American Journal of Law & Medicine, 31 (2005): 349-363

Quackery

Maxwell J. Mehlman[†]

Everyone condemns medical quackery. Government regulators seek to protect us from it. Alternative providers strive to distance themselves from it. Orthodox medicine wants to stamp it out.

The question is: What constitutes "quackery"? How do we distinguish quacks from mainstream practitioners? Even more problematic, how do we distinguish between quackery, which everyone agrees is beyond the pale and therefore should be fair game for sanction, and practices that, while unorthodox, should be tolerated in the interests of promoting medical progress and patient choice? These are particularly challenging questions now, when a number of factors are combining to undermine the hegemony of mainstream medicine, when some of the same forces that spurred the growth of quackery in the 19th century are remerging, and when neo-conservatives are clamoring for greater freedom of choice for health care consumers.

This article begins with a brief history of quackery in America and the factors that encourage its growth. The article then attempts to distinguish between quackery and acceptable medical practice. The article concludes by discussing how best to protect patients from quackery.

I. QUACKERY PAST AND PRESENT

The origin of the term "quackery" is obscure. One theory is that it comes from the Dutch word "quacksalber," which means "quackery" in Dutch.[1] The term became widely used in the United States during the 19th century. Then, as now, it was derogatory.[2] It described hucksters, charlatans, and snake oil salesmen.[3] Nineteenth-century quacks included the Thompsonians, who touted the virtues of

---

[†] Arthur E. Petersilge Professor of Law and Director, The Law-Medicine Center, Case School of Law, and Professor of Bioethics, Case School of Medicine. The author wishes to thank Megan O'Donnell for her research assistance.

[1] *See* WILLIAM H. HELFAND, QUACK, QUACK, QUACK 14 (2002). Other theories link it to the German word for quicksilver (mercury), on the supposition that it was used to refer to healers, including Paracelsus, who prescribed the heavy metal to their patients. *See, e.g.*, The History of Quackery, Wellness Directory of Minnesota http://www.mnwelldir.org/docs/history/quackery.htm (last visited February 25, 2005). Still others think it refers to someone who touts nostrums by making a noise like a duck. ANN ANDERSON, SNAKE OIL, HUSTLERS AND HAMBONES 7 (2000).

[2] *See* HELFAND, *supra* note 1, at 13-14.

[3] *See id*. at 14.

steam baths and puke weed,[4] and homeopaths, who, according to Paul Starr, "saw disease primarily as a matter of spirit":

> [W]hat occurred inside the body did not follow physical laws. The homeopaths had three central doctrines. They maintained first that diseases could be cured by drugs which produced the same symptoms when given to a healthy person. This was the homeopathic "law of similars"—like cures like. Second, the effects of drugs could be heightened by administering them in minute doses. The more diluted the dose, the greater the "dynamic" effect. And third, nearly all diseases were the result of a suppressed itch, or "psora."[5]

Quacks concocted and hawked patent medicines, including Hamlins Wizard Oil, James Soothing Syrup (which contained heroin), Lungardia (containing, among other things, turpentine and kerosene), and Tuberculene (which contained creosote).[6] Benjamin Franklin's mother-in-law devised "Widow Read's Ointment for the Itch."[7] The first successful prosecution under the Pure Food and Drug Act of 1906 was against the maker of "Cuforhedake Brane-Fude."[8]

Yet the 19th century quacks were not simply unscrupulous entrepreneurs who took advantage of gullible patients. They emerged in response to serious shortcomings of mainstream American medicine. In the early 19th century, orthodox practitioners emulated Dr. Benjamin Rush, a signer of the Declaration of Independence.[9] Rush and his disciples advocated three principal remedies for whatever ailed the patient: phlebotomy or bleeding, the use of purgatives, and blistering with caustic poultices.[10] Bleeding was necessary, Rush believed, because disease resulted from "morbid excitement caused by capillary tension."[11] In fact, bleeding just served to weaken patients, often hastening or assuring their deaths. Purging was accomplished with calomel, a powder of mercury chloride, which caused a "heavy flow of saliva, bleeding gums, mouth sores, tooth loss, and an unfettered, bloody evacuation of the bowels."[12] Rather than aiding patients, it caused dehydration. Blistering simply caused pain. In the words of one historian of quackery, "Rush's medical theories were unfortunately both archaic and lethal."[13]

In the meantime, illness and injury were rampant. The germ theory of disease had not yet been discovered. Sanitation and good nutrition were virtually unknown. Hospitals were charnel houses.[14]

Faced with unresolved disease and horrific standard treatments, it is not surprising that many people sought relief by going to what might be considered quacks. Patent medicines were milder than the purgatives, and often contained soothing ingredients like alcohol and opium.[15] Homeopathy used tiny amounts of

---

4 *See* ANDERSON, *supra* note 1, at 29.

5 PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 96-97 (1982).

6 *See* ANDERSON, *supra* note 1, at 29.

7 SUSAN GILBERT, MEDICAL FAKES AND FRAUDS 32 (1989).

8 JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH –CENTURY AMERICA 4 (1974).

9 ANDERSON, *supra* note 1, at 22-23.

10 *Id.*

11 *Id.* at 22

12 *Id.* at 23.

13 *Id.*

14 *Id.*

15 *See* ANDERSON, *supra* note 1, at 23, 34-35; *see also* HELFAND, *supra* note 1, at 34; STARR, *supra* note 5, at 96-97.

active substances that produced few ill effects.[16] Even the electrical gadgetry that captivated the public toward the end of the 19th century usually did not cause serious injury.[17] Moreover, the quacks ventured into rural areas and frontier lands devoid of trained physicians.[18]

The quacks also appealed to the anti-elitist sentiment of many Americans. During the presidency of Andrew Jackson, a movement led by the herbalist Samuel Thompson succeeded in repealing most of the state medical licensure laws.[19] Orthodox practitioners were viewed as being more interested in preserving their turf than in upholding scientific truth. "Idealists cast the triumph of medical professionalism as the protection of vulnerable clients from the laissez-faire jungle; cynics, or realists, regard it rather as the raising of a monopolistic, self-serving oligarchy upon the backs of the sick."[20] Quackery also resonated with the American spirit of self-help. Patent medicines, "presented as standardized, were accepted by consumers because they were purportedly reliable, milder than the doctor's prescription, easy to take and provided the means for personalized choice and personalized administration. These were desired qualities that enabled men and women to take care of themselves without requiring professional help."[21] This gave rise to the phenomenon of "over-the-counter" medications—preparations that could be bought without a doctor's prescription. The trade association for manufacturers of over-the-counter products, the Proprietary Association, started out in the 19th century as the lobbying group for purveyors of patent medicines.[22]

What is striking is that so many of the conditions that gave rise to quackery in the 19th century are present today.[23] After a half-century of major therapeutic breakthroughs in the form of antibiotics and vaccines, medical progress seems to have slowed. No cures have been found for the major killer diseases. Treatments, such as invasive surgery and chemotherapy, can be harsh. Promised advances in genomic medicine remain elusive. Patients who have tried standard approaches to no avail or who are skeptical or frightened of them may feel they have nothing to lose by trying unorthodox alternatives.

Another factor that may drive patients toward quackery is the commercialization of mainstream medicine. As Timothy Jost pointed out in 1995, physicians "increasingly view themselves as businessmen engaged in commerce rather than as professionals . . . ."[24] The premium placed on patient volume by managed care produces assembly-line medicine where physicians spend little time with patients. In contrast, observes Michael Young, "[m]ost quacks manage a superb 'bedside manner.' Since they can't really provide a cure if major disease is present, they specialize in promises, sympathy, consideration, concerns, and reassurance. The patient responds to such attention."[25] It is supremely ironic that the victims of a

---

[16] *See* STARR, *supra* note 5, at 96-97.

[17] *See* ANDERSON, *supra* note 1, at 34.

[18] HELFAND, *supra* note 1, at 44.

[19] *See* ANDERSON, *supra* note 1, at 29.

[20] HELFAND, *supra* note 1, at 44 (quoting ROY PORTER, HEALTH FOR SALE 16 (1989)).

[21] YOUNG, *supra* note 8, at 34.

[22] *Id.* at 24.

[23] Susan Gilbert attributes the popularity of modern-day quackery to desperation, vanity, laziness, fear of doctors, and deception. *See* GILBERT, *supra* note 7, at 42-47. But clearly there are other less pejorative explanations.

[24] Timothy S. Jost, *Oversight of the Quality of Medical Care: Regulation, Management or the Market?*, 37 ARIZ. L. REV. 825, 840 (1995).

[25] James H. Young, *Why Quackery Persists*, *available at* http://www.quackwatch.org /01QuackeryRelatedTopics/persistance.html (last visited Dec. 16, 2004). Young believes that the

practice condemned for its rapaciousness should prize it for the tender way in which it treats them.

A related factor is the high cost of standard medical care. One reason that some health insurance plans have begun to cover complimentary and alternative medicine ("CAM"), for example, is that they expect CAM to save them money.[26] Chiropractors are often the primary health care providers in poor and rural communities that cannot afford to support a regular physician's practice.[27]

Quackery also can help promote patient privacy. Patent medicines were developed in the 19th century in part to permit patients to obtain treatment for embarrassing problems without having to meet face-to-face with or identify themselves to a physician.[28] This is one of the main reasons for the popularity of dietary supplements and internet pharmacies,[29] which are sources of quack remedies.

Nineteenth-century quacks often exploited religious beliefs. For example, Mesmerism, the idea that healing could be accomplished by putting people into trances, was popular with a number of New England Universalist ministers,[30] and connected with the broader faith-based healing movement.[31] Many of these beliefs survive today, in sects like Christian Science and Jehovah's Witnesses. Modern faith-based practitioners, for example, promote "remote prayer"[32] and the laying-on of hands as effective therapeutic techniques.[33] The persistence and indeed resurgence of organized religion in the United States, particularly evangelical denominations, creates fertile ground for what many scientific practitioners would consider quackery.

Finally, just as nineteenth-century quacks saw themselves as champions of free-market entrepreneurship,[34] the anti-regulatory, neo-conservative economic

---

quack's excellent rapport with the patient helps explain why therapeutic failure rarely reduces patient loyalty.

[26] *See* Kathleen Boozang, *Is the Alternative Medicine? Managed Care Apparently Thinks So*, 32 CONN. L. REV. 567, 577-78 (2000). Managed care expects to save money on surgery and prescription drugs; *See* John Weeks, *Is Alternative Medicine More Cost-Effective?*, MEDICAL ECONOMICS, Mar. 20, 2000, at 139.

[27] *See* Monica Smith & Lynne Carber, *Chiropractic Health Care in Health Professional Shortage Areas in the United States*, 92 AM. J. PUB. HEALTH 2001 (Dec. 2002).

[28] *See* HELFAND, *supra* note 1, at 49 (" . . . one could obtain a proprietary product anonymously and no one else, including the physician, would ever know").

[29] *See* Linda C. Fentiman, *Internet Pharmacies and the Need for a New Federalism: Protecting Consumers While Increasing Access to Prescription Drugs*, 56 RUTGERS L. REV. 119, 122 (2003); Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?* 37 WAKE FOREST L. REV. 97, 136 (2002).

[30] John Buescher, *Spiritualism,* DICTIONARY OF UNITARIAN UNIVERSALIST BIOGRAPHY, *at* http://www.uua.org/uuhs/duub/articles/spiritualism.html (last visited Jan. 28, 2005).

[31] *See* Barry Nobel, *Religious Healing in the Courts: The Liberties and Liabilities of Patients, Parents, and Healers*, 16 PUGET SOUND L. REV. 599, 608 (1993).

[32] *See* R.F. Palmer et al., *A Randomized Trial of the Effects of Remote Intercessory Prayer: Interactions with Personal Beliefs on Problem-Specific Outcomes and Functional Status*, 10 J. ALTERNATIVE & COMPLIMENTARY MED. 438-48 (2004).

[33] *See* D.S. Wilkinson et al., *The Clinical Effectiveness of Healing Touch*, 8 J. ALTERNATIVE & COMPLIMENTARY MED. 33-47 (2002).

[34] Young describes 19th century patent medicine vendors as follows:

> [T]he big-scale patent medicine maker, during the first half of the 19th century, blazed a merchandizing trail. He was the first American manufacturer to seek out a national market. He was the first producer to help merchants who retailed his wares by going directly to consumers with a message about the product. He was the first promoter to test out a multitude of psychological lures by which people might be enticed to buy his wares. While other advertising in the press was drab, his was vivid; while other appeals were straightforward, his were devilishly clever. The patent medicine promoter was a pioneer,

philosophy that prevails inside the Beltway creates conditions conducive to modern quackery. For example, Republican lawmakers in Congress repeatedly (though unsuccessfully) have introduced a bill entitled the "Access to Medical Treatment Act" that would broaden the ability of licensed health care professionals to treat patients with alternative approaches.[35] As one of the original sponsors, Senator Robert Dole (R-Kan.), stated: "In a free market system, it seems to make sense to make available non-harmful alternative medical treatments to individuals who desire such treatments, without the Federal Government standing in the way."[36] The latest Republican cure for the rising costs of health care is "consumer-driven health plans," which attempt to give patients incentives to make wise health care purchasing choices by saddling them with a significant portion of first-dollar health care costs.[37] But as Haavi Morreim points out, this gives patients (now called consumers) greater freedom to opt for complimentary and alternative medicine: "In a shift to consumer-directed health plans, CAM modalities could be more easily available to those who want them, without intruding on common resources."[38] CAM is not necessarily quackery, but greater freedom to choose CAM implies greater freedom to choose whatever the patient can get her hands on, including quackery.

It is impossible to know whether the market for quackery has increased in recent years, if only because we have not yet defined the term.[39] Nevertheless, as the

---

> marching at the head of a long procession of other men with ships, shoes and sealing wax to sell.

Young, *supra* note 8, at 21.

[35] *E.g.*, H.R. 2085, 108th Cong., (2003).

[36] Michael E. Horwin, *"War on Cancer": Why Does the FDA Deny Access to Alternative Cancer Treatments?*, 13 ALB. L. J. SCI. & TECH. 681, 695 (2003).

[37] *See generally* Wendy K. Mariner, *Can Consumer-Choice Plans Satisfy Patients?: Problems with Theory and Practice in Health Insurance Contracts*, 69 BROOK. L. REV. 485, 495-514 (2004).

[38] Haavi Morreim, *A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science*, 31 J.L. MED. & ETHICS 222, 230 (2003). As Morreim states:

> Given that most CAM modalities are relatively inexpensive, most if not all decisions about CAM would be made by patients themselves, spending from their own personal accounts within their deductibles. The person who prefers massage over drugs for fibromyalgia, or the arthritis patient who prefers acupuncture, can make this choice without haranguing an insurer or paying the entire tab out of pocket.

Id.

[39] It has become fashionable, for example, to claim that CAM is enjoying a resurgence. *See* Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 194 (1998) ("The most recent alternative medicine resurgence largely results from a generational pursuit of independence and nonconformity."); Andrew M. Knoll, *The Reawakening of Complementary and Alternative Medicine at the Turn of the Twenty-First Century: Filling the Void in Conventional Biomedicine*, 20 J. CONTEMP. HEALTH L. POL'Y 329, 335 (2004) ("[S]ome explanation must be given to justify the resurgence of CAM as more than mere desire for caring without substantive curing."). Knoll basis his claim on the results of two studies which show an 8 percent increase in the number of respondents between 1993 and 1997 who stated that they used CAM. *Id*. at 330; David M. Eisenberg et al., *Unconventional Medicine in the United States*, 328 NEW ENG. J. MED. 246, 248 (1993); David M. Eisenberg et al., *Trends in Alternative Medicine Use in the United States*, 280 JAMA 1569, 1571 (1998), *cited in* Knoll, *supra*, at footnotes 2 and 3. A Los Angeles Times Article states that sales of herbal remedies increased 100 percent between 1994 and 1998, and that "historians trace the resurgence of alternatives to the back-to-nature 1960's . . . ." Terence Monmaney & Shari Roan, *Hope or Hype?; Alternative Medicine is Edging into the Mainstream, with Californians Leading the Way. The Appeal is Complex, and Debate Rages About its Effectiveness and Scientific Oversight*, L.A. TIMES, Aug. 30, 1998, at A1. On the other hand, in an article criticizing Paul Starr's THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE for overstating the dominance of mainstream medicine, Michael Goldstein argues that what he calls "medical pluralism" has remained "omnipresent over time." Michael Goldstein, *The Persistence and Resurgence of Medical Pluralism*, 29 J. HEALTH POL. POL'Y & LAW 925, 928 (2004). Goldstein adds that "the current usage reflects a pattern among the entire population that has continued for at least the past fifty years." *Id*.

foregoing discussion shows, numerous factors in operation today are conducive to the practice of unorthodox medicine, including quackery. The threat of quackery is real. But so is the threat that practices that should be permitted will be tarred as quackery. How do we tell the difference?

II. WHAT IS QUACKERY?

While everyone agrees that quackery is bad, there is virtually no discussion, let alone agreement, on what the term covers. Quackery may turn out to be one of the impossible-to-define but prohibited phenomena like "pornography" that one simply knows when one sees it.[40] But this would seriously complicate the task of regulating quackery, since one would have to wait until one saw it to do anything about it, by which time significant harm may have occurred. Therefore, it seems worth making an effort to define the term.

The House Select Committee on Aging in 1986 issued a report defining "quack" as "anyone who promotes medical schemes or remedies known to be false, or which are unproven, for a profit."[41] Science writer Susan Gilbert similarly states that "[m]anufacturing or selling an unproved remedy is quackery. The yardstick that scientists and lawyers use to distinguish legitimate medicine from quackery is scientific method, the reliance on experiments rather than intuition or opinion."[42]

But as Haavi Morreim points out, much of mainstream medicine is unproven:

> Standard medicine is not nearly so scientific as is usually assumed. Among other factors, there are far too many phenomena to study; limited research resources are often directed as much by political and commercial interests as by medical needs; actual practices do not reflect well the science that has been gathered; the most pristine science is often the least useful in the real world care of ordinary patients.[43]

As Morreim notes, a large proportion of mainstream practice has lacked scientific support, including pulmonary artery catheterization, angioplasty, bypass surgery, arthrosopic debridement of the osteoarthritic knee, hormone replacement therapy, high-dose chemotherapy with autologous bone marrow transplantation for breast cancer, and the overuse and underutilization of antibiotics.[44] Not all of the examples involve high tech medicine, either; Morreim cites a finding that fewer than twenty-five percent of health care workers washed their hands before and after caring for patients.[45]

The terms "quackery" and "quack" do not appear in any federal or state laws or regulations, with one irrelevant exception.[46] However, the meaning of the terms has

---

[40] Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

[41] HOUSE SELECT COMM. ON AGING, SUBCOMMITTEE ON HEALTH AND LONG TERM CARE, QUACKERY: A $10 BILLION SCANDAL, H.R. DOC. NO. 98-262, at 4 (1984).

[42] Gilbert, *supra* note 7, at 15-16.

[43] Morreim, *supra* note 38, at 222.

[44] *Id.* at 223-25.

[45] *Id.* at 225 (citing W.E. Bischoff et al., *Handwashing Compliance by Health Care Workers: The Impact of Introducing an Accessible, Alcohol-Based Hand Antiseptic*, 160 ARCH. INT. MED. 1017, 1017 (2000)). Morreim also asserts that orthodox medicine wastes far more resources than alternative approaches. *Id.* at 227-28.

[46] The exception is a requirement in the administrative rules of West Virginia, pertaining to the content of technical and adult education courses, that students in a course entitled "Trends in

been addressed in a number of court cases. The opinions in these cases take two different approaches. One approach focuses on the quack's claim to medical skills that he or she does not possess. Several of these cases involve libel suits. *Baker v. Haldeman-Julius*, for example,[47] was a libel action in which the plaintiff, who had developed certain remedies for cancer, sought damages from the publisher of an article that had labeled him, among other things (e.g., "yokel-baiter"), a quack.[48] In the course of its opinion affirming the lower court's denial of the defendant's demurrer, the Supreme Court of Kansas referred, without citation, to the definition of "quack" as "a boastful pretender to medical skill and a medical charlatan," and defined "charlatan" as "one who makes unwarrantable pretensions, especially as a vendor of remedies."[49] In another libel case, *Brinkley v. Fishbein*, [50] the Fifth Circuit cited the definition of the term "quack" from the *Century Dictionary*: "an ignorant or fraudulent pretender to medical skill."[51] A district court in Texas adopted the same definition in another libel case against the same defendant, *Hoxsey v. Fishbein*.[52] In *McFadden v. U.S. Fidelity and Guarantee Co*.,[53] a Mississippi appellate court relied on the *American Heritage College Dictionary*, which defines "quack" as "an untrained person who pretends to be a physician and dispenses medical advice and treatment."[54]

In *State v. Hoffman*, the Supreme Court of Utah adopted the same interpretation of the term "quackery" in affirming a conviction for the practice of medicine without a license.[55] The defendant had diagnosed several undercover agents in the following way:

> Appellant had [the agent] sit down, place her index finger in a circle drawn on top of a small plastic box. Appellant took a silver pendulum fastened on a chain and swung it several times over the box. Before swinging the pendulum, appellant placed lists of words in the circle which appeared to be types of diseases. When the disease of mercury poisoning was placed in the circle, the pendulum began to move radically and appellant stated that [the agent] had mercury poisoning.[56]

The defendant also claimed he could "broadcast" cures by placing his hand over magnets and turning the magnets toward patients in other cities and states.[57] In rejecting the defendant's argument that the state licensure law abridged the free exercise of religion, the court observed that "[t]he legislature is protecting the people from the quacks who would deceive them into thinking they were receiving medical relief when, in reality, they were being deprived of their money without the remotest possibility of cure."[58]

Health Care Objectives" will "list four possible indicators of quackery." W. VA. CODE ST. R. § 126-44M-4 (2004).

47 Baker v. Haldeman-Julius, 88 P.2d 1065 (Kan. 1939).

48 *Id.* at 1066.

49 *Id.* at 1067.

50 Brinkley v. Fishbein, 110 F.2d 62 (5th Cir. 1940).

51 *Id.* at 64.

52 Hoxsey v. Fishbein, 83 F. Supp. 282 (N.D. Tex. 1949).

53 766 So. 2d 20 (Miss. Ct. App. 2000).

54 *Id.* at 24, (citing THE AMERICAN HERITAGE COLLEGE DICTIONARY 1116 (3d ed. 1993)).

55 State v. Hoffman, 558 P.2d 602 (Utah 1976).

56 *Id.* at 603.

57 *Id.* at 603-04.

58 *Id.* at 605-06. The court noted that "[t]his type of quackery also prevents people who may be or are in dire need of competent aid by their either delaying or foregoing proper treatment." *Id.* at 606.

In another case involving a prosecution for an alleged violation of a state medical licensing law, the Supreme Court of Florida focused on the nature of the alleged quack's actions rather than on his lack of skill. In that case, *Curley v. State*,[59] the court overturned the conviction of a faith healer for the unlicensed practice of medicine on the ground that the defendant was not practicing medicine:

> He never used or prescribed drugs, nor did he use any instruments. About all that he usually did was to touch the body of persons who came to him, as many did, with his fingers at various points on the body, some times at one or two, some times at several points, meanwhile praying silently to himself. He believed that he had some marvelous power from on High to heal practically all of the ills of the flesh.[60]

The court explained that the purpose of the medical licensure law was to protect the public against "ignorant quacks and scheming charlatans who would attempt to pose as members of the great medical profession and assume the ability to diagnose diseases and prescribe drugs or perform operations for their cure."[61] So long as faith healers "do not invade the province of the medical profession and assume the ability to diagnose diseases and prescribe drugs or other medical or surgical or mechanical means to restore the health of those who go to them," they do not violate the statute.[62]

Neither the "lack of skill" nor the "scope of practice" approach is satisfactory. The notion that quacks can be identified simply by the fact that they pretend to have skills that they do not possess would entrap competent, mainstream practitioners who misrepresented their lack of skill or experience. So long as the practitioners provided reasonable care, the fact that they were not candid about their qualifications, while objectionable and perhaps even actionable, does not by itself make their treatment quackery.[63] The Supreme Court of Florida's interpretation in

---

[59] Curley v. State, 16 So. 2d 440, 442 (Fla. 1944).

[60] *Id.* at 441.

[61] *Id.* at 442.

[62] *Id.*

[63] Indeed, courts are divided over whether physicians must truthfully inform patients of their level of skill and experience as part of the informed consent process. In *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996), a patient suffering from headaches was referred to a neurologist, who operated on her for an enlarging aneurysm at the bifurcation of the basilar artery. The surgery left the patient an incomplete quadriplegic, unable to walk or control her bowel or bladder functioning and with partial impairment of her vision, speech, and upper body coordination. Prior to the surgery, the patient had questioned the surgeon about his experience, and was told that he had performed the surgery in question "dozens" and "lots" of times. In fact, although he had performed 30 aneurysm surgeries during his residency and 6 since then, he had operated on basilar bifurcation aneurysms only twice, and had never operated on a large basilar bifurcated aneurysm such as the plaintiff's. The plaintiff contended that the surgeon should have advised her of his limited experience and referred her to a more experienced surgeon, who could have been found at the Mayo Clinic, only 90 miles away. A jury decided in favor of the plaintiff, but an appellate court reversed, stating that a physician had no duty to divulge the extent of his experience to patients. The Supreme Court of Wisconsin reinstated the verdict, holding that "[a] reasonable person in the plaintiff's position would have considered such information material in making an intelligent and informed decision about the surgery." *Id*. at 505.

In 2002, the Supreme Court of New Jersey reached a similar result in *Howard v. University of Medicine and Dentistry of New Jersey*, 800 A.2d 73 (N.J. 2002). A defendant, Robert Heary, who was Professor of Neurosurgery and Director of the UMDNJ's Spine Center of New Jersey, performed surgery to correct the plaintiff's cervical myopathy secondary to cervical stenosis and a significantly large C3-C4 disc herniation. The patient was rendered a quadriplegic. According to the plaintiff, Dr. Heary had said that he was board-certified in neurosurgery and that he had performed 60 corpectomies during the 11 years he had practiced neurosurgery. In fact, Heary was only board-eligible, and he had

Curley, on the other hand, would protect individuals who provided all sorts of dubious treatments so long as they did not diagnose disease and did not use drugs or medical or surgical techniques. Although purveyors of dietary supplements, naturopathy, homeopathy, herbal remedies, hypnosis, biofeedback, magnetic fields, Reiki, gi gong, and chiropractic ultimately may not be deemed quacks, there is no reason to exempt them automatically from being considered for that status merely by virtue of the techniques that they use.

One theme that appears in the foregoing court decisions is the idea that quacks fleece people, which suggests that a sine qua non of quackery is its commercial motive. Thus, the court in *Baker* excoriates the "vendor of [quack] remedies,"[64] while in *State v. Hoffman*, the court complains of quacks whose victims are "being deprived of their money without the remotest possibility of cure."[65] Similarly, Susan Gilbert refers to quacks as people who "peddle unproved remedies for profit."[66] And, as noted earlier, the 1986 report of the House Select Committee on Aging defined "quack" as "anyone who promotes medical schemes or remedies known to be false, or which are unproven, *for a profit*."[67] This suggests that nostrums that

---

performed only approximately twenty-four corpectomies. In addition to suing the physician for malpractice, the plaintiff's sought to sue him for fraud and deceit. The Supreme Court of New Jersey declined to permit the plaintiff to pursue the fraud-and-deceit claim, but held that he could proceed on the basis that the physician had failed to obtain his informed consent to the procedure. The court's reasoning includes an illuminating discussion of the difference between intrinsic and extrinsic risks:

> We recognize that a misrepresentation about a physician's experience is not a perfect fit with the familiar construct of a claim based on lack of informed consent. The difficulty arises because physician experience is not information that directly relates to the procedure itself or one of the other areas of required medical disclosure concerning the procedure, its substantial risks, and alternatives that must be disclosed to avoid a claim based on lack of informed consent. But the possibility of materiality is present. If defendant's true level of experience had the capacity to enhance substantially the risk of paralysis from undergoing a corpectomy, a jury could find that a reasonably prudent patient would not have consented to that procedure had the misrepresentation been revealed. That presumes that plaintiff can prove that the actual level of experience possessed by defendant had a direct and demonstrable relationship to the harm of paralysis, a substantial risk of the procedure that was disclosed to plaintiff. Put differently, plaintiff must prove that the additional undisclosed risk posed by defendant's true level of qualifications and experience increased plaintiff's risk of paralysis from the corpectomy procedure.

Id. at 84-85.

But other cases have rejected this type of claim. In *Ditto v. McCurdy*, 947 P.2d 952 (Haw. 1997), the Supreme Court of Hawaii ruled that a physician does not have an affirmative duty to disclose his or her qualifications to a patient prior to providing treatment. The plaintiff had been disfigured as a result of breast-augmentation surgery. She claimed, among other things, that the physician, who was certified as a cosmetic surgeon by the American Board of Cosmetic Surgeons, which is not recognized by the American Society of Medical Specialties, had a duty to inform her that he was not board-certified by the ASMS-recognized American Board of Plastic and Reconstructive Surgeons.

In *Duttry v. Patterson*, 771 A.2d 1255 (Pa. 2001), a throat cancer patient had questioned the surgeon about how often he had performed the type of surgery he had recommended. The surgeon allegedly told her that he did the procedure approximately once a month. In fact, he had only done it 9 times in the past 5 years. After the patient suffered complications following a rupture at the site of the surgery, she sued, claiming that the physician's misrepresentation deprived her of the ability to give her informed consent. The Supreme Court of Pennsylvania sided with the defendant, holding that "the evidence of a physician's personal characteristics and experience is irrelevant to an informed consent claim." Importantly, the court added that this conclusion does not change even if the patient specifically asks about the physician's experience.

64 *Baker*, 88 P.2d at 1067.

65 *Hoffman*, 558 P.2d at 606.

66 GILBERT, *supra* note 7, at 19.

67 HOUSE SELECT COMMITTEE ON AGING, *supra* note 41, at ii (emphasis added).

were given away freely would not be considered quackery. But they could still cause patient harm.

A term that is often used as though equivalent to medical quackery is health care "fraud."[68] As mentioned earlier, the dictionary definition used by the Fifth Circuit in *Brinkley* and by the district court in Texas in *Hoxsey* said a quack was "an ignorant or *fraudulent* pretender to medical skill."[69] The question is: what constitutes medical "fraud," and is it the same as "quackery"?

As a matter of state tort law, "fraud" generally implies knowledge that a representation is false, or at least reckless disregard of the truth.[70] The federal False Claims Act penalizes the "knowing" presentation of a false or fraudulent claim, which includes "actual knowledge" of the falsity or fraudulence of the representation, "deliberate disregard" of its truth or falsity, and "reckless disregard" of the truth.[71] The Medicare and Medicaid fraud and abuse statute makes it a felony to act "knowingly and willfully,"[72] although the meaning of the term "willfully" is the subject of considerable controversy.[73]

Equating medical quackery with fraud, in short, implies a high degree of *scienter* part of the offender. But what about someone who does not "know" that a claim that an intervention works is false—for example, someone who firmly believes that the claim is true? If there were scientific studies showing the claim to be false, the believer might still be guilty of fraud by deliberately or recklessly disregarding the scientific data, but, as already pointed out, few medical interventions have been subjected to rigorous scientific testing.[74] Even without valid and reliable test results, an approach might still seem to be quackery if it lacked a plausible scientific rationale, such as homeopathy, whose proponents at one time believed that "nearly all diseases were the result of a suppressed itch or 'psora,'"[75] or chiropractic, which blamed most illnesses on a misalignment of the vertebrae.[76] But there are entire medical traditions that do not rest on what are thought of as modern scientific principles. Traditional Chinese medicine, for example, purports to have identified a "channel system" of sensation in the human body, with definite,

---

[68] *See Brinkley*, 110 F.2d at 64; *Hoxey*, 83 F. Supp. at 282.

[69] *Brinkley*, 110 F.2d at 64; *Hoxsey*, 83 F. Supp. at 282 (emphasis added). Gilbert states: "Any remedy that lacks proof of its effectiveness is a fake. If the remedy is used to deceive people, it is called a fraud, a term that also describes the practice of this deception. Manufacturing or selling an unproved remedy is quackery." Gilbert, *supra* note 7, at 15-16.

[70] The precise *scienter* requirement varies from state to state. Connecticut defines fraud as an untrue statement whose maker knew it to be false. Billington v. Billington, 595 A.2d 1377, 1379 (Conn. 1991). In Ohio, fraud is a "knowing misrepresentation." Gaines v. Pre-Term Cleveland, Inc. 514 N.E.2d 709, 712 (1987). Pennsylvania defines it as a representation "made falsely, with knowledge of its falsity or recklessness as to whether it is true or false," Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994), as does Texas. Stone v. Lawyers Title Insurance Co., 554 S.W.2d 183, 185 (1977). Minnesota defines fraud as a false representation that the representer knows to be false, or "assert[s] it as of his own knowledge, without knowing whether it is true or false." Davis v. Re-Trac Manufacturing Corp., 149 N.W.2d 37, 39 (Minn. 1967). Illinois defines fraud as a false statement that the maker knows or believes to be false. Soules v. General Motors Corp., 402 N.E.2d 599 (Ill. 1980).

[71] 31 U.S.C. § 3729(a)-(b) (2004).

[72] 42 U.S.C. § 1320-A-7b (2004).

[73] *See* Douglas A. Blair, *The "Knowingly and Willfully" Continuum of the Anti-Kickback Statute's Scienter Requirement: Its Origins, Complexities, and Most Recent Judicial Developments*, 8 ANN. HEALTH L. 1 (1999).

[74] *See supra* notes 43-45 and accompanying text.

[75] STARR, *supra* note 5, at 97.

[76] *See* Brown v. Shyne, 151 N.E. 197, 200 (N.Y. 1926) (Crane, J., dissenting) ("The theory of the chiropractics is that most, if not all, diseases come from pressure on the nerves caused by vertebra deviating from the normal.").

specifiable routes.[77] Ruiping Fan observes that researchers since the 1950s have attempted in vain to locate the physical "tubing" of these channels, but maintains that their failure does not invalidate the practice of acupuncture:

> Given that the propagated sensation along channels as a phenomenon has been available for thousands of years and continues to be confirmed by patients in the present time, research on the channel phenomenon does not have to be designed for looking for "objective" anatomical constructions apart from the patient's real experiences. For traditional Chinese medicine, patients' concrete experiences and feelings are equally objective facts for research as particular physical structures.[78]

Nor are Chinese acupuncturists necessarily dismayed by findings that patients report pain relief from "sham" acupuncture—in this case, inserting needles into the "wrong" sites.[79] As Fan explains:

> No one can deny the crucial importance of randomized clinical trials as a standard method for modern scientific medicine. However, traditional Chinese medicine cannot accept such trials as its standard method. In order to conduct a randomized clinical trial, we would need to assemble a group of patients with the same disease diagnosis for testing the efficacy of a drug (namely, the same disease and the same drug are essential conditions for undertaking the trial). However, traditional Chinese medicine is about the individual; it is highly unlikely to result in the same symptom-complex diagnosis for a group of patients and to prescribe the same herbal medicines to treat them.[80]

In summary, there is no satisfactory definition for what constitutes medical quackery. The term cannot simply refer to medical practices that are unproven, since that would encompass a significant proportion of what most people would consider legitimate medical practice. Quackery cannot be defined as pretending to have skills that one does not possess, since, unfortunately, that too probably characterizes a significant number of mainstream practitioners. Nor does it make sense to limit quacks to those who diagnose illness or use drugs, medical devices, or surgical techniques. This would disqualify purveyors of dietary supplements, which rely on self-diagnosis by purchasers and as a matter of law are not considered drugs. Finally, quackery cannot be limited to fraud, since that would protect purveyors who believed their remedies worked without having an adequate scientific foundation to support their beliefs.

Faced with this impasse, one option is to abandon the effort to identify what counts as quackery. But this would forego recognizing a category of medical interventions that is unqualifiedly inappropriate. This in turn could create the impression that all approaches to the treatment and diagnosis of illness are minimally acceptable, even if they are not all equally acceptable. Such a pluralistic attitude could expose vulnerable patients to serious harm, both physical and

---

[77] Ruiping Fan, *Modern Western Science as a Standard for Traditional Chinese Medicine: A Critical Appraisal*, 31 J.L. MED. & ETHICS 213, 218 (2003).

[78] *Id.* at 219.

[79] *See* Acupuncture, NIH Consensus Development Conference Statement (Nov. 5-7, 1997), *at* http://odp.od.nih.gov/consensus/cons/107/107_statement.htm.

[80] Fan, *supra* note 77, at 219-20.

financial. The question, then, is where to draw the line between the acceptable and the unacceptable.

III. WHERE TO DRAW THE LINE

A starting point for determining where to draw the line between quackery and other types of interventions is to identify what motivates us to condemn quackery. What is so bad about it?

One concern is that quackery physically harms patients.[81] Yet Morreim asserts that mainstream medicine causes more harm than unconventional interventions, given the number of injuries caused by mainstream medical errors and adverse drug reactions.[82] Perhaps, then, what bothers us about quackery is that, unlike mainstream medicine, it creates a risk of harm to patients without providing any offsetting benefit. Indeed, even a relatively harmless intervention[83] can injure patients if it is ineffective, since it could deter patients from availing themselves of beneficial alternatives. In *Rutherford v. United States*,[84] for example, the Supreme Court upheld the FDA's effort to block patients from using an unapproved cancer treatment on the ground, *inter alia*, that this could lead them to forego the benefits of mainstream chemotherapies.[85] The problem is that, as Morreim points out, the efficacy of many mainstream practices remains unproven.[86] So what bothers us about quackery must be more than just that it creates a risk of harm without known, countervailing benefits.[87]

As discussed in Section II, criticisms of quackery often refer to its deceptive or fraudulent nature. This implies some degree of *scienter* on the part of the quack. The quack in some sense must *know* that the remedy does not benefit the patient, or that whatever benefit it provides clearly is outweighed by the harm it causes. In short, the quack tricks the patient into believing that the remedy will be helpful when it will not be.

But then why is quackery so persistent? Why do people fall for it if it does not work or if it harms them? Certainly people can be gullible, and arguably a person

---

[81] *See* Michael H. Cohen, *Of Rogues and Regulation: A Review of the Role of Complementary and Alternative Medicine: Accommodating Pluralism*, 27 VT. L. REV. 801, 812 ("'fraud control' refers to 'preventing dangerous and deceptive practices . . . ' ").

[82] Morreim, *supra* note 38, at 227.

[83] I use the term "relatively" since it is a truism that no medical intervention is completely risk-free.

[84] 442 U.S. 544 (1979).

[85] *See id.* at 556 (observing that "an otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect (citation omitted). But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible"). This may explain why none of the definitions of quackery in the case law mentions harm, but focus instead on the idea that quackery provides no benefit to the patient. *Rutherford* involved efforts by the Food and Drug Administration to prevent the sale of laetrile, a substance made from apricot pits touted for its supposed ability to treat cancer. For a history of the Laetrile controversy, see JAMES HARVEY YOUNG, AMERICAN HEALTH QUACKERY 205-34 (1992). Interestingly, the plaintiffs in the *Rutherford* case were terminal cancer patients, meaning that they had exhausted conventional remedies. As the District Court noted, "the vast majority of Laetrile patients first underwent the relevant conventional treatments." Rutherford v. United States, 487 F. Supp. 1287, 1296 (W. D. Okla. 1977), *remanded*, 582 F.2d 1234 (10th Cir. 1978), *rev'd*, 442 U.S. 544 (1979).

[86] *See* Morreim, *supra* note 38, at 222-26; *see also supra* note 45 and accompanying text.

[87] A concept of quackery that focused on the threat of direct or indirect patient harm also would tend to exclude relatively harmless interventions for conditions for which there were no effective treatments.

who is ill and desperate for help is likely to be especially susceptible to the wiles of the charlatan. But one would expect that patients eventually would realize they were being duped. It is perhaps understandable that the proverbial snake-oil salesman could pull into a 19th century village, make a killing, and skedaddle before anyone made a fuss, but surely the townspeople would lynch the next con artist who rode into town. Why is quackery not so self-destructive?

The answer is twofold. First, quack remedies may appear to work when the patient's improvement is caused by the natural course of the illness. As one prominent critic of quackery points out, "most remedies are self-limiting and improve with time regardless of treatment."[88] But quack remedies also may actually "work." That is, they may generate a placebo effect, which can make the patient feel better or even improve the patient's health by triggering the patient's own disease-fighting capabilities.[89]

At present, there is considerable controversy about whether a placebo effect in fact exists or whether the purported improvement seen in patients is the result of observer bias or the natural course of the ailment. A 2001 analysis of studies in the medical literature concluded that there was no actual placebo effect except in subjective outcome measures, such as pain,[90] and a follow-up analysis reached the same conclusion.[91] However, even a positive effect on pain or other subjective symptoms would be a significant outcome from the patient standpoint.

Far from considering a placebo effect to be quackery, the Supreme Court in *American School of Magnetic Healing v. McAnnulty*[92] rejected an argument by the Postmaster General that soliciting customers to teach them how to heal through the power of the mind was mail fraud, stating:

> There can be no doubt that the influence of the mind upon the physical condition of the body is very powerful, and that a hopeful mental state goes far in many cases, not only to alleviate, but even to aid very largely in the cure of an illness from which the body may suffer. And it is said that nature may itself, frequently if not generally, heal the ills of the body without recourse to medicine, and that it cannot be doubted that in numerous cases nature when left to itself does succeed in curing many bodily ills. How far these claims are borne out by actual experience may be matter of opinion.[93]

Similarly, in *Jurich v. General Motors Corp.*, a Missouri Court of Appeals acknowledged that "[t]he prescribing of placebos is, in appropriate cases, a recognized form of medical treatment," and therefore the plaintiff, who complained

---

[88] JAMES HARVEY YOUNG, THE HEALTH ROBBERS: A CLOSE LOOK AT QUACKERY IN AMERICA 457 (1993), *available at* http://www.quackwatch.org/01QuackeryRelatedTopics/persistance.html.

[89] For a thorough discussion of the placebo effect, see Kathleen Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687 (2002). There is a peculiar tendency to consider a placebo effect not to be "real." In *State v. Hoffman*, for example, the court complained that "These ill people think they are being cured, when, in fact, they are receiving no *real* help." 555 P.2d at 606 (emphasis added). The court does not distinguish between no benefit and a placebo benefit.

[90] Asbjorn Hrobjartsson & Peter C. Gotzsche, *Is the Placebo Powerless?: An Analysis of Clinical Trials Comparing Placebo with No Treatment*, 344 NEW ENG. J. MED. 1594 (2001).

[91] Asbjorn Hrobjartsson & Peter C. Gotzsche, *Is the Placebo Powerless?: Update of a Systematic Review with 52 New Randomized Trials Comparing Placebo with No Treatment*, 256 J. INTERNAL MED. 91 (2004).

[92] 187 U.S. 94 (1902).

[93] *Id.* at 104.

that he was given a placebo instead of an active drug to treat back pain, could not assert a cause of action for deceit.[94]

This brings us back to the issue of knowingly deceiving patients. There is considerable debate over the ethics of medical deception,[95] but at least some physicians and bioethicists believe that producing a placebo effect through deception may be appropriate in some circumstances.[96] In any event, it is hard to regard deception as quackery, that is, as beyond the pale of acceptability, so long as the practitioner intends to benefit the patient by producing a placebo effect.

The gravamen of quackery therefore may boil down to a question of intent. If the purveyor intends to provide net benefit to the patient, then the purveyor is not a quack, even though the benefit is produced by a placebo effect that is itself the result of knowing deception. On the other hand, a person who hawks a nostrum *knowing* that it does not produce a placebo effect or that, although it may produce one, it ends up causing net harm to the patient, is a quack.

There are two problems with this approach, however. First, it is difficult to determine a person's intent. Clever quacks would take pains to avoid admitting that they knew that their products provided no patient benefit or caused net harm. Second, this approach would reward intentional ignorance, a head-in-the-sand attitude in which quacks simply avoided learning whether or not their products worked.

The alternative is to adopt an objective standard to identify when someone can be said to know that a product does not produce patient benefit. One option is to consider something quackery when it flies in the face of currently accepted medical and scientific knowledge. But the history of medicine shows that this test can easily become a means of cementing a prevailing school of thought and armoring it against valid criticism and needed progress. Consider peptic ulcers.[97] It took ten years for the mainstream medical community to accept the results of Australian research that showed that most ulcers were caused by bacteria, not by stress or spicy foods.[98]

A practice also could be deemed to be quackery when it had been tested and not found to produce net patient benefit. But this option would result in very few practices being considered quackery, since so few have been tested, and even fewer tested properly so that a benefit would have been detected if one actually had been produced.

In short, we are left with no handy, *a priori* way to identify quackery.

But this does not mean that all medical practices must be deemed acceptable. The law has a strategy to deal with this situation: a combination of presumptions and burdens of proof. In the case of new drugs and medical devices, the presumption is against acceptance, and the manufacturer bears the burden of convincing the FDA

---

[94] Jurich v. General Motors Corp., 539 S.W.2d 595, 600 (Mo. Ct. App. 1976).

[95] *See* Boozang, *supra* note 89, at 719-45.

[96] *Cf. id.* at 720 (stating that "even while balking at patient deception, most ethical literature reserves the right to lie under necessary circumstances, including, in the medical context, the administration of placebos").

[97] *See* NIH Consensus Conference, *Helicobacter pylori in Peptic Ulcer Disease*, 272 JAMA 65, 68 (1994) ("The discovery of H pylori as a gastrointestinal pathogen [in the 1980s] has had a profound effect on current concepts of the pathogenesis of peptic ulcer disease."), *cited in* Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 424 n.224 (2002).

[98] *See* Jay Siwek, *Is a Stomach Ulcer an Infectious Disease?,* WASH. POST, Nov. 9, 1993, at Z19. Researchers thought that the bacteria they detected on their slides of stomach tissue was a contaminant.

that a product is safe and efficacious for its labeled indications.[99] Medical and surgical practices, on the other hand, are presumed acceptable, and the burden is on a complainant—a patient, state medical board, or the Federal Trade Commission—to prove that the practice is unacceptable.[100] This approach also applies to off-label prescribing of approved drugs and devices.[101]

What about the subject of this symposium, dietary supplements? Since the passage of DSHEA, manufacturers cannot legally make health claims for their products without scientific data and FDA approval.[102] But DSHEA allows dietary supplements to bear "structure/function" claims on their labeling that closely resemble health claims,[103] and health claims are routinely made in pro-supplement advertising and websites. A prominent website, for example, makes product claims for "memory supplements," "prostate healthy nutrients," "heart healthy nutritional supplements," "herbs for menopause," and lists supplements that "boost the immune system," "interrupt the replication of many pathogens," are "anti-inflammatory," can ameliorate "diabetic nerve damage," and so on.[104] Rigorous scientific testing supports none of these claims. So long as a manufacturer sticks to "structure/function" claims, the presumption is in favor of acceptance and the FDA has the burden of showing that the supplement is unsafe or is making unsustainable claims.[105] Since the law does not require dietary supplement manufacturers to test their products for efficacy, including a placebo effect, prior to marketing, dietary supplements are well-positioned to take advantage of a "know-nothing" approach to avoid being identified as quackery.

The real question, then, is whether the risk that patients will be injured or tricked into thinking that a dietary supplement "works," even if just by producing a placebo effect, compels a shift in the presumption and burden-of-proof. Or, to put it another way, what justifies treating dietary supplements differently than other drugs and medical devices? The answer depends on how tolerant we want to be of the risk of quackery.

---

[99] *See* 21 U.S.C. § 355 (2000); 21 U.S.C. § 360(e) (2000).

[100] Gunning v. Cooley, 281 U.S. 90, 95 (1930).

[101] *See* David Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281 (1989).

[102] *See Dietary Supplement Safety Act: How is FDA Doing 10 Years Later?: Hearing before the Senate Committee on Government Affairs*, 108th Cong. (2004) (statement of Ronald Davis, M.D.), *available at* http://hsgac.senate.gov/index.cfm?Fuseaction=Hearings.Testimony&HearingID=179&WitnessID=642&IsTextOnly=1.

[103] 21 U.S.C. § 343(r)(6)(2004).

[104] *Your Guide to the Most Popular Nutritional Supplements and Dietary Supplements*, *at* http://www.nutritional-supplement-info.com (last visited Feb. 23, 2005).

[105] *See* REPORT OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS 2 (1997), *available at* http://www.health.gov/dietsupp/final.pdf.