomb.

Before beginning the main portion of the argument, he pauses to dispatch the notion (more popular among CAM advocates than detractors) that CAM needs a different bioethics than that employed by conventional medicine. He points out both that the principles at the heart of conventional Western-derived bioethics are widely applicable (even outside of the realm of medicine) and that much of conventional-medicine bioethics is already asking questions that extend beyond its stated principles (e.g., what does it mean to be culturally competent and how can physicians become so?) [1]. He also mentions that some CAM organizations are making fruitful use of conventional principles in their codes of ethics, for example [2].

Then he turns to three possible obligations physicians could have in regard to CAM: (1) a duty (to the patient) to ask patients about CAM, (2) a duty (to CAM practitioners and proponents) to promote the scientific study of CAM, and (3) a duty (to both) to integrate CAM into conventional care. His arguments about the first are fairly straightforward, and can be summed up by the idea that “the need to learn about common forms of CAM stems from a similar obligation physicians have to understand environmental risks and lifestyle choices” [3]. In short, a physician’s choice to discuss or not discuss CAM should have nothing to do with his or her stance about the treatments themselves. Vaught’s discussion of the third duty makes mention of the integration of chiropractic—a system based on theories that definitely conflict with scientific ones—into care as an example of how such integration can

benefit patients. He points out that proponents of integrative medicine “focus...on the [efficacy of the] method itself, not the underlying theory” with good results [4].

The more unusual argument is about what physicians owe to their not-quite-colleagues. Vaught makes the interesting point that physicians have an ethical obligation not *only* to patients but to CAM practitioners to promote justice, which is to say fairness. Fairness entails avoiding generalizations about either CAM practitioners or medical doctors: “misrepresentation is not limited to CAM. Some [conventional, licensed] physicians have been guilty of fraud and misrepresentation” [5].

So what does the unfairness look like? Vaught expresses concerns that some arguments against testing CAM practices scientifically lead to a double standard of evaluation, “raising the bar of evidence for CAM providers while applying a lower standard of evidence [required] to justify...use of more conventional treatment” [6]. He points out, quite rightly, that those who deride CAM techniques *because* they are not based on scientifically accepted mechanisms are saying that “it is not just the lack of studies that [make CAM dangerous], but the very nature of the practices themselves that deem them unworthy of consideration” [7]. Vaught explains that this argument rests on two substantial assumptions:

(a) that all valid knowledge will prove coherent with some characteristic of established contemporary science, and (b) that the likelihood that a claim will eventually have this coherent relation to contemporary science can be judged on the basis of present knowledge....The most obvious difficulty with the argument is that the failure of a CAM provider to provide a scientifically supportable biological mechanism for a given treatment modality does not, in itself, render the treatment unworthy of clinical consideration. It may merely point to the limitation of our current state of scientific knowledge [8].

He goes on to remind readers that CAM treatments aren't the only ones that can be dangerous—a number of FDA-approved conventional treatments (e.g., arthritis drugs) have been pulled from the market when longitudinal trials (and lawsuits or news reports, I might add) show harmful side effects [9]. Vaught makes the extremely cogent point that *not every treatment* in conventional medicine is supported by high-quality evidence, and thus physicians are “forced” to rely on less-tested treatments—and the mechanisms by which many conventional treatments work, even one as widely popular and trusted as aspirin [8], remain in question—just as they do for many CAM treatments.

This would-be double standard applies to behavior, in addition to evidence. A willingness to experiment with things that aren't completely certain is central to the culture of conventional medicine. The behavior that CAM detractors argue would be irresponsible with regard to CAM is outright encouraged within conventional

medicine. Vaught gives two examples: hazardous lifesaving treatments and off-label use of drugs. He relates the story of a medical team that, in a last-ditch effort to save a teenage girl with a severe case of rabies, subjected her to a highly dangerous and untested treatment—a medically-induced coma and an experimental drug cocktail—and were “praised because their gamble paid off” [6].

He elucidates some similarities between these ER heroics and their more mundane cousin, off-label prescribing. His considerations of physicians’ reasons for prescribing drugs for a purpose other than the one for which they’ve been approved echo probable reasons for administering CAM treatments: “it may be that a physician has had success with it in the past [or]...there may not be an approved pharmaceutical to treat a specific condition...or...age group” (e.g., the drug is used in pediatrics even though it was not tested on children) [10]. These ideas point to other reasons CAM is sought and administered.

The more extreme version of a condition for which there is no FDA-approved treatment is a condition that is not on the medical map. Vaught notes that “patients also may wish to include CAM modalities when they [have] conditions that are not recognized by, or may seem bizarre to, conventional providers” [11]. These things may be considered “bizarre” if the patient uses the language of religious traditions that are not mainstream in America (e.g., the example Vaught gives: soul loss). Even if described in less supernatural language, they may still be dismissed as merely “vague” or “chronic.” This seems to point to the need to *do something* to respond to these conditions, whether that’s giving them consideration in conventional medical terms or allowing CAM treatments for them to coexist with medical treatments for medically recognized conditions.

Also, as Vaught points out, in some circumstances (e.g., chronic pain), a CAM treatment is *much* less invasive than the alternatives, which is to say it “it limits or makes pharmaceutical intervention [and their side effects] unnecessary” [4]. This is an important distinction—the dialogue about chronic conditions appears to focus primarily on conventional treatments’ lack of success and on the frustration of dealing with chronically ill patients, not on the invasiveness of the treatments. The idea that *limiting* pharmacological treatment should be a goal of mainstream medicine is notable.

Though, as Vaught cautions, “the fact that physicians must sometimes resort to unproven therapies does not legitimize the use of every unproven therapy” [10], he draws these parallels to show that CAM and conventional medicine have much in common and as such should be treated similarly. “If,” he says, the “restrictions [skeptics advocate putting on CAM] were applied equitably [to conventional medicine], physicians would lose a wide range of conventional treatment modalities” that are supported by low-quality or case-report evidence [9]. Physicians, he argues, “treat CAM unfairly...when they leave a patient with the impression that *all* conventional therapies have been tested for safety and efficacy” [5; italics mine] or tar all CAM practices with the same inappropriately broad brush. In short, physicians

“should not hold CAM to standards that conventional medicine is itself unable to achieve” [10].

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CLINICAL PEARL

The Lipid-Lowering Properties of Red Yeast Rice

David J. Becker, MD, and Ram Y. Gordon, MD

When I saw Mr. S in my office 9 years ago, he had high cholesterol, with a low-density lipoprotein cholesterol (LDL-C) of 180 mg/dl, so I started him on statin therapy. Six months later, his lipids were significantly improved and I tried to renew his prescription for atorvastatin. He gave me a sly grin and told me that he had stopped taking it. Instead, he was taking red yeast rice, an over-the-counter herbal medication he had heard about on a local radio station. I had never heard of this supplement, but when several more patients related almost identical stories, I began to listen to them. It seemed to work especially well in patients who developed myalgias, or muscle aching, after they took statins, which occurs in up to 15 percent of patients in clinical practice. It was well-tolerated and seemed to lower cholesterol almost as well as conventional therapy.

Red yeast rice, used in China since 800 CE as a food colorant and medication, is made by culturing a yeast, *Monascus purpureus*, on rice. It is widely available and popular; sales of red yeast rice in the United States totaled \$20 million in 2008 [1]. Still, I was quite reluctant to recommend it to my patients. Many physicians have appropriate concerns about using over-the-counter products that have not been rigorously evaluated in double-blinded randomized controlled trials. The small studies that have been conducted are often funded by the manufacturer of the supplement, presenting a conflict of interest. Yet our patients are taking more and more supplements; the nutraceutical market in the U.S. has grown to \$15 billion over the past few years. Patients often do not tell their physicians that they are taking supplements, and this can lead to adverse drug interactions with prescribed medications. For example, products made from the herb St. John's Wort, commonly used for depression, can significantly alter the lipid-lowering effect of statins, including rosuvastatin, making it dramatically less effective [2].

As a preventive cardiologist in private practice, I have an interest in intensive lifestyle modification programs and have led such a program for 16 years. Based on my clinical observations about the possible efficacy of red yeast rice, one of my partners and I decided to design a trial evaluating the lipid-lowering effects of both lifestyle changes and supplements. This involved an unusual twist for a cardiologist in private practice—getting internal review board approval for the study, recruiting patients, and obtaining funding.

After securing grants from the Commonwealth of Pennsylvania and other sources, we designed and conducted several randomized controlled trials evaluating the

efficacy and safety of red yeast rice in different populations with hyperlipidemia. The studies were all funded by independent sources with no industry involvement. We examined the effects of lifestyle changes (education, diet, exercise, and stress management) on lipids and compared red yeast rice's lipid-lowering effect to that of a placebo. We added other lipid-lowering supplements, fish oil and phytosterols, to red yeast rice, to evaluate their combined effects. We also tested our theory that red yeast rice might be better tolerated than statins in patients who had developed statin-associated myalgias. Our work on red yeast rice exemplifies how a supplement used by many patients can be rigorously studied and evaluated for efficacy and safety.

Despite these trials, the use of these products remains controversial for the following reasons:

1. *Is it a supplement or a drug?* The FDA ruled in 1998 that a proprietary product containing red yeast rice (Cholestin), used in a trial by Heber [3], was a drug, and removed it from the market because one of its active ingredients was identical to the prescription drug lovastatin (Mevacor), made by Merck. The FDA has subsequently removed several other red yeast rice products for the same reason, but many products remain readily available to consumers, including several brands used in recent trials.
2. *Products are not standardized* and the quantity and quality of active ingredients (in this case, monacolins, which are also the source of red yeast rice's characteristic red color) are variable. We recently studied the level of monacolins in 12 different red yeast rice products and found a 100-fold difference in the levels of monacolins among them [4]. In addition, an agricultural byproduct called citrinin, which is carcinogenic in animals, was present in several brands. This lack of consistency is a common issue in many over-the-counter supplements.
3. *There is a lack of mortality data for red yeast rice.* Only one study has evaluated mortality, and more data are needed [5].
4. *Many patients prefer taking alternative therapies to prescription drugs.* Most physicians appropriately recommend statin therapy for their hyperlipidemic patients. However, almost 50 percent of patients stop taking their statin within 1 year or refuse to take statins altogether because of a fear of potential side effects or a desire to take "natural" products.
5. *The product is available over the counter,* and patients may take it without physician oversight. Red yeast rice and statins have similar potential side effects, including liver toxicity and muscle damage. Patients should only take it under the supervision of a physician and should have laboratory monitoring at least twice a year to evaluate lipid parameters and liver function.

The recent trials involving red yeast rice have led to the following conclusions:

1. Red yeast rice is effective in lowering LDL-C, total cholesterol, and triglycerides and may modestly raise HDL-cholesterol. Studies suggest LDL-C lowering effects of 21-30 percent.
2. Red yeast rice may be effective lipid-lowering therapy for patients who have experienced statin-associated myalgias [6]. There are several reasons why red

yeast rice seems to be better tolerated than statins. There are 14 different naturally occurring monacolins. One of these, monacolin K, is structurally identical to lovastatin, but the dose of monacolin K needed to lower LDL-C cholesterol 25 percent is about 6 mg per day—much less than the standard 20-40 mg doses of lovastatin that were used in clinical trials. The amount of monacolin K in red yeast rice may be low enough to avoid triggering myalgias, or the other monacolins in red yeast rice may act synergistically to lower cholesterol without causing musculoskeletal discomfort.

3. Red yeast rice may be an alternative for patients with hyperlipidemia who want a “natural” therapy and refuse to take statins. There are safe red yeast rice products on the market, but some products contain little active ingredient (monacolins) and/or citrinin, a potentially nephrotoxic byproduct of fermentation. All red yeast rice products remain unregulated and their legal status is ill-defined.

In conclusion, red yeast rice is an over-the-counter supplement that has been used in China for centuries and has lipid-lowering effects. More recently, it has become popular among Americans, who often view it as an alternative to statins. Unlike most herbal supplements, it has been fairly well-studied and shown to be effective and safe in several randomized placebo-controlled clinical trials [7]. For this reason, it has been used as an example of a traditional Chinese medication that is effective and may have a role in contemporary Western medicine. Because it is an unregulated supplement, different products are not standardized. Until regulation and standardization improve, its use will remain controversial.

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HEALTH LAW

Choosing Alternative Treatments for Children

Kavitha V. Neerukonda, JD, MHA

Adults have the right to reject any type of medical treatment, whether for religious or other reasons, as long as they are deemed to have decision-making capacity. When parents make decisions for their children on religious or other grounds, however, states may intervene because they have a duty to protect the well-being of children who are not legally old enough to make their own decisions. Many cases that have come to the attention of the state turn on the question of whether a parent has the right to choose alternative therapy over conventional medical treatment for a child.

Courts have not ruled consistently for one side over the other because the constitutional rights of parents, such as freedom of religion, right to privacy, and fundamental liberty to raise their children as they desire, provide strong support for parents' right to decide. However, courts must weigh the constitutional interests of parents against the state and federal governments' interests in protecting the children to whom they owe a duty [1]. Most cases that reach the courts seek state intervention to prevent serious injury or death of the child, but in cases in which the child has died, the charges brought against parents are not child abuse and neglect, but homicide.

Thirty-nine states have religious exemptions in their civil codes on child abuse or neglect, and 19 states have religious defenses to felony crimes against children that shelter parents from misdemeanor violations if they treat the children through prayer in accord with the beliefs of a recognized religion. The scope of religious exemption and defense laws varies widely, however [2].

In one of the following three cases, the state was determined to have legitimate concern for the well-being of a child; in another, the parents were given full control of their child's medical therapy; and in the third, a child's death sparked a homicide charge against the parents.

In the Matter of the Welfare of the Child of Colleen and Anthony Hauser [3]

Daniel Hauser, 13, was diagnosed with Stage IIB nodular sclerosing Hodgkin disease. Daniel's parents are strong believers in the holistic benefits of Nemenhah, a Native American healing practice, although they do not hold themselves out as Native Americans. In fact, the Hausers are traditional Catholics. The State of Minnesota intervened in Daniel's case when his physicians raised concerns about his not receiving medical treatments deemed imperative to his survival [4]. The court ruled that Daniel's parents violated Minnesota's long-standing statutory requirement

that parents must provide “necessary medical care” for a child [5-8] and required them to consent for chemotherapy treatment for their son.

When Daniel was diagnosed, his family physician referred him to oncology specialists at a children’s hospital where it was determined his cancer should be treated with chemotherapy. Daniel’s mother consented to a first round of chemotherapy treatment for her son. Although Daniel’s lymphoma responded well to the chemotherapy, he suffered side effects. Daniel reported being sick to his stomach, weak, and unable to walk. Daniel’s parents consulted with five physicians at the Mayo Clinic and other academic medical centers for second opinions. All medical advice pointed the Hausers toward chemotherapy as the best treatment option for Daniel. Most children, 80-95 percent, in Daniel’s situation go into remission within 5 years of the recommended chemotherapy. All of these physicians were of the opinion that if Daniel did not adhere to the treatment, he would not survive. Daniel’s parents did not continue chemotherapy after the first round, based upon their strong beliefs in alternative medicine [9].

Daniel’s mother testified that she was “starving” Daniel’s cancer with methods including doses of high-pH water to make his body more alkaline (because cancer cannot survive in an alkaline environment) and a diet of greens, proteins, and no sugars. She admitted these remedies were found on the Internet. Daniel’s physicians reported the Hausers to the county’s department of child protective services after Daniel stopped chemotherapy [9].

The Minnesota court ruled that, while Daniel’s parents might have strongly believed the alternative forms of therapy were best for him, they were, in fact, breaking Minnesota law. The court found Daniel’s parents to be loving and caring parents and allowed him to stay in their custody, provided they continued the medically necessary therapy. The court stated it would have been bound by Minnesota law and intervened in Daniel’s medical treatment whether or not his tumor had grown larger without the medically advised therapy. However, the court made mention of wanting to relax the state law to allow those who choose alternative forms of therapy to do so if the alternative forms of treatment have been proven effective [3].

In Re Hofbauer

When Joseph Hofbauer, 7, was diagnosed with Hodgkin disease, his physician recommended radiation and chemotherapy as the appropriate medical treatments. After receiving several opinions from medical doctors, Joseph’s parents decided to take their son to Jamaica where he received nutritional or metabolic therapy, including injections of laetrile. When Joseph and his parents returned home to New York, the state intervened after learning that Joseph was not receiving the recommended chemotherapy from his attending medical doctor. The court ruled that Joseph’s parents did not violate New York law since they were providing an acceptable course of medical treatment for their child, taking into consideration all of the surrounding circumstances [10].

New York law states that a neglected child is “one who is less than eighteen years of age whose physical condition has been impaired or is in imminent danger of becoming impaired as a result of the failure of his parent to exercise a minimum degree of care in supplying the child with adequate...medical...care” [10, 11].

The court ruled, based upon expert testimony, that Joseph’s parents had chosen treatment for their son that was not completely rejected by all responsible medical authorities and had sought accredited medical opinions when making their decision. Several studies have proven that the metabolic treatment Joseph received could control his disease and is not as toxic as conventional treatment. A New York state-licensed physician, who was a proponent of metabolic therapy, monitored Joseph’s case along with another physician. Joseph’s parents and his physicians reported that he was responding well to the metabolic therapy and that his appetite and energy level were good. Joseph’s parents also stated they would consider conventional medical treatment if at any time Joseph’s condition seemed to deteriorate [12].

Taking all of the circumstances into consideration and aligning them with New York law, the court found that Joseph’s parents consulted with numerous physicians, had continued to closely monitor their son’s progress with several physicians, and never ruled out the option of conventional therapy if their son’s condition worsened [13].

In this case, the court felt that Joseph’s parents had made an educated and informed decision about their son’s medical treatment. The fact that metabolic therapy is not wholly rejected by the medical community and that Joseph’s condition did not deteriorate after receiving the therapy gave the court grounds to uphold Joseph’s parents’ decision to use alternative treatment for their son.

State of Wisconsin v. Dale and Leilani Neumann

In what is believed to be the first case in Wisconsin involving faith healing in which one person died and another was charged with homicide, Dale and Leilani Neumann were convicted of homicide after their 11-year old daughter died from untreated diabetes.

Wisconsin has a religious exemption to child abuse and neglect laws that allows parents to use religion or faith-based rituals as an effective defense for not choosing conventional medical treatments for their children. In this case, however, the Neumanns were charged with homicide, not child abuse and neglect, so the religious exemption was not applicable [14].

News reports state that Kara Neumann, 11, had not seen a medical doctor since she was 3 years of age and died of untreated diabetes. Kara was reportedly in a coma, surrounded by family and friends praying for her, when her aunt called 911 to report Kara’s state and express her concern. When authorities arrived at the Neumann residence, Kara was unresponsive and efforts to revive her were unsuccessful [15].

The Neumanns belong to the Unleavened Bread Ministries, a small church that favors prayer over medicine. At their trial, reporters wrote that the Neumanns stated they did not regret their course of action and believed in prayer as the best healing method for themselves and their children [15].

Experts say inconsistencies in Wisconsin law that allow the defense of religion in some cases e.g., child abuse or neglect, but not in other cases, e.g., homicide, are grounds for Kara's parents to appeal their conviction to the Supreme Court of Wisconsin [14]. Time will tell how far the appeal goes and how the court will rule on the religious exemption in state law. Meanwhile, the case has stirred controversy for Wisconsin lawmakers, who are proposing legislation to address it.

Conclusion

Balancing parents' rights to raise their children and a state's right to protect the children in their communities is no easy task, even when most states have religious exemptions to their child abuse or neglect laws. Courts straddle the line when it comes to analyzing cases involving alternative forms of medicine chosen for minors. Courts have ruled in favor of both parents and states, depending on the circumstances. The Neumann case brings to light a different question about child abuse and neglect laws to protect medically untreated children—do state laws with religious exemptions for child abuse and neglect apply to homicide or manslaughter, and what is the intent of the laws that are in place? Wisconsin legislators may tackle this very issue soon and, if they do, could spur other states to review inconsistencies in their own laws.

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POLICY FORUM

Licensure of Complementary and Alternative Practitioners

Michael H. Cohen, JD, MBA, MFA, and Harry Nelson, JD

How States Control Health Care Licensure

For over 120 years, the Supreme Court has upheld the principle that states may regulate the practice of medicine and determine what is and is not lawful [1]. In *Dent v. West Virginia*, the State of West Virginia refused a license to Frank Dent, a member of the “eclectic” sect of physicians who incorporated botanical remedies into medicine. Dent had graduated from the American Medical Eclectic College of Cincinnati, but could not establish that he had attended a medical college recognized by West Virginia, passed a designated examination, or practiced in West Virginia for 10 years.

Dent argued that, by refusing him a license, West Virginia deprived him of due process of law. The Supreme Court disagreed, holding that “the power of the State to provide for the general welfare of its people authorizes it to prescribe all such regulations as in its judgment will secure or tend to secure them against the consequences of ignorance and incapacity, as well as of deception and fraud” [2].

Around the time of *Dent*, the states began enacting medical licensing statutes. Today, all states define the “practice of medicine,” in part, by using such words as *diagnosis*, *treatment*, *prevention*, *cure*, and *prescribe*, in connection with *disease*, *injury*, and *mental or physical condition* [3]. State law came to designate the practice of medicine without a license as a crime.

Subsequent cases relied on the *Dent* holding to interpret the medical licensing statutes and uphold prosecutions against a variety of complementary and alternative medicine (“CAM”) practitioners. For example, in *People v. Amber*, an acupuncturist argued that the statutory prohibition on unlicensed “practice of medicine” referred only to “Western allopathic medicine” and did not encompass systems such as Chinese acupuncture, which differs in its “philosophy, practice and technique” [4]. The court disagreed, holding that any “‘sizing up’ or a comprehending of the physical or mental status of a patient” constitutes diagnosis, which is part of the practice of medicine [5]. Similarly, other cases involved prosecutions of practitioners of modalities such as hands-on healing [6], iridology [7], and homeopathy [8]. In each case, courts interpreted statutory terms such as “diagnosis” and “treatment” broadly. Courts have also resisted constitutional challenges to health care licensure on a variety of fronts, including challenges based on free exercise and due process limitations [3].

Licensing of Allied Health Professionals and Complementary Care Providers

Allied health providers, such as dentists, psychologists, and nurses, have their own distinct licensing statutes. The key difference is that medical licensure, known as “unlimited” licensure, grants physicians broad leeway to diagnose and treat disease, whereas licensure for allied health professionals, known as “limited” licensure, carves out a narrower scope of practice [9]. Exceeding that designated scope of practice is considered the unlawful practice of “medicine.”

In response to the prosecution of CAM practitioners for unlicensed medical practice, efforts arose to garner statutory licensing for different CAM professional groups. Presently, chiropractors are licensed in every state; acupuncturists and massage therapists, in over 40 states; and naturopathic physicians, in at least 15 [10].

Like allied health professionals, CAM practitioners have limited licensure and a designated scope of practice. For example, chiropractors can manipulate the spine and provide certain ancillary therapies but may not diagnose and treat disease or otherwise practice “medicine;” massage therapists may deal with emotional content that arises during bodywork, but may not practice “psychology.” The legal boundaries of scope of practice vary and are sometimes difficult to ascertain [9].

The Different Kinds of Licensure

There are several different kinds of licensure. Under *mandatory licensure*, an individual cannot practice without a state license. For example, an individual may not practice “medicine” unless licensed as a physician. With *title licensure*, the state requires an individual to meet specified requirements in order to use a particular professional title. Some states use title licensure for the practice of psychology or counseling. *Registration* involves registering a practice and disclosing information about training and experience to a state consumer protection agency.

Typically, mandatory and title licensure require much higher standards than simple registration. For example, chiropractic licensure typically requires 4,200 hours of education, including basic medical sciences and clinical experience, and passage of the National Board of Chiropractic Examiners (NBCE) written exam [11]. The terminology can get confusing, however, because some boards granting title licensure use the term “registration”—for example, the Massachusetts medical licensing board calls itself the “Board of Registration in Medicine.”

States also use exemptions to licensure as a mechanism to authorize health care practices. For example, in response to the proliferation of interstate electronic communications among clinicians, some states have elected (in lieu of explicit telemedicine statutes) to carve out exemptions from state licensing laws to provide that out-of-state physicians who periodically consult with in-state physicians about in-state patients are not considered to be practicing “medicine” within the state [9]. Similarly, some states exempt practices such as reflexology from medical and massage therapy licensing laws [9].

One interesting variation is a California statute authorizing health care practices by nonlicensed health care professionals, so long as they do not practice “medicine,” make appropriate disclosures to consumers, provide appropriate informed consent, and meet other specified requirements [12].

Licensure as Opposed to Certification, Accreditation, and Credentialing

It is important to distinguish licensure from related concepts such as certification, accreditation, and credentialing. Licensure refers to specific review and approval (and ongoing oversight) by the state of an individual’s right to a license. By contrast, certification ordinarily refers to a review process by a third-party *professional* organization, typically involving the satisfaction of defined criteria, such as completion of a particular training program. Certification can be either a prerequisite for licensure or, in some cases, an alternative. For example, many states require acupuncturists to be certified by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). Professional certifications, however, do not always have licensing implications; states may, for example, require a practitioner to be certified without imposing a requirement of licensure.

Accreditation refers to the application of uniform standards to the educational organizations and programs that train people for certification or licensure. Often, the standards for licensure include a requirement of graduation from one of a limited number of specified accredited programs. The U.S. Department of Education (DOE), for example, has authorized the Council on Chiropractic Education to accredit chiropractic colleges. Similarly, the DOE has authorized the Accreditation Commission for Acupuncture and Oriental Medicine to accredit acupuncture programs.

Credentialing refers to efforts by organizations to ascertain the licensure and other qualifications or credentials of their health care practitioners. Typically, aspiring members of a credentialing organization submit applications setting forth their qualifications for review and approval of their credentials. Some states require self-governing bodies to perform peer review and credentialing functions within health care organizations.

Why Health Care Licensure Matters

From the state’s perspective, health care licensure protects patients from unskilled or unscrupulous practitioners. From the standpoint of health care professionals and groups, licensure offers legitimacy, credibility, and greater access to patients.

For CAM practitioners, licensure is a double-edged sword. On the one hand, licensure offers the state’s imprimatur of legitimacy and access to greater integration with conventional medical care. But for some practitioners, licensure also has a “dark side.” Many healing practices—particularly those from folk traditions—rely on more intuitive sources of knowledge and fit less comfortably into highly structured systems. From the latter perspective, regulation represents a potentially

unhealthy crystallization of healing work into the Western, analytical mindset and subjects practitioners to regulatory mazes they might rather avoid [9].

Most health care providers, from neurologists to shamans, fit somewhere in the spectrum of mandatory licensure, title licensure, registration, or exemption from licensure. A practitioner who does not fall within one of these four categories could be considered to be engaged in unlicensed medical practice (or the unlicensed practice of another profession).

Although, historically, regulation began with the effort to protect physicians affiliated with the American Medical Association from competition with other practitioners [13], the regulatory trend today is toward medical pluralism and greater inclusion of a variety of practitioners [10]. Due in part to such inclusion, CAM practitioners are increasingly being integrated into conventional medical settings, including academic medical centers [14].

The trend towards medical pluralism and inclusion of CAM practitioners appears to be accelerating as a result of the federal Patient Protection and Affordable Care Act (ACA) enacted in March 2010. Notably, for example, Section 2706 of the ACA includes a nondiscrimination provision, championed by chiropractors, that prohibits health care payors from discriminating “against any health care provider who is acting within the scope of that provider’s license or certification under applicable State law” [15, 16]. Elsewhere, the ACA calls for the inclusion of CAM practitioners in new community-based, interdisciplinary health teams (Section 3502) and recognizes both CAM practitioners and chiropractors as part of the health care workforce for purposes of a new National Healthcare Workforce Commission. It will be interesting to see whether the expanding role (and possibility of federal funding) for CAM services leads to an influx of new practitioners and changes in state licensing requirements.

The existence of licensure for CAM professionals makes it more likely that they and conventional medical professionals will exchange referrals and continue to integrate the divergent practices and philosophies relating to patient care.

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MEDICINE AND SOCIETY

Integrative Medicine and Cancer Care

David S. Rosenthal, MD, and Anne M. Doherty-Gilman, MPH

Complementary and alternative medicine, commonly known as CAM, is tremendously popular in the United States and many parts of the world as a means for staying well and managing health concerns [1]. In the United States alone patients spend an estimated \$36 to \$47 billion on CAM therapies [2, 3]. In a National Health Interview Survey in 2007, 37 percent of adults reported that they use at least one form of CAM [4]. A 2008 American Cancer Society study concluded that as many as 61 percent of cancer survivors used some form of CAM [5]. Over the past decade, CAM practices have become even more popular, especially among individuals with chronic diseases such as cancer [6, 7]. A center at the National Institutes of Health, the National Center for Complementary and Alternative Medicine (NCCAM), studies the efficacy and safety of CAM practices [8].

Unfortunately, the term “CAM” causes consternation among many of our professional colleagues who perceive that their patients are forgoing conventional therapy. That is generally not the case. This controversial term should be changed, since the words “complementary” and “alternative” have different meanings and should not be connected by “and.” Complementary therapies are those used to complement or to be used *alongside* conventional methods of therapy, whereas alternative methods refer to those that are used *instead* of known conventional therapies. The term “integrative therapies” more accurately describes the complementary treatments being used in U.S. medical settings alongside conventional practices in a therapeutic environment. Centers for integrative medicine are being established in many academic medical centers [9].

Why CAM?

Patients are incorporating integrative therapies into their health care for many reasons; Snyderman and Weil’s definition of integrative medicine sums up why [10]. They describe integrative medicine as the combination of the best of both conventional and *evidence-based* CAM therapies that encourages patient participation, emphasizes the patient-caregiver relationship and shared decision making, recognizes the contribution of the therapeutic encounter itself, and seeks to optimize the body’s innate healing capacity [10]. All of these qualities are strong draws for patients, and, whether they turn to CAM therapies for these reasons or to improve overall wellness, enhance their lifestyle, or for prevention, it’s the duty of the medical community to work with our patients to meet their needs while providing the best care possible.

We've learned that many CAM interventions such as acupuncture, massage therapy, and meditation can benefit cancer patients, helping them to cope with the disease and reduce stress and symptoms (those related both to therapy and the disease process itself) [11-13]. However, there are many interventions referred to as "alternative medicine" that are unproven and could harm patients who believe they can be cured of diseases like cancer. Moreover, the majority of people who use CAM do not share this information with their primary care doctors. According to a survey by Eisenberg et al., patients don't think it's important for their doctors to know, or their physicians never asked about CAM usage [14]. As there are many drug-drug, drug-herb and antioxidant-drug interactions, it is extremely important for physicians to ask about CAM usage and for patients to share their use of CAM [15-17]. It is our duty as medical professionals to encourage this conversation.

Many leading cancer centers have established integrative medicine programs where complementary therapies such as acupuncture, massage therapy, nutrition counseling, physical activity, and stress management techniques are offered alongside conventional cancer therapies [9]. These programs often provide guidance to patients in choosing the most safe and effective CAM therapies to incorporate into their plan of care.

There is an increasing body of research on the benefits of many CAM practices. Studies provide evidence that some integrative therapies benefit cancer patients by improving their quality of life and reducing disease symptoms and treatment side effects [18]. Research on botanicals and herbs is often aimed at efficacy and safety. Clinical studies demonstrate concerns regarding the safe use of some botanicals with chemotherapy and radiation therapy, inasmuch as some may reduce the effectiveness of certain chemotherapies and others may reduce metabolism of an active drug, enhancing its potential toxicity [19].

The "A" for "alternative" in CAM does exist, and we need to acknowledge that sometimes—no matter how many conversations we have with our patients and no matter how high the level of evidence is that supports the standard treatment—some patients still do not want chemotherapy, radiation, surgery, or another conventional therapy. Instead, they choose to pursue an alternative therapy for any number of reasons—perhaps because it is part of a cultural tradition to which they belong, because they believe that natural products are less toxic than conventional treatments but equally effective, or because they believe that the alternative treatment will offer the certainty of a "cure" for chronic and unpredictable diseases like cancer [20-24]. *Alternative* medicine clinics can be very expensive, they rarely provide any evidence that they are curing diseases, and they typically do not perform research or report their results except in catchy advertisements.

Patients have a right to explore all health care options, and it is our responsibility to help guide them through their decision-making process. We've seen at Dana-Farber Cancer Institute (DFCI), for example, that patients are often unaware that some alternative medicine claims don't have evidence to back them. The Leonard P.

Zakim Center for Integrative Therapies at Dana-Farber offers evidence-supported services ranging from acupuncture to music therapy to qigong, educational services such as patient and professional lectures and informational materials, and clinical research on a number of complementary therapies in a wide range of patient populations, from breast cancer patients 2 years out of therapy to head and neck cancer patients on active treatment [25].

Dialogue on integrative medicine is also taking place on a larger scale. DFCI, with Memorial Sloan-Kettering Cancer Center, MD Anderson Cancer Center, and the American Cancer Society established the International Society for Integrative Oncology [26]. Six years later, the society, an organization for professionals in a variety of disciplines dedicated to studying and facilitating cancer treatment through the integration of complementary therapeutic options, has more than 300 members. The society's mission is to educate oncology professionals, patients, caregivers, and others about the efficacy, clinical benefits, toxicities, and limitations of state of the art integrative therapies.

Conclusion

CAM remains controversial within the medical community. We need to remember that patients usually want to do everything possible to cure their diseases and optimize quality of life as they progress through treatment. All patients, whatever their state of health, deserve to be presented with all available evidence-based options for maximizing their health and quality of life. Integrative therapies can be helpful in managing pain, fatigue, and anxiety, and it is our responsibility to support patients in making informed choices. We need to talk with our patients about integrative therapies as potential nonpharmacologic options, encourage them to discuss their thoughts with us, and embrace the complementary therapy community so that we can offer the most safe and effective whole-person care possible.

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HISTORY OF MEDICINE

Chiropractic's Fight for Survival

Steve Agocs, DC

Although the chiropractic profession now occupies a largely mainstream place in the health care spectrum of the United States, this has not always been the case. From its formation in 1895 by founder Daniel David (D. D.) Palmer [1], the chiropractic profession faced a plan of containment and elimination by the American Medical Association (AMA) that continued for nearly a century. It took an antitrust lawsuit filed against the AMA in 1976 to reveal the magnitude and scope of the AMA's plan. Despite generations of organized medical opposition, chiropractors did what most other groups of professionals failed to do: they maintained a separate and distinct identity from the practice of medicine while growing in an otherwise hostile environment created by the AMA and its component state associations [2].

During the 1800s, there were a variety of medical sects vying for market share in the United States. Homeopaths, eclectics, naturopaths, and osteopaths, as well as the so-called "regular" orthodox medical practitioners, all had a stake in shaping the dominant health care paradigm [2]. The medical practitioners organized the American Medical Association in 1847 with the primary goals of standardizing medical education and instituting a program of medical ethics [3]. By 1849, the AMA had taken on the role of investigating the various competing sects of medicine and challenging them on the basis of their ethics [3]. The AMA took the position that the other forms of medicine, including the newly discovered chiropractic profession, were unethical and "unscientific." Many authors, however, have made the argument that the AMA's intent was to decrease competition for financial reasons rather than to protect the public from unethical practitioners [4, 5].

Medical doctors from this fledgling group broadcast the message that their practice alone was scientifically based, despite the fact that their approach to medicine was no more scientific than that of the professions they were competing with [6]. This claim, however, was an important first step in marginalizing other professions as "unscientific" or "pseudoscientific" and allowed this sect of medicine to organize and professionalize quickly and eventually exert a massive influence on all aspects of health care policy in this country for generations [6]. Not coincidentally, the AMA's efforts resulted in the transformation of American medicine from a modest, even menial profession into one of sovereignty, power, and financial affluence [5].

By convincing state legislators that their profession was scientific while all others were not, the AMA and its state member associations were able to gain protection in the form of endorsement for educational programs and laws that limited "irregular"

practice. The system of schools and hospitals, as well as the legislation protecting them, led to a “golden age of doctoring” that lasted until the 1970s [2]. Orthodox or “allopathic” medicine enjoyed virtually complete dominance of the health care market in the United States. With the exception of chiropractors, competing professions shrank to nonexistence or were absorbed into the orthodox medical profession, as in the case of osteopaths [4].

From its inception, chiropractic was looked upon as a menace by medical authorities. Palmer’s first chiropractic patient was a partially deaf janitor named Harvey Lillard, whose hearing improved dramatically under Palmer’s care. Following his development of chiropractic, Palmer used both incredible claims of cures as well as an antimicrobial platform to advertise his practice. Neither endeared him to the medical authorities in Iowa or Illinois [7].

Palmer intended to keep chiropractic techniques a family secret, but a near-fatal railroad accident caused him to change his plans, and he established the first chiropractic school, now known as Palmer College of Chiropractic, in 1897 [1, 8]. A good number of Palmer’s early students were medical doctors or had been trained in other health care disciplines prior to learning chiropractic [9]. Palmer established a unique theory about the nature of disease and emphasized the role of the patient’s body and its innate healing ability, rather than doctors’ treatments, as the key to health.

Chiropractic’s first challenge as a profession was the licensure laws that protected medical practice. While there were provisions in some states for chiropractors to practice as “irregulars,” in most states chiropractors faced the possibility of arrest and imprisonment for “practicing medicine without a license.” The first known case of this occurred in 1905, when Wisconsin chiropractors E. J. Whipple and G. W. Johnson were convicted at the urging of A. U. Jorris, DO, the first osteopath to be elected to Wisconsin’s board of medical examiners [9, 10]. In fact, an early issue of the *Journal of the American Osteopathic Association* commended “Dr. A. U. Jorris in his fight against chiropractors” [11]. D. D. Palmer himself spent 23 days in Scott County jail for the same offense in Iowa in 1906 [8]. Recognizing the need for a protective organization of their own, chiropractic leaders founded the Universal Chiropractors’ Association in 1906, primarily to provide legal representation for chiropractors facing legal persecution.

In 1907, however, *Wisconsin v. Morikubo* found the first gap in organized medicine’s armor. Chiropractor Shegataro Morikubo was arrested for practicing osteopathy and medicine without a license. Indeed, there is ample evidence that Morikubo established his practice in LaCrosse, Wisconsin, specifically to test and challenge the precedent set in Whipple and Johnson’s case [10]. The trial ended in the legal establishment of chiropractic as a separate and distinct profession from medicine and osteopathy, largely on the basis of chiropractic’s unique philosophy [12].

Despite this legal precedent, at least 672 chiropractors throughout the country were arrested and jailed for the practice of “medicine” or chiropractic without a license over the next several decades, some many times [13, 14]. Records exposed during the discovery phase of the *Chester C. A. Wilk et al. v. AMA et al.* case showed that medical doctors were encouraged by the AMA to accuse chiropractors of ethical violations [15]. There was the additional problem that no state had established an official license for chiropractors, so in many cases chiropractors were harassed for practicing without a license that did not exist in the first place.

This changed in 1913, when Kansas became the first state to establish a separate chiropractic board and fully legalize the practice of chiropractic [16]. Other states quickly moved in the same direction. By the end of the 1920s, more than half of the states had legalized chiropractic. Louisiana was the last state to do so in 1974 [13]. Even the state chiropractic boards, however, were not safe from the pressures of the medical associations. State boards were routinely challenged and sometimes dissolved due to pressures on state legislators from the AMA and its state member associations [17]. All the while, the AMA waged an ongoing campaign against chiropractors, using the popular media, medical journals, and any other source that could be used to describe chiropractic as a “cult” [18].

Now that chiropractors could legally practice in most states, the AMA advocated adoption of “basic science” examinations that all doctors had to meet to qualify for a license. These exams were biased heavily toward those with standard medical training—since chiropractors received no training in medical procedures such as surgery and obstetrics. Chiropractors found it nearly impossible to pass the exams or gain licenses in states that adopted them. For example, Nebraska established a Basic Science Board and examination in 1927. From 1929 until 1950, not a single chiropractic license was granted in the state due to the inability of chiropractors to pass these unfair examinations [19]. The basic science examinations kept the number of chiropractors legally practicing in a state to a minimum. It was not uncommon for chiropractors to practice without licenses in states with such restrictions, creating additional opportunities for charges against them.

The AMA’s plan to undermine chiropractic became even more organized with the establishment of the Committee on Quackery in 1963. This AMA committee adopted a plan that was devised in 1962 by the Iowa Medical Society under the leadership of Robert B. Throckmorton. The so-called “Iowa Plan” outlined the “containment of the chiropractic profession” that “will result in the decline of chiropractic.” [15, 18] Action steps outlined in this plan included “encourage ethical complaints against doctors of chiropractic,” “encourage chiropractic disunity,” “oppose chiropractic inroads in health insurance,” and “oppose chiropractic inroads into hospitals,” among others [15, 18]. Joseph Sabatier, chairman of the Committee on Quackery, said that “rabid dogs and chiropractors fit into about the same category.... Chiropractors were nice but they killed people” [20].

The massive scope and methodical nature of this plan were exposed in hundreds of thousands of pages of AMA documents that were brought to light in the 1976 trial *Chester C. A. Wilk et al. v. AMA et al*, which started one year after the Committee on Quackery was disbanded [21]. AMA writers ghostwrote television and movie scripts, as well as Ann Landers' widely read newspaper column and any other media outlet that could be used to tarnish the reputation of chiropractic in the public eye. The AMA even encouraged the distribution of antichiropractic materials to high school guidance counselors so they would dissuade interested students from pursuing careers in it [15, 18]. During the 11-year court battle that ensued, the AMA settled three lawsuits by relaxing its position on the referral of patients to chiropractors by medical doctors. In 1980, the AMA revised its Principles of Medical Ethics to reflect this new position, allowing medical doctors to be free to choose the patients they served, the environment they served in, and the other types of practitioners they associated with [22].

In 1987, United States District Judge Susan Getzendanner found the AMA and its codefendants guilty of violating the Sherman Antitrust Act. In her decision, Getzendanner asserted that "the AMA decided to contain and eliminate chiropractic as a profession" and that it was the AMA's intent "to destroy a competitor" [22].

While it took some years for old habits to fade away, in the current era medical doctors and chiropractors openly refer to each other for diagnostic services, treatment, and co-management of cases, and chiropractors serve alongside medical practitioners in clinics and hospitals all over the country.

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OP-ED

Resisting the Understandable Appeal of CAM

Michael Shermer, PhD

For many years now there has been considerable debate between so-called complementary and alternative medicine (CAM) and mainstream science-based medicine. In reality there is no debate because there is only science-based medicine and everything else that has yet to be tested. Most of CAM falls into this latter category. This does not automatically mean that all CAM claims are false, only that most of them have yet to be tested through the rigorous methods of science, which begins with the null hypothesis that holds that the hypothesis under investigation is not true (null) until proven otherwise. A null hypothesis states that X does not cause Y. If you think X does cause Y, then the burden of proof is on you to provide convincing experimental data to reject the null hypothesis.

The statistical standards of proof needed to reject the null hypothesis are substantial. Ideally, in a controlled experiment, we would like to be at least 95-99 percent confident that the results were not due to chance before we offered our provisional assent that the effect may be real. Everyone is familiar with the process through news stories about the FDA's approving a new drug after extensive clinical trials. The trials to which they refer involve sophisticated methods to test the claim that drug X (say a statin drug) improves outcomes in disease Y (say cholesterol-related atherosclerosis). The null hypothesis states that statins do not lower cholesterol and thus have no effect on atherosclerosis. Rejecting the null hypothesis means that there was a statistically significant difference between the experimental group that received the statins and the control group that did not.

In most cases CAM hypotheses do not pass these simple criteria. They have either failed to reject the null hypothesis or they haven't even been rigorously tested to find out whether or not they could.

What, then, is the pull of CAM for so many people? According to a 2002 survey of U.S. adults conducted by the National Center for Health Statistics and the National Center for Complementary and Alternative Medicine, 74.6 percent of respondents had used some form of complementary and alternative medicine, but only 11.8 percent had "sought care from a licensed or certified" practitioner, suggesting that "most individuals who use CAM self-prescribe and/or self-medicate" [1]. The most common CAM therapies used were prayer (45.2 percent), herbalism (18.9 percent), breathing methods (11.6 percent), meditation (7.6 percent), chiropractic (7.5 percent), yoga (5.1 percent), body work (5 percent), diet-based therapy (3.5 percent),

progressive relaxation (3.0 percent), mega-vitamin therapy (2.8 percent), and visualization (2.1 percent) [2].

A 2004 survey of 1,400 U.S. hospitals found that more than 25 percent offered such alternative and complementary therapies as acupuncture, homeopathy, and massage therapy. According to researchers Sita Ananth of Health Forum, an affiliate of the American Hospital Association, and William Martin, PsyD, of the College of Commerce at DePaul University in Chicago: “More and more, patients are requesting care beyond what most consider to be traditional health services. And hospitals are responding to the needs of the communities they serve by offering these therapies” [3].

Herein lies one answer to understanding why CAM sells. There is a market demand for it. Why? One possibility is that people are turning to alternative medicine because their needs are not being met by traditional medicine. As the late medical historian Roy Porter was fond of pointing out, before the twentieth century this certainly was the case [4]. Medical historians, in fact, are in agreement that until well into the twentieth century it was safer not to go to a doctor. This led to the success of such nonsense as homeopathy—a totally worthless nostrum that did no harm, thus allowing the body to heal itself.

Another explanation may be found in examining what CAMers are offering that mainstream physicians are not: TLC. By this I do not just mean a hand squeeze or a hug, but an open and honest relationship with patients and their families that provides a realistic assessment of the medical condition and prospects. People are going alternative because in too many instances physicians have become highly skilled technicians—cogs in the cold machinery and massive bureaucracy of modern HMO medicine.

I witnessed the effect directly over the course of a decade during my mother’s illness with the recurring and malignant meningioma brain tumors to which she finally succumbed. In the process I gained a deeper understanding of why people turn to alternative medicine. Don’t get me wrong—my mother’s doctors were brilliant, her care the very best available, and we have no regrets about what might have been. And that’s the point. Even under such ideal conditions I found the whole experience frustrating and unfulfilling: it was nearly impossible to get honest and accurate information about my mom’s condition—misinformation and (usually) no information were the norm; neither my father nor I could get doctors to return our calls; and despite my best efforts, the relationship with her physicians (with the exception of her oncologist, whom I befriended) could not have been more detached.

I found it rather telling, for example, that when I identified myself as “Dr. Shermer” (a lie of omission, not commission, since I do have a PhD), I got faster results at the hospital than when I was merely “Mr. Shermer”—but I still found it difficult to get calls returned. Even worse, when my mom’s oncologist (one of the country’s best-known and well respected in his field) called her surgeons, he too heard too many

dial tones. If physicians show such a remarkable lack of professional courtesy with their own colleagues, what are the rest of us to expect?

More than anything patients want information. They want to know what is really going on. They don't want jargon. They don't want false hope or unnecessary pessimism. Studies show that patients do better when they know in detail all the steps they will have to take in their recovery process—probably because it allows them to anticipate, plan, and pace themselves. Knowledge is power, and physicians are modern-day shamans. Patients want the power that knowledge brings, and that empowerment cannot be given in the 8.5 minutes the average doctor spends per patient per visit. Patients want a relationship with their primary caretaker that allows them to ask the important questions and expect honest answers.

Physicians tend to deliver monologues when they should be having dialogues. The reasoning process of diagnosis, prognosis, and treatment goes on inside their heads, and what comes out is a glossed telegram of truncated lingo. The physician-patient connection is a one-way street, an authority-flunky relationship top heavy in arrogance and off-putting to anyone with a modicum of self-esteem and social awareness. If I could reduce all this into a single request, it is this: Talk to patients as though they are thoughtful, intelligent people capable of understanding and deeply curious about their condition.

So...we should turn to CAM then, right? Wrong. An even deeper problem is that CAMers lack much medical knowledge and (especially) scientific reasoning, making them dangerous. The 2002 study referenced above found that 54.9 percent of respondents used CAM in conjunction with conventional medicine but did not always tell their primary care physician, thus leading to possibly deadly mixtures of drugs and herbs [1]. It is not a matter of everything to gain and nothing to lose by going CAM (even if your doc offers no hope), because quack medicines cost money, cause harm, and, most importantly, take away valuable time that could and should be spent with loved ones in this already too-short stay we have with each other.

Besides TLC, the cognitive pull of CAM is anecdotal thinking. Since humans are pattern-seeking animals, we credit whatever we did just before getting well as the vector of healing. If A appears to be connected to B, we assume that it is unless proven otherwise. This is the very antithesis of the science-based system of the null hypothesis. The recent medical controversy over whether vaccinations cause autism reveals the power of anecdotal thinking. On the one side are scientists who have been unable to find any causal link between the symptoms of autism and the vaccine preservative thimerosal, which breaks down into ethyl mercury, the culprit du jour for autism's cause. On the other side are parents who noticed that shortly after having their children vaccinated autistic symptoms began to appear. These anecdotal associations are so powerful that it causes people to ignore contrary evidence: ethyl mercury is expelled from the body quickly (unlike its chemical cousin methyl mercury) and therefore cannot accumulate in the brain long enough to cause damage, and rates of autism diagnoses did not decline in children born after thimerosal was

removed from vaccines.

The anecdotal thinking upon which CAMers rely—even if unconsciously and with the best of intentions—can be particularly dangerous in the hands of those whose intentions are less than ethical. Thus it is that any medical huckster promising that A will cure B has only to advertise a handful of successful anecdotes in the form of testimonials, and the human brain will do the rest. By way of example from the annals of medical quackery, witness the case of John R. Brinkley, one of the greatest medical quacks of the first half of the twentieth century, and his nemesis Morris Fishbein, the quackbusting editor of the *Journal of the American Medical Association*. Their decades-long struggle, which criss-crossed the American heartland throughout the 1920s and 1930s, represents this tension between folk and scientific medicine, well summarized in Pope Brock's 2008 book *Charlatan: America's Most Dangerous Huckster, the Man Who Pursued Him, and the Age of Flimflam* [5].

What Brinkley was selling was what all men want—sexual vitality—and he developed a surgical technique that offered the type of firm results that his male clientele so desperately sought: goat testis sewn right into the patient's scrotum, which he likened to “embedding a marble in an apple.” Come one, come all. And they did, to the tune of \$750 per surgery, advertised widely in newspapers (an AMA study revealed that over half of all newspaper advertising at the time was for patent medicines) and the new-fangled technology—radio—which Brinkley took to like an evangelist to television. The ads featured testimonials from happy men who proclaimed their restored manhood, and these anecdotes drove customers to Brinkley's practice, making him a rich man. But as his business grew, he got careless, performing operations both before and after happy hour, and fobbing off work to assistants whose medical credentials were even shadier than his own (Brinkley graduated from the unaccredited and improbably named Eclectic Medical University of Kansas City). The result was dozens of dead patients [5].

This got the attention of the ambitious Morris Fishbein, whose career coincided with the rise of the AMA's attempt to rein in flimflammy through accrediting medical colleges and licensing practitioners. Fishbein made his public mark in 1923 when the *Chicago Daily News* sent him to investigate the “Hot Girl of Escanaba” (Michigan), a woman who suffered from a temperature of 115 degrees for two weeks. Fishbein exposed her as a “hysterical malingerer” when he discovered that a flesh-colored hot water bottle was employed to elevate rectal thermometer readings. For the next two decades Fishbein pursued the country's “most daring and dangerous” swindler, as he called Brinkley, until he finally brought him down in a decisive courtroom confrontation [5].

Fishbein's promotion of science-based medicine was heroic. Medical flapdoodle flourishes today on the Internet, so every medical association and journal needs a quackbusting Fishbein on its staff, for without such eternal vigilance folk medicine will trump scientific medicine in the minds of patients. And thus it is that skepticism

should be our default rule of thumb when it comes to CAM claims.

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OP-ED

Medicine's Great Divide—The View from the Alternative Side

Deepak Chopra, MD

I might as well begin by being blunt. There is no love lost between the medicine I was taught in medical school and the kind I practice now, which used to travel under the name of mind-body medicine. It acquired ayurveda (the traditional medicine of India) along the way and now incorporates influences from many other strains of healing. The relationship between conventional and alternative medicine is like a bad marriage, only in reverse. It began with a divorce, has moved to the stage of wary mediation, and holds some prospects of reaching a shy courtship some day in the future.

The grounds for the divorce are bitter. Conventional medicine is offended that alternative medicine even exists. For the average physician, to hear that an allergy patient is taking extract of nettle to treat his symptoms or that a breast cancer patient is being treated with coffee enemas and a macrobiotic diet arouses scorn. Over a decade ago, when the *New England Journal of Medicine* reported that Americans pay more visits annually to alternative practitioners than to MDs [1], the attitude of the editorial writer was barely disguised dismay and disbelief. It was as if the whole country had turned its back on jet travel to return to the horse and buggy.

Yet at bottom no one could really object to the aims of alternative medicine, which are to bring relief to the whole patient. Sick people come to us in hopes that their suffering will end. If millions of them have been seeking holistic treatments instead of the two-pronged approach of conventional medicine—drugs and surgery—their motivation isn't irrational. The average appointment with an MD lasts only a few minutes; there is minimal interaction with the physician (someone undergoing coronary bypass surgery is likely to spend fewer than 15 minutes face-to-face with the surgeon prior to the procedure); the risks of complications, side effects, and iatrogenic disease are far from minimal; the language of diagnosis tends to be strange if not entirely opaque to the layman; worst of all, if the patient winds up being hospitalized, he will lose dignity and control over his own life for a time, being thrust into an environment that feels indifferent at best, cold and frightening at worst.

In other words, the other party in the divorce—those who have lost faith in conventional medicine—has its own valid reasons. But after this blunt assessment, I'd like to move on to the present stage of the relationship, which is wary mediation. The two camps are not as opposed as they once were. Twenty-five years ago the possible efficacy of traditional healing modalities, herbs, Eastern therapies like acupuncture, and even mind-body medicine was so foreign as to be entirely alien.

Today there are still die-hard skeptics, of course. But in a mood of expanded tolerance, an MD can look at the research on neurotransmitters, cell membrane receptors, and brain physiology, which has made enormous strides in recent decades. Taken as a whole, this research describes the body as an integrated system that exchanges information continuously between the mind, via the brain, and every cell in the body.

In a nutshell, we now realize that for every mental state there must be a corresponding state of physiology. With real-time scans from functional MRIs staring them in the face, MDs have no reason to look upon the placebo effect, for example, as “not real medicine.” When patients feel relief from chronic pain by being given a sugar pill, the body’s endorphins are filling the same receptor sites in the brain that externally administered opiates fill. There can be a wary mediation between alternative and conventional medicine because science is serving as the mediator. One party in the divorce can no longer claim to be the only one supported by evidence, research, and blind trials. As a prime example, I’d cite the well-publicized research by Dean Ornish, MD, and his team on how comprehensive lifestyle changes, including stress management and meditation, along with improved diet and exercise, can reverse even severe coronary heart disease [2]. His research showed that comprehensive lifestyle changes affect gene expression, turning on disease-preventing genes and turning off genes that promote cancer and heart disease [3]. Additional research in collaboration with Nobel laureate Elizabeth Blackburn, PhD, also indicates that these lifestyle changes can lengthen telomeres, the ends of chromosomes that control how long we live [4].

One sign of growing reconciliation comes in the form of softened terminology. Instead of calling it alternative or holistic medicine, as I’ve been doing, the more acceptable term is complementary and alternative medicine (CAM), which sends the signal, “See? I am not your foe. We can cooperate. We’re complementary.” Which is true. The public has been told for decades now that the primary causes of suffering are no longer infectious disease, epidemics, and lack of proper sanitation. Those have been replaced by lifestyle disorders, which are largely preventable.

The problem is that an MD’s practice is badly set up to promote prevention. Visits are too short. Doctors aren’t adequately trained beyond their specializations. Their habits are focused almost entirely on drugs and surgery as treatment modalities. Prevention is considered too “soft,” and yet, if you shift the burden of prevention to the patient (which most MDs are more than happy to do), there is enormous resistance. The public has been given countless warnings about smoking, poor diet, and lack of exercise, yet we have by no means eradicated lung cancer, obesity, coronary artery disease, and type II diabetes. Lifestyle disorders prove intractable when people cling to bad lifestyle habits and resist adopting good ones. We remain a nation of sedentary overeaters, paying pious lip service to prevention while doing less than enough about it.

This is where CAM makes significant inroads, because one of its main themes is the return of power to the patient. Books with titles like “You Can Heal Yourself” irk physicians, but they empower patients. MDs should welcome the whole trend to self-treatment instead of taking the scornful attitude that nothing works but the modalities taught in medical school. The real mystery—one that deeply intrigued me 25 years ago—is that so many therapies that totally disagree with one another manage to bring results. Ayurveda isn’t qigong; yoga isn’t Reiki; none of them is a placebo. Yet somehow healing exists, and the channel it takes can be quite unexpected and inexplicable.

The inconvenient truth that “you can heal yourself” has always been the foundation of medicine. The body is the locus of the healing system; physicians assist this complex, little-understood system. They do not actually do the healing. If this feels threatening to MDs, there is much more room for pride to take a fall. To touch upon only recent headlines, there is evidence that the underlying science for antidepressants is faulty if not entirely invalid. Patients suffering from depression have been shown to have no genetic irregularities of the kind that would promote imbalances of serotonin in the brain; in addition, it seems that the most popular class of antidepressants, SSRIs (selective serotonin reuptake inhibitors), may not be acting on the brain as they claim to act, or are acting with less efficacy than claimed [5]. And although the American Heart Association tells us about 2 million angioplasty and coronary bypass procedures are performed each year at a cost of \$100 billion, a randomized controlled trial published in April 2007 in *The New England Journal of Medicine* found that angioplasties and stents do not prolong life or even prevent heart attacks in stable patients (i.e., 95 percent of those who receive them) [6].

Conventional medicine also faces the mysterious “decline effect”—established medications steadily lose their effectiveness over time, as if the newer generation of patients has different, less receptive physiologies. Add to this the hidden flaws in research studies. Since the average MD knows nothing about this topic, we would all do well to read Jonah Lehrer’s eye-opening *New Yorker* article, “The Truth Wears Off” [7]. Here are some disturbing highlights.

What Lehrer is primarily concerned with is replicability, the term scientists use for repeating an experiment and arriving at the same result. Certainly the most important findings in science have been repeated many times over. Not necessarily. Some results, particularly in medicine, are not holding up at all. Lehrer cites prominent examples of antipsychotic drugs and the use of aspirin to prevent heart attacks. These treatments are still widely endorsed in the medical literature, ignoring the fact that the decline effect is in full swing, meaning that the original results expected from these treatments are simply not there anymore or have declined to a fraction of what they once were.

For me, the most distressing aspect of the decline effect is how widely it is being ignored. Medicine is the branch of science that touches most people’s lives most closely. A 2005 review article in the *PLoS Medicine* examined the 49 most cited

articles in leading medical journals [8]. Lehrer writes, “of the thirty-four claims that had been subject to replication, forty-one per cent had either been directly contradicted or had their effect sizes significantly downgraded” [7]. If that isn’t troubling enough, there is the huge problem, also widely ignored, of results that get accepted without being replicated either enough or at all. For example, there has been a widespread fad for claiming that genetic differences between men and women account for differing risks in acquiring disorders as various as schizophrenia and high blood pressure. Yet a probe of the underlying research found serious flaws in the vast majority of the studies. And worse was to come: “out of four hundred and thirty-two claims, only a single one was consistently replicable.” One!

Logic tells us that just because one proposition (A) is fallacious, it doesn’t make a contending proposition (B) more true. At this point, MDs rely too much on that logical truism, grudgingly admitting that there may be problems with conventional medicine, but those problems don’t prove that CAM is any better. My purpose isn’t to justify the vast universe of healing modalities that exist outside Harvard Medical School. I look instead toward the next phase of this reverse marriage, which is shy courtship. If both sides stopped being defensive, they would see that they share core values: treating the whole patient, reducing suffering, closing the gap between healer and healed, and doing the least harm while bringing the greatest good. Speaking personally, I stand for alternative medicine while remaining a board-certified endocrinologist, and the reason I straddle two worlds is that I envision *expanded* medicine in the future, not alternative or mainstream medicine as divergent choices or warring camps.

What would this expanded medicine look like? An adequate answer would take thousands of words. Basically, it requires a lot more marriage counseling between the estranged parties. With that in mind, I have little desire to debate with skeptics and scientists who disdain CAM and falsely claim that only their side is valid and evidence-based. The mystery of healing remains unsolved. If we combine wisdom and science, tradition and research, mind and body, there is every hope that the mystery will reveal its secrets more and more fully. For example, for the last 30 to 40 years we have documented the effect of stress on cardiovascular disease, but we have only recently begun to look into what the opposite of stress could do for our well-being. The experiences of joy, compassion, and meditative quiescence could be powerful tools to restore homeostasis and strengthen our self-repair mechanisms. The next step will be to remodel medical school curricula so that future physicians are not wandering in the dark as my generation did, totally ignorant, if not blind, about treatments outside our narrow band of knowledge. Expanded medicine is the answer, I am sure of that. The only question is how long and crooked a path it will take to get there.

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