

VOLUNTARY SELF-REGULATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE PRACTITIONERS

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"The urge to regulate is stronger than the sex drive."¹

I. INTRODUCTION

Complementary and alternative medicine (CAM) has been practiced and used in this country continuously since the nineteenth century.² All of the forms of care present then are still present today including botanical medicine ("Thomsonians"), health food ("Grahamites"), homeopathy, hydrotherapy, healing touch ("mesmerists"), osteopathy, naturopathy, chiropractic, and Christian Science.³ In the 1920s and early 1930s, three studies reported CAM usage of thirty-four percent, eighty-seven percent, and ten percent.⁴ Thirty percent of those born before 1945 use CAM compared with about one-half of those born between 1945 and 1964 and seventy percent of those born between 1965 and 1979.⁵ Although there may

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¹ Jose MA. Emmanuel A. Caral, *Lessons from ICANN: Is Self-Regulation of the Internet Fundamentally Flawed?*, 12 INT'L J.L. & INFO. TECH. 1, 1 (2004) (internal quotation marks omitted) (quoting Alan Schwartz, *Unconscionability and Imperfect Information: A Research Agenda*, 19 CAN. BUS. L.J. 437, 438 (1991)).

² Michael S. Goldstein, *The Persistence and Resurgence of Medical Pluralism*, 29 J. HEALTH POL. POL'Y & L. 925, 928 (2004).

³ *Id.* at 927.

⁴ *Id.* at 928; see also LOUIS S. REED, *THE HEALING CULTS: A STUDY OF SECTARIAN MEDICAL PRACTICE: ITS EXTENT, CAUSES, AND CONTROL* 1 (1932) (finding that as of 1932, there were over 30,000 CAM practitioners in the United States).

⁵ Ronald C. Kessler et al., *Long-Term Trends in the Use of Complementary and Alternative Medical Therapies in the United States*, 135 ANNALS INTERNAL MED. 262, 265 (2001).

have been a period of diminished use of CAM in the 1930s and 1940s, there has been a continual increase in usage since the 1960s.⁶

There are academic and social definitions of CAM,⁷ but in this Article I use a legal definition. A Minnesota statute states:

“Complementary and alternative health care practices” means the broad domain of complementary and alternative healing methods and treatments, including but not limited to: (1) acupressure; (2) anthroposophy; (3) aroma therapy; (4) ayurveda; (5) cranial sacral therapy; (6) culturally traditional healing practices; (7) detoxification practices and therapies; (8) energetic healing; (9) polarity therapy; (10) folk practices; (11) healing practices utilizing food, food supplements, nutrients, and the physical forces of heat, cold, water, touch, and light; (12) Gerson therapy and colostrum therapy; (13) healing touch; (14) herbology or herbalism; (15) homeopathy; (16) nondiagnostic iridology; (17) body work, massage, and massage therapy; (18) meditation; (19) mind-body healing practices; (20) naturopathy; (21) noninvasive instrumentalities; and (22) traditional Oriental practices, such as Qi Gong energy healing.⁸

Similar detailed language is also used in a Rhode Island statute,⁹ but California adopted a more general approach, defining it in the negative.¹⁰ The statute refers to legislative findings that

complementary and alternative health care practitioners . . . are not providing services that require medical training and credentials. . . . [and further] that these nonmedical complementary and alternative services do not pose a known

⁶ *Id.*; see also Peter Wolsko et al., *Alternative/Complementary Medicine: Wider Usage Than Generally Appreciated*, 6 J. ALTERNATIVE & COMPLEMENTARY MED. 321, 321 (2000) (“Recent studies demonstrate dramatic increases in use of and expenditures for alternative medicine in the United States.” (citations omitted)). Almost half of the population in many industrialized and developing countries regularly use CAM. Gerard Bodeker & Fredi Kronenberg, *A Public Health Agenda for Traditional, Complementary, and Alternative Medicine*, 92 AM. J. PUB. HEALTH 1582, 1582 (2002). For an example of CAM’s continued importance and relevance, see The Prince of Wales, Speech on Integrated Health Care at the World Health Assembly (May 23, 2006), available at http://www.princeofwales.gov.uk/speeches/health_23052006.html.

⁷ See, e.g., Ted J. Kaptchuk & David M. Eisenberg, *Varieties of Healing. 2: A Taxonomy of Unconventional Healing Practices*, 135 ANNALS INTERNAL MED. 196, 196–97 (2001) (describing the difficulty in defining alternative medicine and attempting to define the term).

⁸ MINN. STAT. ANN. § 146A.01(4) (West 2006).

⁹ R.I. GEN. LAWS § 23-74-1(a)(3) (2005).

¹⁰ CAL. BUS. & PROF. CODE § 2053.5(a) (West 2006).

risk to the health and safety of California residents, and that restricting access to those services due to technical violations of the Medical Practice Act is not warranted.¹¹

The statute itself is an exemption from the Medical Practices Act for persons who provide a statutorily defined disclosure statement and who do not perform any of a short list of controlled acts.¹² The legal definition of CAM therefore includes both a general component based on safety—the fundamental policy justification for all public health regulation—as well as a non-exclusive list of specific, safe, unregulated health care modalities that are more or less found widely in contemporary American society.

Next to allopathy,¹³ homeopathy was once the most well-known and successful school of medicine until the allopaths consolidated regulatory control over the practice and professions of medicine in the first two decades of the twentieth century and used it to eradicate as much of the competition as they could.¹⁴ “In 1898, homeopaths had 9 national societies, 33 state societies, 85 local societies and 39 other local organizations, 66 general homeopathic hospitals, 74 specialty homeopathic hospitals, 57 homeopathic dispensaries, 20 homeopathic medical colleges, and 31 homeopathic medical journals,”¹⁵ and in 1902, there were 15,000 practitioners.¹⁶ By 1980 there were 128 homeopaths and no homeopathic

¹¹ 2002 Cal. Legis. Serv. ch. 820, § 1(c) (West).

¹² CAL. BUS. & PROF. CODE § 2053.6. Idaho has a similar statute. IDAHO CODE ANN. § 54-1804(1)(j) (West 2006).

¹³ “Allopathy” is a word coined by Samuel Hahnemann, M.D., the founder of homeopathy, to describe non-homeopathic theories of medicine. 1 RICHARD HAEHL, SAMUEL HAHNEMANN: HIS LIFE AND WORK 66–67 (J. H. Clarke & F. J. Wheeler eds., Marie L. Wheeler & W. H. R. Grundy trans., Homoeopathic Pub. Co. 1922) (1825) (the authoritative biography of Hahnemann). The term quickly became associated with the numerically dominant regular physicians—also called the “regulars”—who in time used science and political skill to dominate medicine. WILLIAM G. ROTHSTEIN, AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY: FROM SECTS TO SCIENCE 232–33 (1972). Allopathy has also been described as scientific, conventional, regular, orthodox, traditional medicine, or biomedicine. MOLSON MED. INFORMATICS, MCGILL UNIV., RELATIONSHIP OF CAM & CONVENTIONAL MEDICINE – PAST, PRESENT, <http://sprojects.mmi.mcgill.ca/cam/relationship.htm> (last visited Oct. 17, 2006); see also SAMUEL HAHNEMANN, ORGANON OF MEDICINE 17 (R. E. Dudgeon trans., Nat’l Library of Med. 5th ed. 1955) (1833) [hereinafter ORGANON] (referring to allopathy as “ordinary medical treatment”).

¹⁴ See PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 116–27 (1982) (discussing how American medical education reform homogenized the profession, and by the 1920s and 1930s physicians dominated the field).

¹⁵ ROTHSTEIN, *supra* note 13, at 236.

¹⁶ JULIAN WINSTON, THE FACES OF HOMEOPATHY: AN ILLUSTRATED HISTORY OF THE FIRST 200 YEARS 538 (1999).

hospitals.¹⁷

I use homeopathy to illustrate how existing regulation of health care providers works for both licensed and unlicensed CAM providers. The effect of allopathic control of laws regulating the practice of medicine has resulted in a patchwork of restrictive or ambiguous laws that cover CAM providers that vary from state to state.¹⁸ The regulatory climate combines with the low number of practitioners to make legislative changes difficult; however, without regulatory changes it is hard for communities of practitioners—especially homeopaths—to grow. In this Article, I recommend that homeopaths and other similarly situated practitioner groups organize on a state-by-state basis around a code of conduct as a means to counteract divisive and restrictive laws as well as internal disputes to achieve solidarity.

In Parts I and II, this Article describes homeopathy and the regulatory environment in which it finds itself. The authority of the state to regulate health care providers is part of its police power to protect the public health. Accordingly, Part III addresses the concept of safety and related concepts in the provision of health care. This Article then briefly identifies different approaches to the regulation of occupations, and then looks specifically at existing regulation of health care professionals. First, this Article examines the monopoly the conventional medical profession holds, as it is one of the primary impediments to the growth of other health professions. Then, this Article examines a constitutional argument against exclusive, universal scope of practice statutes. In Part IV, the response of the Health Freedom Movement¹⁹ to the existing regulatory scheme for health care professionals is discussed. In Part V, this Article discusses options for the community of practitioners of homeopathy. This Article then concludes by stating that voluntary self-regulation around a code of conduct is the most viable alternative for homeopathy—and other unregulated CAM modalities—in the context of an exemption from the medical practice acts that is contingent on a disclosure statement to compensate for informational asymmetries in the health care market.

Parts III and IV of this Article also provide a framework for

¹⁷ *Id.*

¹⁸ See *infra* Part III; see also David M. Eisenberg et al., *Credentialing Complementary and Alternative Medical Providers*, 137 ANNALS INTERNAL MED. 965, 969–71 (2002).

¹⁹ See *infra* Part IV.E (discussing the Health Freedom Movement).

looking at how information is related to safety: the basis for regulation of health care providers. If the modalities themselves are safe, then the only danger is informational. This Article applies ethical principles to a safety analysis in both the social order (medicine and law) and the economic order, concluding reform of scope of practice laws would be best for collective and individual good and suggesting that the principles developed in the paper for analyzing safety issues can be applied more widely in analyses of allocation of resource problems in the health care system.

Annex A is a model code setting up a voluntary self-regulation scheme for CAM practitioners that is intended not only to legitimate CAM practitioners, but to foster integration of CAM practitioners into the existing health care infrastructure.

II. ABOUT HOMEOPATHY

Homeopathy is a school of medicine²⁰ now referred to as a “whole medical system[]” by the National Institutes of Health Center for Complementary and Alternative Medicine.²¹ It is a “complete system of medical theory and practice”²² that was more or less fully developed prior to the theory and practices of allopathic medicine.²³ Homeopathy has also been characterized as a professionalized health care system with its own theory of health and disease,

²⁰ In the law, homeopathy, naturopathy, and other practices have traditionally been referred to as “schools of medicine.” *See generally* TEX. CONST. art. XVI, § 31 (“The Legislature may pass laws prescribing the qualifications of practitioners of medicine in this State, and to punish persons for mal-practice [sic], but no preference shall ever be given by law to any schools of medicine.”); *Ex parte* Halsted, 182 S.W.2d 479, 487 (Tex. Crim. App. 1944) (stating that “schools of medicine” means “the system, means, or method employed, or the schools of thought accepted, by the practitioner” (internal quotation marks omitted)).

²¹ National Center for Complementary and Alternative Medicine, Whole Medical Systems: An Overview (2004), <http://nccam.nih.gov/health/backgrounds/wholemed.htm>.

²² *Id.*

²³ The history of medicine in the nineteenth century and the rise of “scientific” medicine are well told in reasoned references to homeopathy. *See, e.g.*, ROTHSTEIN, *supra* note 13, at 152–74; STARR, *supra* note 14, at 96–112. More detailed histories of homeopathy can be found in Harris L. Coulter, *Science and Ethics in American Medicine: 1800–1914*, in 3 HARRIS L. COULTER, *DIVIDED LEGACY: A HISTORY OF THE SCHISM IN MEDICAL THOUGHT* 20–26, 101–10 (1973); MICHAEL DEAN, *THE TRIALS OF HOMEOPATHY: ORIGINS, STRUCTURE AND DEVELOPMENT* (2004). In Martin Kaufman’s 1971 book, Kaufman concluded with the observation that homeopathy was all but dead; but when he revisited it in the mid 1980s he found a growing movement. *Compare* MARTIN KAUFMAN, *HOMEOPATHY IN AMERICA: THE RISE AND FALL OF A MEDICAL HERESY* 174–75 (1971), *with* Martin Kaufman, *Homeopathy in America: The Rise and Fall and Persistence of a Medical Heresy*, in OTHER HEALERS: UNORTHODOX MEDICINE IN AMERICA 99, 121–23 (Norman Gevitz ed., 1988). The preeminent historian of the homeopathic community, Julian Winston, has provided a rich look at homeopathy from within the community. *See generally* WINSTON, *supra* note 16.

schools and standardized curricula to teach its concepts, delivery system of a network of practitioners, United States Food and Drug Administration (FDA) federally regulated medicines and pharmacies, regulations in several states, social and professional structures and expectations, and national certification and school accreditation functions.²⁴ It has grown several hundred percent in recent years.²⁵

The distinction between homeopathy and other CAM modalities is important. Homeopathy, like traditional Chinese medicine and Ayurveda, is a complete system of medicine. In this sense it is unlike reiki and other techniques and methods referred to in the Minnesota statute.²⁶ It is a drug-based system with extensive literature that is predominantly practiced by physicians licensed in conventional medicine. A shortcoming of the legal definition of CAM is that its measure of demarcation—from allopathic medicine—is safety. This is correct and serves the general public health purpose but it does not recognize either the public health enhancements that come from collectives of practitioners—such as continuing education and a code of conduct—nor does it recognize that homeopathy is not a technique that can be learned in a short period of time. To be sure, some acute prescribing can be learned easily, but it takes years of technical training and practice to acquire the skills necessary to utilize the full scope of its power in all types of disease, especially chronic diseases.

Homeopathy was developed by Samuel Hahnemann, M.D. (1755–1843) over a period of about fifty years.²⁷ In 1790, having become discouraged with the often violent and dangerous medical practices of his time, Hahnemann was translating a work of the eminent Edinburgh physician William Cullen from English to German.²⁸ Cullen addressed the medicinal power of Cinchona bark—also known as *Cortex Peruvianus*—to cure malaria over the space of some twenty pages and concluded its effect was due to it being a stomach tonic by stating, “I have endeavoured [sic] to explain, in my

²⁴ See ALTERNATIVE MEDICINE: EXPANDING MEDICAL HORIZONS: A REPORT TO THE NATIONAL INSTITUTES OF HEALTH ON ALTERNATIVE MEDICAL SYSTEMS AND PRACTICES IN THE UNITED STATES (1992), available at <http://www.naturalhealthvillage.com/reports/rpt2oam/altsystems.htm> (commonly known as the Chantilly Report).

²⁵ Wayne B. Jonas et al., *A Critical Overview of Homeopathy*, 138 ANNALS INTERNAL MED. 393, 394 (2003).

²⁶ See *supra* note 8 and accompanying text.

²⁷ ROTHSTEIN, *supra* note 13, at 152.

²⁸ See generally HAEHL, *supra* note 13, at 37 (noting Hahnemann’s translation of Cullen).

first outlines of practical medical science, that the bark in this instance acts through its tonic effect on the stomach, and I have found nothing in any writings which could make me doubt the truth of my statements.”²⁹

Hahnemann attacked this line of thinking vigorously and in the ensuing empirical activity he discovered the principles of homeopathy:

By combining the strongest bitters and the strongest astringents we can obtain a compound which, in small doses, possesses much more of both these properties [stomach tonic] than the bark, and yet in all Eternity no fever specific can be made from such a compound. The author should have accounted for this. This undiscovered principle of the effect of the bark is probably not very easy to find. Let us consider the following : Substances which produce some kind of fever (very strong coffee, pepper, arnica, ignatia-bean, arsenic) counteract these types of intermittent fever. I took, for several days, as an experiment, four drams of good china twice daily. My feet and finger tips, etc., at first became cold; I became languid and drowsy; then my heart began to palpitate; my pulse became hard and quick; an intolerable anxiety and trembling (but without a rigor); prostration in all the limbs; then pulsation in the head, redness of the cheeks, thirst; briefly, all the symptoms usually associated with intermittent fever appeared in succession, yet without the actual rigor. To sum up: all those symptoms which to me are typical of intermittent fever, as the stupefaction of the senses, a kind of rigidity of all joints, but above all the numb, disagreeable sensation which seems to have its seat in the periosteum over all the bones of the body—all made their appearance. This paroxysm lasted from two to three hours every time, and recurred when I repeated the dose and not otherwise. I discontinued the medicine and I was once more in good health.³⁰

Hahnemann then reasoned—using inference to the best explanation—that since Cinchona bark caused symptoms that matched and cured intermittent fever, the medicinal effect of a medicine could be measured by the symptoms it caused in a healthy

²⁹ *Id.*

³⁰ *Id.* at 36–37. Dean translates the same passage, but recites that Hahnemann took only three drachms, not four. DEAN, *supra* note 23, at 17.

person.³¹

Homeopathy revolves around three principles. The first principle is that the medicinal effect of a substance can be measured by giving the substance to a healthy human.³² The process of giving substances and recording the symptoms caused by the substance is known as “provings” or “human pathogenic trial.”³³ After administration of the substance, the symptoms are recorded and indexed both by drug and symptom.³⁴

The second principle has two components: first, disease is known by assessing the signs and symptoms presented by the patient; second, generally speaking, all of the symptoms and signs a person presents with are caused by one disease.³⁵

The third principle is the “law of similars,” *similia similibus curentur*, or “let likes be cured by likes.”³⁶ The patient is carefully evaluated and all of the signs and symptoms of the disease are noted down.³⁷ The homeopath then consults with the symptom indexes (repertories) to compare the signs and symptoms of the natural disease with the signs and symptoms of the remedies (the artificial disease), narrowing down the matches to a few remedies.³⁸ For these remedies, the homeopath studies the drug indexes and finally selects the remedy whose medicinal effect most closely matches that of the disease.³⁹ Once given, the remedial disease annihilates the natural disease in the vital sphere, and since the disease and the symptoms are the same, the symptoms disappear.⁴⁰

Interestingly, no technology is used to evaluate the patient or

³¹ ROTHSTEIN, *supra* note 13, at 153. For further explanation of the scientific logic used by Hahnemann, see DEAN, *supra* note 23, at 16.

³² ORGANON, *supra* note 13, at 82; ROTHSTEIN, *supra* note 13, at 153–54.

³³ ROTHSTEIN, *supra* note 13, at 154.

³⁴ *Id.*

³⁵ *Id.* at 153. This was a common idea at the time.

³⁶ *Id.* at 153–54.

³⁷ *Id.* at 154.

³⁸ ORGANON, *supra* note 13, at 82–84.

³⁹ *Id.* at 82–83.

⁴⁰ *Id.* There is tremendous confusion on this point, with many homeopaths and organizations stating that the remedy stimulates the inherent healing power of the organism. This is a naturopathic accretion to homeopathy, as Hahnemann was excoriated by his fellow homeopaths for stating that the vital force did not have any healing powers. See HAEHL, *supra* note 13, at 282; John Lunstroth, *Similars, Stimulants and Cures*, in HOMEOPATHY IN PRAC. (2001), available at http://www.txsoho.com/Articles/articles_files/Similars_article.pdf (defining and explaining the concept of “vital force”). A more complete description of homeopathy is provided in Annex B, Appendix 1 of the online version of this Article. John Lunstroth, *Voluntary Self-Regulation of Complementary and Alternative Medicine*, ALB. L. REV., <http://www.albanylawreview.org/article.php?id=69> (follow “Annex B: A Model Code of Conduct for Homeopathic Communities” hyperlink).

drugs. Rather, the patient—or prover—elucidates the symptoms under the careful questioning of the homeopath and the signs of the disease are discerned by the patient, other observers, and the homeopath.⁴¹

In 1796, Hahnemann published his first article describing the homeopathic system.⁴² That article had two parts. In the first part, Hahnemann described the system; in the second part, he described the symptoms of fifty-nine substances, all but a few being plants.⁴³ The first part would be rewritten once before becoming the manual of homeopathy—*Organon der Heilkunst*, translated as *Organon of Medicine* or *Organon of the Medical Art*—which was to undergo five major revisions.⁴⁴ The second part would become the first *Materia Medica* or *Materia Medica Pura*.⁴⁵ The *Organon* and the *Materia Medica Pura* are still in use today.

By the end of the eighteenth century, Hahnemann began to address the problem that the drugs he was using not only cured the disease, but often caused additional symptoms.⁴⁶ He began to dilute the drugs and observed that their medicinal effect remained, but they no longer caused unwanted additional symptoms.⁴⁷ Thus began the use of dilutions and ultimately ultradilutions.

Between 1815 and 1820, Hahnemann developed the system of succussing—vigorously agitating the solutions between dilutions—further developing the medicinal effect of the drug.⁴⁸ A substance that has been diluted and succussed according to the detailed instructions in the *ORGANON* is known as a homeopathic remedy, although any substance diluted or not can be used homeopathically or—according to the law of similars—to treat disease.⁴⁹ Hahnemann himself proved over one hundred substances, all of which are routinely used in homeopathic practice today.⁵⁰

⁴¹ See *ORGANON*, *supra* note 13, at 82–84 (describing the homeopath's methodology of determining illness).

⁴² See Samuel Hahnemann, *Essay on a New Principle for Ascertaining the Curative Powers of Drugs, with a Few Glances at Those Hitherto Employed*, reprinted in *THE LESSER WRITINGS OF SAMUEL HAHNEMANN* 249 (R. E. Dudgeon trans., 1993) (1796).

⁴³ *Id.* at 265–303.

⁴⁴ See generally *ORGANON*, *supra* note 13.

⁴⁵ See generally *id.*

⁴⁶ See ROTHSTEIN, *supra* note 13, at 153 (describing the logical conclusion Hahnemann reached that cinchona both caused and cured malaria).

⁴⁷ *Id.* at 155.

⁴⁸ DEAN, *supra* note 23, at 44; *ORGANON*, *supra* note 13, at 138.

⁴⁹ ROTHSTEIN, *supra* note 13, at 156.

⁵⁰ WINSTON, *supra* note 16, at 7.

III. HOMEOPATHY IN THE UNITED STATES TODAY

Homeopathy was introduced to the United States in 1825.⁵¹ It quickly took hold and flourished by the late nineteenth century.⁵² In 1902, there were some 15,000 practitioners.⁵³ By 1963, the number had dwindled to 1,477, and by 1980 there were only 128 practitioners.⁵⁴ Prior to the 1980s, all homeopaths were conventional doctors,⁵⁵ but in the 1980s, after much discussion in the physician dominated community, lay students were accepted by the teachers.⁵⁶ They began educating other lay practitioners, and by the end of the 1980s there were enough trained unlicensed homeopaths to start their own national organization.⁵⁷ Unfortunately, the unlicensed homeopaths and the allopathically trained homeopaths did not see eye to eye. The unlicensed homeopaths accused the homeopathic allopathically trained doctors of being ill-trained in homeopathy, and the medical doctors saw their unlicensed brethren as being naïve and incompetent about medical science.⁵⁸ This rift has substantially healed.⁵⁹ Although the exact numbers are unknown, there are probably between 500 and 600 homeopaths practicing in the United States today; the 259 certified and 128 conventionally trained medical doctor homeopaths can be found in 35 states.⁶⁰

⁵¹ ROTHSTEIN, *supra* note 13, at 158.

⁵² *Id.*

⁵³ WINSTON, *supra* note 16, at 538.

⁵⁴ *Id.*

⁵⁵ *See id.* For purposes of this Article, the words “conventional” and “allopathic” are used to refer to health care providers (and their school of medicine) that are licensed to use the title “medical doctor” or “physician.” The legal right to describe oneself as a “medical doctor” or “physician” is artificial and confusing to the public, as there are now many types of doctors and physicians. Just as naturopathic doctors or physicians are required to use the adjective “naturopathic,” chiropractic, etc. so should the conventional doctors be required to properly identify themselves, and the monopoly on being a “physician,” “doctor,” or “medical doctor” should be withdrawn by society. *See infra* Part IV.C (discussing the deleterious effects of the legal monopoly which conventional medical doctors operate over the practice of medicine).

⁵⁶ WINSTON, *supra* note 16, at 403–04.

⁵⁷ *See id.* at 496. For the current state of the organization, see generally North American Society of Homeopaths, <http://www.homeopathy.org/about.html> (last visited Oct. 17, 2006).

⁵⁸ *See* WINSTON, *supra* note 16, at 401–03.

⁵⁹ For an account of the rise of lay homeopathy and the response of the homeopathic medical community, see WINSTON, *supra* note 16, at 386–412.

⁶⁰ These numbers were estimated based on online membership directories. *See* American Institute of Homeopathy, Online Member Directory, <http://www.homeopathyusa.org/onlinedirectory> (last visited Oct. 17, 2006); Homeopathic Academy of Naturopathic Physicians, Directory of Diplomates, <http://www.hanp.net/general/directory> (last visited Oct. 17, 2006). There is some overlap between organizations, and presumably not all competent homeopaths are either certified or are members of the American Institute of Homeopathy or

In 1982, a group of homeopaths, at that time medical doctors and lay members of the community, formed the Council for Homeopathic Education (CHE) to standardize homeopathic education and accredit schools,⁶¹ but the organization accomplished little. The lay practitioners from England brought with them a new educational model, and by the late 1990s there were enough schools of homeopathy in the United States—approximately twenty-five⁶²—to call for a renewed effort at accreditation and standardization of a curriculum.⁶³ In 2000, CHE sponsored a series of meetings to which educators and the leadership of the community were invited.⁶⁴ The meetings resulted in a standardized curriculum based on those used in Europe, which has a much longer history of an active homeopathic community.⁶⁵ However, efforts to operationalize the curriculum and seek status as an accrediting agency from the Department of Education for the CHE have been met by the CHE board of directors with such fear of government intervention and antagonism by proponents of market regulation, that the CHE remains a powerless institution in the community. Only three schools have adopted or are attempting to adopt the curriculum and CHE standards for accreditation.⁶⁶

In 1991, a year after the unlicensed homeopaths organized, a group of licensed and unlicensed practitioners formed the Council for Homeopathic Certification (CHC).⁶⁷ At that time there were

Homeopathic Academy of Naturopathic Physicians (HANP). The membership directories also indicate that approximately twenty-two certified homeopaths are also MDs and nineteen are also NDs. Not all trained and practicing homeopaths choose to be in listings; therefore, it is not unreasonable to assert that there are probably between 400 and 500 homeopaths practicing in the United States. This number is consistent with those compiled by Julian Winston who estimates there were 410 homeopaths in 1996. WINSTON, *supra* note 16, at 538.

⁶¹ COUNCIL ON HOMEOPATHIC EDUC., STANDARDS AND COMPETENCIES FOR THE PROFESSIONAL PRACTICE OF HOMEOPATHY IN NORTH AMERICA 2 (2001), *available at* <http://chedu.org/2001%20Standards%20.pdf> [hereinafter CHE STANDARDS AND COMPETENCIES].

⁶² *See* National Center for Homeopathy, Educational Organizations and Programs, http://www.homeopathic.org/resource_edu.htm (last visited Oct. 17, 2006) (listing educational programs currently available).

⁶³ *See* Council on Homeopathic Education, Homeopathic Standards, <http://www.chedu.org/standards.htm> (last visited Oct. 17, 2006) (stating that CHE is now able, and has, “establish[ed] standards for the education of homeopathic practitioners”).

⁶⁴ CHE STANDARDS AND COMPETENCIES, *supra* note 61, at 2.

⁶⁵ *See generally* WINSTON, *supra* note 16, at 408–12 (discussing the extensive history of homeopathy in England).

⁶⁶ COUNCIL ON HOMEOPATHIC EDUCATION, ACCREDITATION APPLICATION AND HANDBOOK 17 (2000), *available at* <http://www.chedu.org/2000%20Accreditation%20Handbook.pdf>.

⁶⁷ *See* Council for Homeopathic Certification, <http://www.homeopathicdirectory.com> (last visited Oct. 17, 2006).

certifications of competence in homeopathy available for medical doctors,⁶⁸ naturopaths,⁶⁹ and unlicensed practitioners through the North American Society of Homeopaths (NASH),⁷⁰ but there was no community-wide standard and the existing certifications were seen as being weak. The CHC has become a model of a successful organization in the homeopathic community, respected by most, and its certification is highly regarded by all. Sitting for the CHC exam requires 500 classroom hours of training, including human health sciences and knowledge of approximately 200 homeopathic drugs.⁷¹ In order to be certified, one must pass the exam, pass another case analysis exam, and present five well-documented cured cases of chronic disease.⁷²

The Federal Food, Drug, and Cosmetic Act defines drugs to include homeopathic remedies and regulates their manufacture and labeling through the Homeopathic Pharmacopoeia of the United States (HPUS).⁷³ There are 1,286 drugs recognized in the HPUS, all but 39 of which are classified as “over-the-counter.”⁷⁴ Although homeopathic practitioners use tinctures, most prescribe substances that have been serially diluted and succussed far beyond the point at which Avogadro’s number would indicate that there are no molecules of the original substance left.⁷⁵ This is perhaps the most troublesome aspect of homeopathy for scientists and others.

⁶⁸ The American Board of Homeotherapeutics offers a Diplomate to medical doctors and osteopaths, but it is not considered as rigorous of a standard as the CHC exam. American Institute of Homeopathy, Specialty Board, <http://www.homeopathyusa.org/specialtyboard/> (last visited Oct. 17, 2006).

⁶⁹ The Homeopathic Academy of Naturopathic Physicians also offers a Diplomate; such status is conferred on naturopathic doctors that have CHC certification by arrangement with the CHC. Homeopathic Academy of Naturopathic Physicians, Specialty Certification (2005), <http://www.hanp.net/membership/specialty>.

⁷⁰ See North American Society of Homeopaths, About NASH, <http://www.homeopathy.org/about.html> (last visited Oct. 17, 2006).

⁷¹ Council for Homeopathic Certification, Certification Requirements, <http://www.homeopathicdirectory.com/requirements.php> (last visited Oct. 17, 2006).

⁷² *Id.*

⁷³ 21 U.S.C. § 321(g)(1) (2000). For more information on homeopathic pharmacy and the information in this paragraph, see John P. Borneman & Robert I. Field, *Regulation of Homeopathic Drug Products*, 63 AM. J. HEALTH-SYS. PHARMACY 86, 89 (2006); Texas Society of Homeopathy, Pharmacy Home, <http://www.txsoho.com/Professionals/pharmacy/index.htm> (last visited Oct. 17, 2006). In some states it is not clear whether the definition of drug includes homeopathic remedies because whereas there is explicit reference to the United States Pharmacopoeia National Formulary, reference to the Homeopathic Pharmacopoeia of the United States is omitted. See, e.g., TEX. HEALTH & SAFETY CODE ANN. § 431.002(14) (Vernon 2005 & Supp. 2006).

⁷⁴ Texas Society of Homeopathy, *supra* note 73.

⁷⁵ See Jonas et al., *supra* note 25, at 393.

Nonetheless, the most commonly used 100 remedies have been in continuous use around the world for more than 150 years, and a majority of the most commonly used 300 remedies have been widely used for more than 100 years. As a result of the dilution they are non-toxic.

Homeopathy is practiced in the United States by a great diversity of health care practitioners.⁷⁶ Conventional medical doctors (MDs), osteopaths, chiropractors, naturopaths (NDs), physicians' assistants, nurse practitioners (NPs), nurses, veterinarians, licensed acupuncturists, massage therapists, and other licensed health care practitioners, and those without any kind of license, use homeopathy as their practice or as an adjunct to their practice.⁷⁷

Twenty-seven states have current laws specifically regarding homeopathy, excluding those states that incorporate the homeopathic pharmacopoeia into their food and drug laws. Fourteen states,⁷⁸ plus the District of Columbia, Puerto Rico, and the Virgin Islands, license naturopathic doctors and include homeopathy in their scope of practice.⁷⁹ Connecticut, Arizona, and Nevada license medical doctors to practice homeopathy,⁸⁰ and Arizona and Nevada specifically authorize homeopathic assistants to practice under the supervision of a homeopathic physician.⁸¹ Texas, Illinois, and Maine include homeopathy in veterinary practice.⁸² Iowa law authorizes a "department of homeopathic *materia medica* and therapeutics in the college of medicine of the

⁷⁶ *Id.* at 394.

⁷⁷ HOLLY J. HOUGH ET AL., U. OF CAL., PROFILE OF A PROFESSION: NATUROPATHIC PRACTICE 77 (2001), available at http://www.futurehealth.ucsf.edu/pdf_files/Naturo2.pdf [hereinafter HOUGH ET AL., PROFILE OF A PROFESSION].

⁷⁸ Alaska, Arizona, California, Connecticut, Hawaii, Idaho, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, and Washington. American Association of Naturopathic Physicians, Licensed States and Licensing Authorities, http://www.naturopathic.org/about_licensing.htm (last visited Oct. 17, 2006). For more information on naturopathy, see HOUGH ET AL., PROFILE OF A PROFESSION, *supra* note 77.

⁷⁹ American Association of Naturopathic Physicians, *supra* note 78.

⁸⁰ ARIZ. REV. STAT. ANN. § 32-2915 (2006); CONN. GEN. STAT. ANN. § 20-12n (West 2006); NEV. REV. STAT. ANN. § 630A.230 (West 2005).

⁸¹ ARIZ. REV. STAT. ANN. § 32-2939; NEV. REV. STAT. ANN. § 630A.035.

⁸² 225 ILL. COMP. STAT. ANN. 115/3 (West 1998 & Supp. 2006); ME. REV. STAT. ANN. tit. 32, § 4853(7)(A) (2006); TEX. OCC. CODE ANN. § 801.151 (Vernon 2004). The FDA Center for Food Safety and Applied Nutrition has indicated homeopathic drugs should be considered no differently for veterinary use than they are for human use. Memorandum from Joseph M. Smucker, Chief, Milk Safety Branch, U.S. Food and Drug Admin., to Reg'l Milk Specialists (Apr. 7, 1997), available at <http://www.cfsan.fda.gov/~ear/mi92-10a.html> ("FDA can find no justification for regulating veterinary homeopathic drugs any differently from other drugs subject to the Federal Food, Drug, and Cosmetic Act. There are currently no FDA approved homeopathic drugs for veterinary use.").

state University of Iowa,”⁸³ and Michigan law authorizes a homeopathic medical college⁸⁴ and requires at least one professor of homeopathy to be employed in the University of Michigan Department of Medicine.⁸⁵ At least seventeen states have laws or regulations defining the standard of care for conventional physicians in relation to CAM modalities.⁸⁶ One such state, Florida, protects all licensed health care providers who practice CAM.⁸⁷

Homeopathy is used in about 3.6 percent of visits to CAM practitioners.⁸⁸ CAM users primarily seek “treatment of health problems that lack definitive cures; that have an unpredictable course and prognosis; and that are associated with substantial pain, discomfort, or side effects from prescription drug medicine.”⁸⁹ In

⁸³ IOWA CODE ANN. § 263.4 (West 2006) (emphasis added).

⁸⁴ MICH. COMP. LAWS ANN. § 390.41 (West 2006).

⁸⁵ *Id.* § 390.5.

⁸⁶ Alaska, California, Colorado, Florida, Georgia, Indiana, Louisiana, Massachusetts, Nevada, New York, North Carolina, Ohio, Oklahoma, Oregon, South Dakota, Texas, and Washington. ALASKA STAT. § 08.64.326(a)(8)(A) (2005); CAL. BUS. & PROF. CODE § 2234.1(a) (West 2006); COLO. REV. STAT. § 12-36-117(jj)(3)(a) (2005); FLA. STAT. ANN. § 456.41 (West 2006); GA. CODE ANN. § 43-34-42.1 (2005); IND. CODE ANN. § 25-22.5-1-2.1 (West 2006); 28 La. Reg. 1589 (Jul. 2002); MASS. GEN. LAWS ANN. ch. 112, § 7 (West 2006); NEV. REV. STAT. ANN. § 630A.040 (West 2006); N.Y. EDUC. LAW § 6527(4)(e) (McKinney 2001 & Supp. 2005); N.C. GEN. STAT. ANN. § 90-14(a)(6) (West 2006); OHIO REV. CODE ANN. § 4731.227 (West 2006); OKLA. STAT. ANN. tit. 59, § 480 (West 2000); OR. REV. STAT. § 677.190(1)(b) (2005); S.D. CODIFIED LAWS §§ 36-4-11, -4-29 (2004) (permitting chelation therapy only); 22 TEX. ADMIN. CODE. § 200.1 (2006); WASH. REV. CODE ANN. § 18.130.180(4) (West 2005). The Federation of State Medical Boards recognized the increased use of CAM and issued a policy statement delineating under what conditions physicians could safely practice CAM modalities. FED. OF STATE MED. BODS. OF THE U.S., MODEL GUIDELINES FOR THE USE OF COMPLEMENTARY AND ALTERNATIVE THERAPIES IN MEDICAL PRACTICE (Apr. 2002), http://www.fsmb.org/pdf/2002_grpol_complementary_alternative_therapies.pdf. The Oklahoma statute is interesting:

Sections 481 through 518 of Title 59 of the Oklahoma Statutes shall be known and may be cited as the “Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act”. It is the intent that this act shall apply only to allopathic and surgical practices and to exclude any other healing practices. Allopathy is a method of treatment practiced by recipients of the degree of Doctor of Medicine, but specifically excluding homeopathy. The terms medicine, physician and drug(s) used herein are limited to allopathic practice. OKLA. STAT. ANN. tit. 59, § 480 (footnote omitted).

⁸⁷ FLA. STAT. ANN. § 456.41.

⁸⁸ PATRICIA M. BARNES ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., COMPLEMENTARY AND ALTERNATIVE MEDICINE: USE AMONG ADULTS: UNITED STATES, 2002, at 8 (2004), available at <http://nccam.nih.gov/news/report.pdf>.

⁸⁹ COMM. ON THE USE OF COMPLEMENTARY AND ALTERNATIVE MED. BY THE AM. PUB., INST. OF MED. OF THE NAT’L ACADS., COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE UNITED STATES 45 (2005) [hereinafter COMM. ON THE USE OF CAM]; see also John A. Astin, *Why Patients Use Alternative Medicine: Results of a National Study*, 279 JAMA 1548, 1550 (1998) (describing multiple variables that “predict[] use of alternative medicine”); Goldstein, *supra* note 2, at 938 (noting that “it is chronic, incurable illness that creates the most significant portion of the nation’s health care needs”).

other words, they seek treatment primarily for chronic diseases.⁹⁰ Although estimates for the cost of treating chronic disease are as high as 78 percent of all health care costs, and some 130 million Americans report having a chronic disease, about 75 percent of Americans feel it is difficult to get adequate care for a chronic condition from either a primary care physician or a specialist—an opinion shared by over half of all physicians and a majority of policy-makers.⁹¹ It is obvious that CAM, including homeopathy, will only continue to grow in social and economic importance.⁹²

IV. REGULATING HEALTH CARE PROVIDERS

Regulation of the health care occupations can be described in the legal, economic, social or moral, and political orders. Recognition of the different contexts in which analyses occur is important, as the terms of analysis determine the norms used and recommended outcomes. Projected or desired outcomes in different orders might conflict.⁹³ For example, while the use of economic analysis in the legal order has been an important element of regulatory analysis since the 1970s, economic analysis can be unrevealing, if not anemic, with regard to norms of the social or moral order.⁹⁴

⁹⁰ Astin, *supra* note 89, at 1550–51; *see also* Jennifer Jacobs, Edward H. Chapman & Dean Crothers, *Patient Characteristics and Practice Patterns of Physicians Using Homeopathy*, 7 ARCH. FAM. MED. 537, 538 (1998) (“[A]ll of the [ten] most common diagnoses of the [homeopathic] patients were for chronic illnesses . . .”).

⁹¹ Goldstein, *supra* note 2, at 939.

⁹² COMM. ON THE USE OF CAM, *supra* note 89, at 48.

⁹³ *See* William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1711 (1999) (“[T]he presumed beneficial effect on competition that has motivated today’s cresting wave of health care disclosure laws turns out to be limited by significant operational barriers. . . . [I]nformed consumerism is incomplete as a normative model for health care because fiduciary responsibilities of intermediaries such as physicians traditionally have been defined apart from economic considerations or a contractual framework. At the same time, however, sizeable social subsidies for health care reintroduce the need for information to support public financial judgments in addition to private ones. These decisions must be made through political rather than market mechanisms. By distinguishing market freedom from political freedom, and individual responsibility from collective responsibility, [it is possible] . . . to tease apart the varied roles of information in furthering personal autonomy, rather than subsuming them within a general ‘right to know.’ The preconditions to achieving particular goals through disclosure are in tension with one another . . .” (footnote omitted)).

⁹⁴ For an example of how the language of “information asymmetry” in the economic order becomes the language of “trust” in the social or moral order, *see* THEODORE M. PORTER, TRUST IN NUMBERS: THE PURSUIT OF OBJECTIVITY IN SCIENCE AND PUBLIC LIFE 202–03, 212–16 (1995). The law and economics movement, a combination of utilitarian ethics, atomistic philosophical liberalism, and Darwinian biology theory, supports an ideal of a selfish, profit-oriented society. *See, e.g.*, Robert C. Ellickson, *Law and Economics Discovers Social Norms*, 27 J. LEGAL STUD. 537, 540 (1998) (“Much of the glue of a society comes not from law

In accord with the philosophically libertarian health freedom movement,⁹⁵ Part III of this Article argues for exemptions from the medical practice acts for CAM providers; however, this Article disagrees with the movement and concludes that organizing providers into communities around a code of conduct is beneficial not only for the profession, but for society as well. Communities of practitioners need not devolve into economically-driven lobbying organizations such as the American Medical Association, but can function for the social or moral purpose of maintaining ethical and practice standards and a complaint procedure.

A. *Justifying Regulation*

The State has the obligation and legal power to regulate occupations to ensure public safety.⁹⁶ The more potentially

enforcement, as the classicists would have it, but rather from the informal enforcement of social mores by acquaintances, bystanders, trading partners, and others.”); Robin Paul Malloy, *Equating Human Rights and Property Rights—The Need for Moral Judgment in an Economic Analysis of Law and Social Policy*, 47 OHIO ST. L.J. 163, 165 (1986) (“When human rights and property rights are assigned equivalent values, the danger emerges that the logical conclusions of economic analysis may result in policy directives so contrary to the normative values of the society that both the economic and legal systems are discredited by society. To the extent that a certain school of economic theory, such as free market economics, becomes associated with human rights policy directives that continually affront the normative values of the general populace, that economic theory loses its credibility in other areas where it might otherwise make a valid, socially acceptable contribution to law and social policy. Indeed, if a free market economy holds the keys to the greatest enjoyment of personal liberty, then proponents of its preservation cannot afford to lock out the use of moral judgment in upholding the natural dignity of the individual.”); Martha C. Nussbaum, *Flawed Foundations: The Philosophical Critique of (a Particular Type of) Economics*, 64 U. CHI. L. REV. 1197, 1214 (1997) (“Aristotle also noticed, however, that the passion for science and simplicity [of economics] frequently lead highly intelligent people into conceptual confusion and an impoverished view of the human world.”).

⁹⁵ See generally American Association for Health Freedom, Health Freedom Foundation: Overview, <http://www.healthfreedom.net/aa/f/showarticlenew.asp?articleid=8> (last visited Oct. 17, 2006) (expressing that the purpose of the Health Freedom Foundation is to educate and protect the rights of consumers and practitioners).

⁹⁶ See *United States v. Lopez*, 514 U.S. 549, 552 (1995) (“As James Madison wrote: ‘The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite.’ This constitutionally mandated division of authority ‘was adopted by the Framers to ensure protection of our fundamental liberties.’” (citation omitted)); *Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004) (“[S]tate lawmakers, not the federal government, are ‘the primary regulators of professional [medical] conduct.’” (quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002) (alternation in original))); LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 47–51 (2000). But see Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 169–70 (2004) (“[T]he nature of medical practice has changed in ways that may make the exercise of federal supervision more plausible. The increasing reliance on the use of advanced technologies has transformed some of its purely local character The delivery of health care services clearly represents a

dangerous the occupation is to the person seeking health care, the greater the need for regulation.⁹⁷

There are two kinds of danger in health care. First, “instrumental danger” arises from the danger of the practice itself. For example, traditional medical procedures, such as surgery and the use of ionizing radiation, are inherently dangerous. The State has a very strong interest in ensuring that surgeons and radiation specialists have minimum competence and are subject to defined oversight. On the other hand, the instruments of complementary and alternative medicine modalities have no inherent danger.⁹⁸ Various states have made lists, which I will discuss below, of controlled or prohibited acts that define the content of instrumental danger. Violations of norms deriving from instrumental danger give

commercial activity within the national economy. . . . The federal government purchases a large chunk of these services, . . . [and it] should make greater use of its spending power to leverage modifications in state laws governing the practice of medicine. . . . [E]ntirely private purchases of physician services may have sufficient connections with interstate commerce to allow for federal regulation. . . . [P]hysicians or clinics may advertise their services to attract both local and distant customers. Moreover, the emergence of ‘cybermedicine’ further erodes the relevance of state borders, raising questions about the unauthorized practice of medicine by physicians not licensed in a particular state and the possibility of overlapping state jurisdiction.” (footnotes omitted).

⁹⁷ See FLA. STAT. ANN. § 11.62 (West 2006) (“It is the intent of the Legislature . . . [t]hat no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose”); CATHERINE DOWER ET AL., U. OF CAL, PROFILING THE PROFESSIONS: A MODEL FOR EVALUATING EMERGING HEALTH PROFESSIONS 8 (2001), available at http://www.futurehealth.ucsf.edu/pdf_files/model2.pdf [hereinafter DOWER ET AL., A MODEL FOR EVALUATING] (“Because regulation is a state police power, grounded in a need to protect the public, state legislators are keenly interested in the level to which a profession’s services put the public at harm. If the risk is relatively high, legislatures are more likely to infringe on an individual’s desire to provide services by insisting that members of the profession be regulated. If risk of harm is relatively low, legislatures may decline to regulate the profession and permit it to operate as any business endeavor might.”).

⁹⁸ See 2002 Cal. Legis. Serv. ch. 820, § 1(b) (West) (“[T]here is no demonstration that [complementary and alternative medicine practitioners’] practices are harmful to the public.”); Martiga Lohn, *Alternative Therapy Office Nears Demise Other State Enforcers Could Handle Complaints*, ST. PAUL PIONEER PRESS (Minn.), Mar. 5, 2005, at B11 (discussing the small quantity of complaints in CAM offices). Safety in CAM can be measured along two axes. On the first, the energetic axis, modalities can be arranged on a scale from the purely physicalist, such as many dietary supplements, to the purely energetic, such as prayer and homeopathy. From a biochemical point of view, instrumental danger can only occur on the physicalist end of the spectrum. But a second axis is also relevant—at one end is highly technological medicine, such as the use of ionizing radiation and most drugs, and at the other end are substances and techniques that themselves cannot be fairly characterized as “scientific” or technological, such as herbs, hands-on healing, etc. Physicalist, technological medicine has the potential to be instrumentally dangerous, whereas, generally speaking, vitalist theories, substances, and techniques do not.

rise to batteries and malpractice cases.⁹⁹

The second kind of danger is indirect, arising from a potential information asymmetry. I refer to it as “informational danger.” Violations of norms protecting against informational danger give rise to lawsuits centered on breach of contract, breach of fiduciary duty, and violation of informed consent rights; when the patient is seen as an autonomous decision-maker, he or she may be centered on the idea that the person receiving the services was unable to properly evaluate the risk of his or her condition or the recommended therapy.¹⁰⁰

The informational environment has three elements: the person seeking services, the information needed to remain autonomous when seeking or getting health care, and the provider.¹⁰¹ Discussing the informational environment of health care is complex because the context or order within which the discussion occurs must be defined.¹⁰² Information can be spoken of in the economic order, legal order, social or moral order, or the political order. For example, three words are often used to describe the person who seeks health care—the first element of the informational environment.

The word “patient” has primarily social or moral meaning. It refers to a person who is seeking health care and makes strong reference to the paternalistic authority of the physician and the passivity of the person seeking health care.¹⁰³ It encompasses the

⁹⁹ These kinds of errors, iatrogenic injuries, play a role in as many as 180,000 deaths a year. Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1851 (1994). Iatrogenic error can be of several types: slips, judgments errors, normal, blatant, dignity affronts, or systemic failure. See *id.* at 1853–54; ELIOT FREIDSON, DOCTORING TOGETHER: A STUDY OF PROFESSIONAL SOCIAL CONTROL 127–37 (1975) (discussing types of mistakes in medicine).

¹⁰⁰ See *infra* notes 117, 294–95 and accompanying text (discussing malpractice based on disclosure and informed consent).

¹⁰¹ See discussion *infra* Part IV.B, C; see also Sage, *supra* note 93, at 1705 & n.8 (explaining patient autonomy as it relates to informed consent). There is considerable ambiguity when the human provider acts as the agent of a managed care organization. Because this Article focuses on health care providers that are not widely integrated into managed care, I will not address the conflicts in information needs and management that occur between the MCO, the human provider, and the person seeking health care. For a lengthy and detailed discussion of the regulation of information in health care, see Sage, *supra* note 93, at 1701.

¹⁰² Sage, *supra* note 93, at 1730–31.

¹⁰³ See Wendy K. Mariner, *Can Consumer-Choice Plans Satisfy Patients? Problems with Theory and Practice in Health Insurance Contracts*, 69 BROOK. L. REV. 485, 492 (2004) [hereinafter Mariner, *Consumer-Choice Plans*] (defining the patients’ informational disadvantage relative to the doctor); Wendy K. Mariner, *Standards of Care and Standard Form Contracts: Distinguishing Patient Rights and Consumer Rights in Managed Care*, 15 J. CONTEMP. HEALTH L. & POL’Y 1, 7–8 (1998) [hereinafter Mariner, *Standards of Care*]

entire spectrum of vulnerability, clearly including persons who are incompetent to make health care decisions about their own care, whether by accident, chronic disease, or the roulette of birth.¹⁰⁴ It is a fiduciary relationship, invoking the highest legal duty owed by one person, the professional, to another, the patient.

The word “client” has different connotations. It references the legal order and the power differential based on information between the physician and the person seeking health care.¹⁰⁵ Clients depend on professionals to guide them in making decisions concerning matters on which the professional has special training and experience. A client has the full panoply of constitutional protection for his or her fundamental right to self-determination—to bodily integrity and autonomy—whereas the state may have an interest in the patient.¹⁰⁶

Lastly, the word “consumer” or “customer” references the economic order. It refers to autonomous beings who make choices in the market place based upon information.¹⁰⁷ To the extent that there are information asymmetries, market interventions are needed to correct the asymmetry and restore the efficiency of optimal autonomy. The words “consumer,” “client,” or “patient” can be used in the political order—depending on the intention of the speaker—as politics encompass the moral or social, legal, and economic orders.

Word choice is useful in discussing the regulation of CAM, as it provides a reminder of who is being regulated and for what reason. I use the words as follows: a “patient” is a person suffering to the

(explaining the passive role of patients in relation to physicians).

¹⁰⁴ For a discussion of the principles used to analyze the constitutional rights of the incompetent and, by extension, of the vulnerable, see John H. Garvey, *Freedom and Choice in Constitutional Law*, 94 HARV. L. REV. 1756, 1758 (1981) (“Because they protect choice, freedoms [such as liberty] produce by their very nature greater unpredictability than do other constitutional protections. . . . The elements of choice and unpredictability create obvious difficulties for the ascription of liberties to individuals incapable of making rational choices. The reason is that the rationales thought to justify protection of the various constitutional freedoms presuppose that the claimant can make rational decisions that will not result in significant social or individual harm.”).

¹⁰⁵ See David C. Reardon, *Abortion Decisions and the Duty to Screen: Clinical, Ethical, and Legal Implications of Predictive Risk Factors of Post-Abortion Maladjustment*, 20 J. CONTEMP. HEALTH L. & POLY 33, 58 (2003) (describing the role of patient as client in relation to physicians).

¹⁰⁶ See *supra* Part IV.D (developing a constitutional argument for the scope of practice reform).

¹⁰⁷ Mariner, *Consumer-Choice Plans*, *supra* note 103, at 494–95, 495 fig.1 (explaining and depicting the differences between consumers and patients).

extent that most people would not be able to think clearly;¹⁰⁸ he or she is dependent on the health care provider for his or her well-being and perhaps very existence. It describes the most vulnerable people who seek health care. A “client” is suffering from milder conditions or chronic conditions which are not life-threatening flare-ups or for which he or she has compensated for. A client has conditions that make them feel vulnerable, but he or she is not intrinsically dependent on the provider. A “consumer” could also be suffering from a mild condition, could be seeking enhancement, or could be the surrogate decision maker for an incompetent. In any event, a consumer has no feelings of dependency and is not seeking a dependent relationship. Clients and consumers can be thought of as having the ability to make independent, informed, and autonomous choices about health care, whereas patients may or may not.¹⁰⁹ I will use the word consumer generically to refer to the person seeking health care without regard to context.

The second element of the informational environment is the informational content consumers need in order to sustain their autonomy by being able to properly evaluate the risks and benefits of a particular health care decision.¹¹⁰ This information is diagnosis or evaluation, prognosis, and information about treatment options.¹¹¹ Until the 1960s, the primary source for this information was the conventional doctor.¹¹² This binary informational structure supported the customer as the patient because the patient was dependent on the physician for all information.¹¹³ Today, the only category of content that is unavailable to the consumer directly is

¹⁰⁸ Mariner, *Standards of Care*, *supra* note 103, at 7–8.

¹⁰⁹ See, e.g., S. DAVID YOUNG, *THE RULE OF EXPERTS: OCCUPATIONAL LICENSING IN AMERICA 2* (1987) (“By tradition, professionals do not ‘sell’ to ‘consumers’; they provide a service for ‘clients.’”); Mark Schlesinger, *A Loss of Faith: The Sources of Reduced Political Legitimacy for the American Medical Profession*, 80 *MILBANK Q.* 185, 198 (2002) (asserting, among other things, that the transformation of patients into “informed consumers” is a threat to the authority of the medical profession).

¹¹⁰ See generally RUTH R. FADEN ET AL., *A HISTORY AND THEORY OF INFORMED CONSENT* 7–9, 235–68 (1986) (analyzing the relationship of autonomous actions and informed consent doctrine).

¹¹¹ *Id.* at 94; AM. HOSP. ASS’N, *THE PATIENT CARE PARTNERSHIP: UNDERSTANDING EXPECTATIONS, RIGHTS AND RESPONSIBILITIES* (2003), http://www.hospitalconnect.com/aha/ptcommunication/content/pcp_english_030730.pdf.

¹¹² For a detailed picture of the environment of the patient or consumer in the 1960s, see DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* 86–100 (1991).

¹¹³ See Frank A. Sloan, *Arrow’s Concept of the Health Care Consumer: A Forty-Year Retrospective*, 26 *J. HEALTH POL. POL’Y & L.* 899, 902 (2001) (stating that, for the most part, patients are passive).

the technical information related to their diagnostic procedures and tests, although even this is changing as MRIs, drugs, and other technology are marketed directly to consumers. Once a consumer has a diagnosis and test results, he or she has access to the same information on prognosis and treatment options as the physician. In fact, often the consumer has access to more information than the physician, as he or she has more time, is more interested in the outcome, and is more willing in many cases to try alternatives that the physician either knows little to nothing of or is negative about, such as CAM.¹¹⁴ It can be argued that the physician has the experience that gives him or her an advantage in evaluating prognosis and treatment; however, this argument is weak both practically and theoretically. Few specialists have experience in all forms of treatment. They rely on writings from the professional press to inform themselves of alternatives, which is not the same thing as direct experience. Furthermore, the trend of “evidence-based” thinking undercuts the authority of professional experience.

The third element of the informational environment is the providers. As experts, they are to provide a diagnosis or evaluation and prognosis, recommend a course of action, provide information about the recommended treatment, and recommend the best provider of the treatment.¹¹⁵ They are also obligated to provide

¹¹⁴ However, data suggests such generalizations are overbroad. In the United States, “about 72% of the 35 million seniors [age 65 and older] . . . have chronic illnesses.” Rebecca Voelker, *Seniors Seeking Health Information Need Help Crossing “Digital Divide,”* 293 JAMA 1310, 1311 (2005). Of seniors, less than 31% have gone online for any reason, including e-mail. *Id.* at 1310. Of those 75 years of age and older, only 18% have gone online. *Id.* Of the nearly 64% of seniors who depend on Medicare who have annual incomes of less than \$20,000, only 15% have gone online; 40% of those with incomes between \$20,000 and \$49,000 per year have gone online; and of those with incomes \$50,000 and above, 65% have used the Internet. *Id.* at 1311. These figures coincide with education levels. *Id.* Of seniors with only a high school education, 18% have gone online; of those with some college, 45% have gone online; and of those with a college degree, 65% have gone online. *Id.* Seniors use the Internet to research drug prices, nutrition, exercise, weight, cancer, heart disease, and arthritis. *Id.* But of those aged between 50 and 64 years, “near seniors,” 75% have used the Internet. *Id.* at 1310. While 53% percent of near seniors have used the Internet to find health information, only 21% of seniors have. *Id.* When asked whether they get “a lot” of health information from the Internet, 24% of near seniors said yes, whereas the figure was only 8% for seniors. *Id.*

¹¹⁵ The duties of conventional doctors with regard to disclosure of CAM and referral to CAM practitioners are not clear. Conventional doctors may have liability if they refer to a CAM practitioner, yet they may have liability if they do not. The problem arises because many conventional physicians are not competent to evaluate CAM therapies. See James A. Bulen, Jr., *Complementary and Alternative Medicine: Ethical and Legal Aspects of Informed Consent to Treatment*, 24 J. LEGAL MED. 331, 349–50 (2003) (“The primary argument against CAM disclosure posits that physicians cannot be expected to evaluate CAM treatments that they do not understand.”). However, Bulen argues the patient-oriented standard for informed consent “requires physicians to evaluate CAM according to the evidence-based approach . . .

information about the limits of their own capability to deliver treatment. Information from the provider can be judged in the legal, social or moral, economic, and political orders. In the legal order, about one-half of the states require the provider to give information that is relevant to the consumer (patient-oriented standard), and about one-half allow the doctor to provide information that is relevant in the doctor's opinion (doctor-oriented standard).¹¹⁶

Conventional physicians have a legal monopoly on the practice of medicine. In the social or moral order, the conventional physicians have a culture of paternalism, although this is changing as autonomy increases and physician authority is eroded by institutional and corporate medicine. In the economic order, the physician-oriented standard can never be efficient or optimal as it institutionalizes an informational asymmetry. Conventional physicians, because of the inequality of their superior position vis-à-vis the consumer, should bear the risk of information inefficiencies especially since there is data that suggests they have little interest in providing relevant information as a group to persons seeking health care.¹¹⁷

Efficacy and safety are often conflated as though they are one

and to disclose safe and effective CAM irrespective of whether the physician practices CAM." *Id.* at 352; see also Edzard Ernst, *Informed Consent in Complementary and Alternative Medicine*, 161 ARCHIVES INTERNAL MED. 2288, 2288 (2001) ("Failure to disclose the availability, benefits, and risks of CAM treatments could give rise to malpractice claims."); Jeremy Sugarman & Larry Burk, *Physicians' Ethical Obligations Regarding Alternative Medicine*, 280 JAMA 1623, 1624 (1998) ("[C]linicians have an obligation to discuss treatment alternatives with their patients and should be frank about their level of understanding of nonconventional interventions."). A very problematic key element in evaluating liability for referrals is the standard of care used to evaluate the acts of the CAM practitioner. See JOHN K. CRELLIN & FERNANDO ANIA, PROFESSIONALISM AND ETHICS IN COMPLEMENTARY AND ALTERNATIVE MEDICINE 71-73 (2002). The general rule is that there is no liability for referring to another physician. David M. Studdert et al., *Medical Malpractice Implications of Alternative Medicine*, 280 JAMA 1610, 1612 (1998). But see Michael H. Cohen & David M. Eisenberg, *Potential Physician Malpractice Liability Associated with Complementary and Integrative Medical Therapies*, 136 ANN. INTERNAL MED. 596, 596-97, 599-601 (2002) (explaining that liability can arise if there is a delay of necessary treatment, if the referring physician knows the CAM provider to be incompetent, or if there is joint treatment and shared liability; suggesting familiarity with the CAM practitioner to whom one refers is important in avoiding liability; and not addressing the issue of whether a physician has a positive duty to disclose CAM therapeutic options, impliedly supporting the physician-based standard of disclosure).

¹¹⁶ See Bulen, *supra* note 115, at 137 n.45, 334-38. See generally FADEN ET AL., *supra* note 110, at 7-9, 90, 96 (discussing the history and theory of informed consent).

¹¹⁷ Only 3% of patients between 50 and 64 years of age, and 1% of those 65 and over, said a physician had ever recommended a particular health or medical website to them. Voelker, *supra* note 114, at 1311.

standard for measuring a therapeutic intervention; in fact, they are very different standards. In the standard formulation, safety refers only to instrumental safety and not to informational safety. Efficacy, on the other hand, is an informational standard: an artificial construct that seems to have more rhetorical value than anything else.¹¹⁸ Randomized controlled trials are used to evaluate this measure, but theoretical analysis,¹¹⁹ historical events,¹²⁰ and recent events¹²¹ all suggest that the idea that one or more randomized controlled trials can provide accurate information on an intervention is at least greatly suspect.

The conventional medical profession insists that competent adults cannot make informed decisions about CAM because only the conventional medical profession can adequately evaluate the safety

¹¹⁸ See, e.g., Schlesinger, *supra* note 109, 199 (finding that political elites and sophisticated citizens are more likely to be aware of health policy issues and to doubt the efficacy and reliability of medical care). For an example of how a concept in medicine is constructed, see MICHEL FOUCAULT, *THE BIRTH OF THE CLINIC: AN ARCHAEOLOGY OF MEDICAL PERCEPTION* 54–56 (A.M. Sheridan Smith trans., Vintage Books 1994) (1963).

¹¹⁹ See generally HARRY M. MARKS, *THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900–1990*, at 244 (1997) (“In the past, therapeutic reformers have made many claims on behalf of randomized controlled trials. Controlled clinical trials would ‘eliminate bias’ in clinical experiments; they would provide a ‘scientific’ basis for assessing therapies; their use would put an end to therapeutic controversies; they would eliminate physicians’ overconfidence and therapeutic excesses.”); J. ROSSER MATTHEWS, *QUANTIFICATION AND THE QUEST FOR MEDICAL CERTAINTY* 143 (1995) (“To what extent does the use of numerical comparison [statistics] confer authority or ‘objectivity’ on therapeutic choices? Viewed in this way, the debates surrounding the rise of the clinical trial engage a much broader issue currently being discussed within the academy; the attempt to show the socially and culturally ‘negotiated’ character of the concept of ‘objectivity’ (as well as the ‘negotiated’ character of therapeutic efficacy.)”); PORTER, *supra* note 94, at 202–16 (analyzing the problem as one in which constructed ideas of mechanical objectivity are necessary for distrusting communities to communicate with one another, replacing expert judgment as being too personal).

¹²⁰ The unsuccessful history of two exemplary large-scale randomized controlled trials, the National Heart and Lung Institute’s Diet-Heart Study and the NIH funded University Group Diabetes Program, is told by Marks. MARKS, *supra* note 119, at 181–96, 204–28.

¹²¹ See generally Michelle J. Naughton et al., *When Practices, Promises, Profits, and Policies Outpace Hard Evidence: The Post-Menopausal Hormone Debate*, 61 J. SOC. ISSUES 159, 159 (2005) (examining the recent development in hormone therapy which “provides an excellent example of how different constituencies with competing objectives can produce health practices and policies of questionable benefit”); Eric J. Topol, *Failing the Public Health — Rofecoxib, Merck, and the FDA*, 351 NEW ENG. J. MED. 1707, 1707 (2004) (explaining how VIOXX received FDA approval based on incomplete trial because “the design and execution of the trial had not anticipated that untoward cardiovascular events might occur”); John Abramson, *Information Is the Best Medicine*, N.Y. TIMES, Sept. 18, 2004, at A15 (referring to cox inhibitors and stating that even after the dangers were discovered, drug companies continued to lead doctors to believe the drugs had benefits exhibiting the “drug industry’s domination of medical knowledge . . . [which] stems from drug companies’ unequal treatment of the clinical trials they sponsor”).

and efficacy of CAM modalities.¹²² In addition, every CAM modality for every disease has not been evaluated.¹²³ The only valid information about CAM is what the conventional medical professionals say they have created through randomized controlled trials.¹²⁴ There is no evidence that the assumptions made by the conventional medical profession—with regard to information on the efficacy of CAM—have any validity whatsoever.¹²⁵ On close inspection, the misrepresentations and gaming that the conventional medical profession does with information about efficacy is another aspect of their attempt to maintain the informational asymmetry for economic ends.¹²⁶ Because CAM

¹²² See, e.g., Marcia Angell & Jerome P. Kassirer, *Alternative Medicine — The Risks of Untested and Unregulated Remedies*, 339 NEW ENG. J. MED. 839, 839 (1998) (“What most sets alternative medicine apart, in our view, is that it has not been scientifically tested and its advocates largely deny the need for such testing. By testing, we mean the marshaling of rigorous evidence of safety and efficacy, as required by the Food and Drug Administration (FDA) for the approval of drugs and by the best peer-reviewed medical journals for the publication of research reports.”).

¹²³ *Id.*

¹²⁴ *Id.* at 840.

¹²⁵ See generally David J. Hufford, *CAM and Cultural Diversity: Ethics and Epistemology Converge*, in THE ROLE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: ACCOMMODATING PLURALISM 15, 17–18 (Daniel Callahan ed., 2002) (presenting the “theoretical plausibility criteri[a]” for evaluating CAM and presenting the assertion that “[e]xisting conventional scientific knowledge is an adequate measure of whether an unconventional claim is true”); Wayne B. Jonas, *Evidence, Ethics, and the Evaluation of Global Medicine*, in THE ROLE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: ACCOMMODATING PLURALISM, *supra*, at 122–23 (“Basic assumptions about the building blocks of the world and the nature of life, health, disease, and treatment are now opening up to the diversity of concepts in the world’s healing traditions.”); Kenneth F. Schaffner, *Assessments of Efficacy in Biomedicine: The Turn Toward Methodological Pluralism*, in THE ROLE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: ACCOMMODATING PLURALISM, *supra*, at 1, 4–6 (presenting common questions used in the evaluation of CAM); Tom Whitmarsh, *The Nature of Evidence in Complementary and Alternative Medicine: Ideas from Trials of Homeopathy in Chronic Headache*, in THE ROLE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE: ACCOMMODATING PLURALISM, *supra*, at 148–49 (suggesting “that the use of complementary therapies and in particular homeopathy should be judged according to the same criteria as are daily used for the practice of medicine in general in the real world”); David J. Hufford, *Evaluating Complementary and Alternative Medicine: The Limits of Science and of Scientists*, 31 J.L. MED. & ETHICS 198, 202–04 (2003) (presenting an example that depicts how “[t]he evidence does not account for CAM advocacy”); E. Haavi Morreim, *A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science*, 31 J.L. MED. & ETHICS 222, 222 (2003) (arguing “that, if critics of CAM expect to limit its influence by holding CAM to the same scientific standards as conventional medicine, they are headed for multifaceted disappointment”).

¹²⁶ Merrijoy Kelner et al., *The Role of the State in the Social Inclusion of Complementary and Alternative Medical Occupations*, 12 COMPLEMENTARY THERAPIES MED. 79, 87 (2004) (“[G]overnment spokespersons explain their slowness to catch up to consumers by referring to concerns about the lack of scientific evidence of safety, efficacy and cost-containment. But does this not really constitute a ‘catch 22’ situation for the CAM groups? The kind of research evidence that is being asked of them costs a great deal to conduct. Yet, they receive little financial support from governments to do the research.”). It should also be kept in mind that

modalities are generally instrumentally safe, the only potential safety problem with efficacy is in emergencies, and training in proper recognition and response to emergencies should suffice to overcome the danger.

The regulation of instrumentally dangerous modalities is clearly justified on safety grounds; however, it is not clear that any regulation but required disclosure is necessary to protect public health from informational danger. Customers and clients are not vulnerable enough to worry about, but there are patients who are very vulnerable. Do they need special regulations to protect them?

Putting aside intentional fraud,¹²⁷ which is covered by civil and criminal fraud laws, threats to the public health arise from information asymmetries in a life-threatening emergency when the provider is incompetent to recognize or treat that particular condition. Requiring training and certification in the recognition of emergencies would solve this problem.

B. Describing Regulation

Commentators on licensing and other regulatory schemes regarding the professions tend to fall into three camps. One camp approaches its analysis as though the government—*sua sponte*—licenses professions for public health reasons.¹²⁸ The opposing camp approaches the analysis as though regulation of professionals—for example, the passage of specific occupation related laws—occurs at the behest of the regulated profession.¹²⁹ A third camp takes the intermediate approach that government and the professions negotiate for a regulatory scheme that meets both the needs of the state and the profession.¹³⁰ The latter two approaches appear to be

there is not much “intellectual property” that can be owned by industry in CAM.

¹²⁷ Most cases of informational danger arise from intentional fraud. *See, e.g.*, OFFICE OF THE PROFESSIONS, N.Y. STATE EDUC. DEP'T, UNAUTHORIZED PRACTICE OF THE PROFESSIONS (2001), available at <http://www.op.nysed.gov/unauthorizedpractice.htm> (“Most illegal practice cases involve imposters actually practicing the professions in private office settings.”).

¹²⁸ *See* GOSTIN, *supra* note 96, at 254–55.

¹²⁹ For the authoritative expression of the acquisition theory, see George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 4 (1971) (“The state has one basic resource which in pure principle is not shared with even the mightiest of its citizens: the power to coerce. The state can seize money by the only method which is permitted by the laws of a civilized society, by taxation. The state can ordain the physical movements of resources and the economic decisions of households and firms without their consent. These powers provide the possibilities for the utilization of the state by an industry to increase its profitability.”).

¹³⁰ *See* Randall Collins, *Market Closure and the Conflict Theory of the Professions*, in PROFESSIONS IN THEORY AND HISTORY: RETHINKING THE STUDY OF THE PROFESSIONS 24, 25–

supported by the scope of licensing. In 1983, there were nearly 1,000 occupations regulated in the fifty states.¹³¹

There are three theories or models of regulation of medical occupations: the market model, the professionalism model, and the hierarchical command and control—or bureaucratic—model.¹³² The distinctions and arguments between the three models have their origin in the early nineteenth century debate between the Federalists, who argued that a governmental presence was needed to guarantee property rights, enforce contracts, and encourage the nascent entrepreneurial ethos, and the Jacksonians who argued against intrusive government and for self-reliance.¹³³ The spectrum from market regulation through voluntary self-regulation to statutory self-regulation should be based primarily on the safety and welfare of the public.

The idea of the market model is that no laws or governmental oversight is needed as the market has forces strong enough to ensure the public's safety.¹³⁴ This model is dependent on criminal and civil fraud laws to regulate unethical behavior and on sufficient informational structures to overcome asymmetries of relevant

26 (Michael Burrage & Rolf Torstendahl eds., 1990) (finding that the professions are in conflict with all other markets including action by the state); Kelner et al., *supra* note 126, at 80 (“[A]ll professions have to enter into a special relationship, or ‘a regulative bargain’ with the state. . . . [N]egotiations with the state are a means by which professions can seek to regulate market conditions to their advantage against competitors and enhance their own privilege and status through social closure.” (citing KEITH M. MACDONALD, *THE SOCIOLOGY OF THE PROFESSIONS* 10 (1995))).

¹³¹ YOUNG, *supra* note 109, at 4.

¹³² William D. White, *Reason, Rationalization, and Professionalism in the Era of Managed Care*, 29 J. HEALTH POL. POL'Y & L. 853, 854 (2004). For a discussion of the market regulated model, see generally YOUNG, *supra* note 109, at 49–52. For the theory of regulation, see generally MILTON FRIEDMAN, *CAPITALISM AND FREEDOM* 135–60 (1972); WALTER GELLHORN, *INDIVIDUAL FREEDOM AND GOVERNMENTAL RESTRAINTS* 105–51 (1956); HERBERT HOVENKAMP, *ENTERPRISE AND AMERICAN LAW: 1836–1937* 105–68 (1991); *THE REGULATED ECONOMY: A HISTORICAL APPROACH TO POLITICAL ECONOMY* (Claudia Goldin & Gary D. Libecap eds., 1994). For general discussions of the regulation of occupations, see generally *OCCUPATIONAL LICENSURE AND REGULATION* (Simon Rottenberg ed., 1980); *REGULATING THE PROFESSIONS: A PUBLIC-POLICY SYMPOSIUM* (Roger D. Blair & Stephen Rubin eds., 1980); Walter Gellhorn, *The Abuse of Occupational Licensing*, 44 U. CHI. L. REV. 6 (1976); Jonathan Rose, *Occupational Licensing: A Framework for Analysis*, 1979 ARIZ. ST. L.J. 189 (1978).

¹³³ Peter D. Jacobson, *Regulating Health Care: From Self-Regulation to Self-Regulation?*, 26 J. HEALTH POL. POL'Y & L. 1165, 1165 (2001). Regulation of the professions dates to Babylon and the Code of Hammurabi (circa 1800 B.C.), which set fees for surgeons' services and sanctions for medical malpractice, among other things. YOUNG, *supra* note 109, at 9 (citing 1 DANIEL B. HOGAN, *THE REGULATION OF PSYCHOTHERAPISTS: A STUDY IN THE PHILOSOPHY AND PRACTICE OF PROFESSIONAL REGULATION* 223 (1979)).

¹³⁴ See generally DOWER ET AL., *A MODEL FOR EVALUATING*, *supra* note 97, at 8 (describing how regulation, as a state police power, is grounded in the need to protect the public's safety).

knowledge about the product. This model occurs primarily in the economic order.

The professionalism model¹³⁵ is more accurately referred to as “self-regulation.”¹³⁶ In this model, the occupation regulates itself through an organization of practitioners (“trade organization”) and commitment to a code of conduct that compensates for informational asymmetries. The organization has membership entry requirements based on minimal competence in the profession. Minimal competency often involves having relevant education and the ability to pass an examination in the field. Once a member, the practitioner is entitled to use a unique title that tells the public the practitioner has met the minimal competency standards and has agreed to practice according to a code of conduct. It also tells the public that standards are community-wide and that there is a complaint process that filters incompetent practitioners out and

¹³⁵ The word “professionalism” is also used in the ethics domain, but there it denotes the concern among educators and others in the occupational community with the fact “professionals” have bad instincts for social justice, patient or client care, politeness, and other qualities that have been associated with the ideal professional, but which may never have existed in fact in the medical profession. For example, the American Journal of Bioethics recently devoted an issue to bioethical “professionalism.” See generally Denise Wear & Mark G. Kuczewski, *The Professionalism Movement: Can We Pause?*, 4 AM. J. BIOETHICS 1 (2004). Some argue that professionalism also includes the meaning of a duty to the public, and, in this sense, it refers to both ethical and regulatory domains. See, e.g., WILLIAM F. MAY, *BELEAGUERED RULERS: THE PUBLIC OBLIGATION OF THE PROFESSIONAL* 12 (2001). Legal professionalism informs ethical professionalism and vice-versa. See discussion *infra* Part IV.

¹³⁶ In 1963, Kenneth J. Arrow brought the market-versus-government discussion to bear on health care. See generally Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963), available at <http://www.who.int/bulletin/volumes/82/2/PHCBP.pdf> [hereinafter Arrow, *Uncertainty*]. He argued that the health care market was asymmetrical inasmuch as it was nearly impossible for patients to verify the quality of medical care and that the optimality gap with regard to risk was not correctable by the market, while the optimality gap of information was only partially correctable:

The general uncertainty about the prospects of medical treatment is socially handled by rigid entry requirements. These are designed to reduce the uncertainty in the mind of the consumer as to the quality of the product insofar as this is possible. I think this explanation, which is perhaps the naive one, is much more tenable than any idea of a monopoly seeking to increase incomes. . . . It is the general social consensus, clearly, that the *laissez-faire* solution for medicine is intolerable.

Id. In a 1972 essay, he revised his initial estimate of the nonmarketability of the risk and settled on professional codes of conduct as essentially a market-based strategy that could fill the gap. See generally Kenneth J. Arrow, *Social Responsibility and Economic Efficiency*, 31 PUB. POL. 303 (1972). If they were widely accepted and established as norms they would act to restore market equilibrium by overcoming the information asymmetries. *Id.* at 313–14; see also Margot Priest, *The Privatization of Regulation: Five Models of Self-Regulation*, 29 OTTAWA L. REV. 233, 242–43 tbl.1 (1977) (depicting models of self-regulation). But see Stigler, *supra* note 129, at 4 (arguing that regulation of professionals *is* caused by the professions to increase income).

provides a means of achieving justice in the event of a tort or other breach of a standard.

In *voluntary* self-regulation, practitioners undertake to organize themselves around a code of conduct; there are no laws regarding the occupation and no statutory protection of the title. In *statutory* self-regulation, a statute is passed in which the State delegates its police powers to the trade organization.¹³⁷ This is the model most frequently found in state regulation of occupations and is exemplified by the medical practice acts (MPAs) in which the State delegates to the medical profession—on a state-by-state basis—the power to regulate medical doctors. Voluntary self-regulation is often seen as a step towards statutory self-regulation. There are also hybrid models between full-blown licensing acts and market regulation, such as registration acts in which practitioners must register to practice absent any other entry requirement.¹³⁸

Voluntary self-regulation has been discussed in this country for several markets: personal information,¹³⁹ advertising,¹⁴⁰ electronic commerce,¹⁴¹ law,¹⁴² corporate responsibility concerning the environment¹⁴³ and human rights,¹⁴⁴ sports,¹⁴⁵ the Internet,¹⁴⁶

¹³⁷ For issues related to state delegation, see generally RANDOLPH P. REAVES, *THE LAW OF PROFESSIONAL LICENSING AND CERTIFICATION* (1st ed. 1984). For issues related to federal delegation, see generally David M. Lawrence, *Private Exercise of Governmental Power*, 61 IND. L.J. 647 (1986); Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171 (1995).

¹³⁸ Hybrid models all rely on the exercise or delegation of governmental power and vary along several axes: level of government involvement; source of power; involvement of the public; accountability to government, public, regulatees; rulemaking; adjudication; sanctions; offenses (regulatory, civil, criminal); membership; and oversight or review. Priest, *supra* note 136, at 242–43 tbl. 1. For more information on licensure models, see generally DOUG ROEDERER & BENJAMIN SHIMBERG, *OCCUPATIONAL LICENSING: CENTRALIZING STATE LICENSURE FUNCTIONS* (1980). For examples of self-regulation with greater government involvement, see generally Michael, *supra* note 137.

¹³⁹ See generally Chris Jay Hoofnagle, *Reflections on the NC JOLT Symposium: The Privacy Self-Regulation Race to the Bottom*, 5 N.C. J.L. & TECH. 213, 213–17 (2004) (indicating how “a race to the bottom” resulted from industry self-regulation of personal information).

¹⁴⁰ See generally Jeffrey S. Edelman, *Self-Regulation of Advertising: An Alternative to Litigation and Government Action*, 43 IDEA 509, 509 (2003) (discussing self-regulation of advertising).

¹⁴¹ See generally Timothy D. Casey & Jeff Magenau, *A Hybrid Model of Self-Regulation and Governmental Regulation of Electronic Commerce*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2002) (discussing self-regulation of electronic commerce).

¹⁴² See generally Randy Lee, *The State of Self-Regulation of the Legal Profession: Have We Locked the Fox in the Chicken Coop?*, 11 WIDENER J. PUB. L. 69 (2002) (discussing self-regulation of the legal profession).

¹⁴³ See generally Randall C. Young, *Industry Self-Regulation and Voluntary Environmental Compliance: A Book Review*, 9 BUFF. ENVTL. L.J. 301 (2002) (discussing self-regulation of environmental matters).

securities,¹⁴⁷ recombinant DNA technologies,¹⁴⁸ and medical records.¹⁴⁹ This Article extends the discussion of complementary and alternative medicine to the practitioner. For reasons that I develop in this Article, voluntary self-regulation is particularly relevant to communities of homeopathic practitioners.

Unlicensed practitioners, licensed non-physician practitioners, and physicians whose community standards do not include the practice of CAM have limited options when considering the actions they can take in response to a hostile or ambiguous regulatory environment. One option is to practice quietly and carefully. The threat of criminal sanctions or the loss of licensure compels a more comprehensive response. In this section, I consider the outline of a judicial response and then look at two other response types both of which result in market regulation of CAM practitioners: statutory self-regulation, such as the Colorado and Ontario statutes,¹⁵⁰ or legislation that exempts CAM practitioners from exclusive scope of practice acts. Legislation has been passed in some communities and proposed in others. I argue that the market model alone is inappropriate and inadequate for whole medical systems such as homeopathy even though homeopathy is instrumentally safe. As the third type of response, I propose voluntary self-regulation as a model that would benefit communities of homeopathic practitioners.

¹⁴⁴ See generally Ronen Shamir, *Between Self-Regulation and the Alien Tort Claims Act: On the Contested Concept of Corporate Social Responsibility*, 38 LAW & SOC'Y REV. 635 (2004) (discussing self-regulation of human rights).

¹⁴⁵ See generally Michael B. LiCalsi, "The Whole Situation Is a Shame, Baby!" — *NCAA Self-Regulations Categorized as Horizontal Combinations Under the Sherman Act's Rule of Reason Standard: Unreasonable Restraints of Trade or an Unfair Judicial Test?*, 12 GEO. MASON L. REV. 831 (2004) (discussing self-regulation of sports).

¹⁴⁶ See generally Caral, *supra* note 1 (discussing self-regulation of the Internet).

¹⁴⁷ See generally Joel Seligman, *Cautious Evolution or Perennial Irresolution: Stock Market Self-Regulation During the First Seventy Years of the Securities and Exchange Commission*, 59 BUS. LAW. 1347, 1347 (2004) (stating that "industry self-regulation subject to SEC supervision generally has been effective").

¹⁴⁸ See generally Charles Weiner, *Is Self-Regulation Enough Today?: Evaluating the Recombinant DNA Controversy*, 9 HEALTH MATRIX 289 (1999) (discussing how individual conference participants self-regulated in relation to recombinant DNA).

¹⁴⁹ See generally Catherine Louisa Glenn, *Protecting Health Information Privacy: The Case for Self-Regulation of Electronically Held Medical Records*, 53 VAND. L. REV. 1605 (2000) (discussing self-regulation of medical records).

¹⁵⁰ See generally Barbara J. Safriet, *Closing the Gap Between Can and May in Health-Care Providers' Scopes of Practice: A Primer for Policymakers*, 19 YALE J. ON REG. 301, 301, 325–31 (2002) (reviewing the scope of practice acts of Colorado and Ontario).

C. Scope of Practice Monopolies and the American Medical Association: Statutory Self-Regulation

In this section, I describe how the profession of conventional medical doctors operationalizes its legal monopoly over the practice of medicine. Although the monopoly has deleterious effects on the economics of the larger health care system—and accordingly on public health—I focus on the deleterious effects it has on the provision of health care and the development of other health care professions. The deleterious effects are found not only in the economic order, but in the social, moral, and political orders. In the economic order, there are tremendous costs imposed on the legislatures of each state and the federal government, distorting the entire system of regulation of health care professionals. In addition, occupations are denied the ability to make a livelihood and all other non-conventional physician-regulated professions are cramped into scope of practice binds that result in competence being incommensurate with legal authority.

In the moral order, the monopoly enhances paternalism and social disparity between conventional medical doctors and all other health care providers, it demoralizes and marginalizes all other health care professions, and causes confusion, dependence, and information asymmetries with the public.

Each state regulates its thirty to forty health professions primarily through licensing or practice acts (statutory self-regulation).¹⁵¹ These acts delegate authority to regulate the occupation to the profession itself which then functions through a board whose members are drawn from the profession.¹⁵² The acts provide the scope of authority of the board and the scope of practice of the profession.¹⁵³ The scope of authority of the board extends to

¹⁵¹ See Jennifer A. Turner, *Going After the 'Hired Guns': Is Improper Expert Witness Testimony Unprofessional Conduct or the Negligent Practice of Medicine?*, 33 PEPP. L. REV. 275, 191 n.121, 290–91 (2006). For examples of practice acts, see generally Medical Practice Act, CAL. BUS. & PROF. CODE §§ 2000–28 (West 2003); Nebraska Regulation of Health Professions Act, NEB. REV. STAT. §§ 71-6201 to -6229 (2003); Medical Practice Act, TEX. OCC. CODE ANN. §§ 151.001 to .056 (Vernon 2004).

¹⁵² See Karen A. Butler, *Health Care Quality Revolution: Legal Landmines for Hospitals and the Rise of the Critical Pathway*, 58 ALB. L. REV. 843, 845–47 (1995) (explaining that most states have enacted credentialing requirements based on peer review); see also CAL. BUS. & PROF. CODE § 2007 (requiring most members of the Medical Board of California to be licensed physicians); NEB. REV. STAT. § 71-6115 (requiring most members of the Board of Occupational Therapy to be members of the profession).

¹⁵³ See, e.g., ALA. CODE § 34-24-53 (2006) (outlining the powers and duties of the Board of Medical Examiners); CAL. BUS. & PROF. CODE §§ 200–05 (outlining the responsibilities of the

licensees, but most acts also criminalize and provide for stiff civil monetary and other penalties for unlicensed persons whose acts stray into the scope of practice of the licensees.¹⁵⁴ For purposes of distinguishing the professions in each state, the scope of practice language becomes very important.

State regulation of health care professionals is justified on safety grounds;¹⁵⁵ however, professionals also use licensing acts for the tacit goal of creating and protecting their economic status.¹⁵⁶ Licensing acts grant economic monopolies to the extent scopes of practice are exclusive.¹⁵⁷ That economic privileges attendant with the license cause the profession to be very jealous of its monopoly and not infrequently cause the legal authority to practice a particular modality is not congruent with competence to practice it.¹⁵⁸ This incongruity arises because over thirty professionals with scopes of practice fighting a turf battle are very expensive and time-consuming, especially when conventional medical doctors hold all the aces. The professionals, acting locally through county and state associations and the American Medical Association (AMA), have been so successful at protecting their turf through aggressive use of their scope of practice laws that they have distorted the entire

Divisions of Licensing and Medical Quality).

¹⁵⁴ Andrew Fichter, *Owning a Piece of the Doc: State Law Restraints on Lay Ownership of Health Care Enterprises*, 39 J. HEALTH L. 1, 23 (2006) (noting that state health laws "universally prohibit anyone from practicing . . . without a license"); see, e.g., ALA. CODE § 34-25-51 (charging individuals who practice without a license with a misdemeanor and a monetary fine).

¹⁵⁵ See *supra* Part IV.A (discussing how safety concerns influence state health care regulation).

¹⁵⁶ See TASKFORCE ON HEALTH CARE WORKFORCE REGULATION, PEW HEALTH PROFESSIONS COMM'N, STRENGTHENING CONSUMER PROTECTION: PRIORITIES FOR HEALTH CARE WORKFORCE REGULATION 21-23 (1998), available at http://futurehealth.ucsf.edu/pdf_files/RTF.pdf [hereinafter PEW TASKFORCE REPORT] (addressing in depth the scope of practice problem); see also STARR, *supra* note 14, at 102-03 (examining the use of licensing acts by physicians to protect against competition). Interestingly, Starr argues that homeopaths and eclectics were not suppressed by licensure because they were, at one point, invited to join the new professional organizations and partake of their benefits. STARR, *supra* note 14, at 107-08. Although, this analysis only applied to the sectarians that were invited and once the door was closed suppression was universal. See YOUNG, *supra* note 109, at 49-51 (stating that licensing restricts entry to the profession, advertising, fee competition and mobility, and that the restrictions on these, without factoring in the benefit conferred by entry restrictions, enhanced licensee earnings by nearly twenty-seven percent). For an extended commentary on the meaning and influence of Starr's work, see *Transforming American Medicine: A Twenty-Year Retrospective on the Social Transformation of American Medicine*, 29 J. HEALTH POL. POL'Y & L. (SPECIAL ISSUE) 621, 757, 781, 815 (2004).

¹⁵⁷ See STARR, *supra* note 14, at 57 (discussing the nineteenth century view of licensing as monopolistic).

¹⁵⁸ See Safriet, *supra* note 150, at 304-05.

health care system.¹⁵⁹ Medical doctors control access to medical care through their exclusive authority to write prescriptions, admit patients to hospitals in non-emergency cases, and within hospitals, control surgery, diagnostic and laboratory tests, nursing care, diet, discharge, transfer to other facilities, as well as “channel access to medical specialists, diagnostic and laboratory tests, nursing homes, and home health care services.”¹⁶⁰

Conventional medicine’s current control of the practice of medicine began in the 1870s when “regular” doctors began to push for the restoration of medical licensing, which had been lost earlier in the nineteenth century.¹⁶¹ These doctors were successful and, being numerically dominant, defined what medicine was and who could practice it.¹⁶² Only people who had licenses could practice conventional medicine, and a definition of what medicine was encompassed every act remotely related to health.¹⁶³

Here are three contemporary statutory definitions of medicine:
California definition of practice of medicine:

Notwithstanding Section 146, any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense, punishable by a fine not exceeding ten thousand dollars (\$10,000), by imprisonment in the state prison, by imprisonment in a county jail not exceeding one

¹⁵⁹ See STARR, *supra* note 14, at 302, 304–06.

¹⁶⁰ MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS’ CONFLICTS OF INTEREST* 6 (1993).

¹⁶¹ *Id.* at 58, 102–05. The use of monopolistic ideas to protect the economic viability of a trade has its proximal origins in the late medieval guild system which ironically was seen as odious in nineteenth century liberal economic thought. See, e.g., 1 HENRI PIRENNE, *A HISTORY OF EUROPE: FROM THE END OF THE ROMAN WORLD IN THE WEST TO THE BEGINNINGS OF THE WESTERN STATES* 205–08 (Bernard Miall trans., Anchor Books ed. 1958) (1956) (describing how the “exclusivism” of city artisans and tradesman lead to solidarity and protectionism of the members).

¹⁶² STARR, *supra* note 14, at 102; Safriet, *supra* note 150, at 306–07.

¹⁶³ STARR, *supra* note 14, at 102, 106.

year, or by both the fine and either imprisonment.¹⁶⁴

Whenever the words “diagnose” or “diagnosis” are used in this chapter, they include any undertaking by any method, device, or procedure whatsoever, and whether gratuitous or not, to ascertain or establish whether a person is suffering from any physical or mental disorder. Such terms shall also include the taking of a person’s blood pressure and the use of mechanical devices or machines for the purpose of making a diagnosis and representing to such person any conclusion regarding his or her physical or mental condition. Machines or mechanical devices for measuring or ascertaining height or weight are excluded from this section.¹⁶⁵

New York definition of practice of medicine:

The practice of the profession of medicine is defined as diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.¹⁶⁶

Texas definition of practice of medicine:

“Practicing medicine” means the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who:

- (A) publicly professes to be a physician or surgeon; or
- (B) directly or indirectly charges money or other compensation for those services.¹⁶⁷

The Federation of State Medical Boards, in its *Essentials of a Modern Medical Practice Act*, recommends the following:

The definition of the practice of medicine should include

1. advertising, holding out to the public or representing in any manner that one is authorized to practice medicine in the jurisdiction;
2. offering or undertaking to prescribe, order, give or administer any drug or medicine for the use of any other person;
3. offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity,

¹⁶⁴ CAL. BUS. & PROF. CODE § 2052(a) (West 2003).

¹⁶⁵ *Id.* § 2038.

¹⁶⁶ N.Y. EDUC. LAW § 6521 (McKinney 2001).

¹⁶⁷ TEX. OCC. CODE ANN. § 151.002(a)(13) (Vernon 2004).

defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;

4. offering or undertaking to perform any surgical operation upon any person;

5. rendering a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient or the actual rendering of treatment to a patient within a state by a physician located outside the state as a result of transmission of individual patient data by electronic or other means from within a state to such physician or his or her agent;

6. rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient; and

7. using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Doctor of Osteopathic Medicine, Physician, Surgeon, Physician and Surgeon, Dr., M.D., D.O. or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis or treatment of human disease or condition unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in the jurisdiction.¹⁶⁸

The statutes and model code are representative of the extraordinary scope of practice that is granted exclusively to medical doctors.¹⁶⁹ It is readily apparent that the exclusive scope covers veterinary services, the treatment of a child by his mother for something as mild as diaper rash, pharmacy, prayer, and certainly most complementary and alternative medicines.¹⁷⁰

Once established, the medical profession had no reason to retreat

¹⁶⁸ FED. OF STATE MED. BDS., ESSENTIALS OF A MODERN MEDICAL PRACTICE ACT (11th ed. 2006), available at http://www.fsmb.org/pdf/GPROL_essentials_eleventh_edition.pdf. The Federation's vision is comprehensive, idealistic, self-serving, and sounds as though it has a mandate from the public as the highest public health authority in the country. See Federation of State Medical Boards, Mission and Goals, <http://www.fsmb.org/mission.html> (last visited Oct. 17, 2006) (providing the organization's missions and goals).

¹⁶⁹ See MICHAEL H. COHEN, COMPLEMENTARY & ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES 26–33 (1998) (discussing the broad scope of practice definitions employed in various states).

¹⁷⁰ See *id.*

from this hegemony and had every reason to defend it vigorously.¹⁷¹ This view is supported by the indictment of the AMA in 1939 for violations of the Sherman Antitrust Act in its efforts to suppress a non-profit group health plan.¹⁷² Although the AMA was unsuccessful in challenging the indictment, it prevailed in its attempts to suppress other cooperative and prepaid group practice plans' efforts.¹⁷³ In the 1950s, the AMA changed its ethical code to effectively allow exploitation of patients and acts contrary to patient interest.¹⁷⁴ Much later, a federal court found that the AMA had engaged in an illegal "lengthy, systematic, successful, and unlawful" restraint of trade and again in violation of antitrust law after making and breaking three settlement agreements with the plaintiff chiropractors.¹⁷⁵ The AMA continues to have an aggressive policy of protection of the universal scope of practice of physicians.¹⁷⁶

The United States Department of Labor lists thirty-eight non-MD/DO health care and medical technology occupations without including acupuncture, naturopathy, homeopathy, massage, or midwifery.¹⁷⁷ This means, conservatively, there are over 1,000 licensing acts for health care practitioners throughout the country,

¹⁷¹ Safriet, *supra* note 150, at 307–10.

¹⁷² See *United States v. Am. Med. Ass'n*, 28 F. Supp. 752, 754 (D.D.C. 1939), *rev'd*, 110 F.2d 703 (D.C. Cir. 1940) (explaining the case history and claims brought against the AMA).

¹⁷³ STARR, *supra* note 14, at 305.

¹⁷⁴ RODWIN, *supra* note 160, at 36.

¹⁷⁵ *Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 371 (7th Cir. 1990).

¹⁷⁶ See generally Myrle Croasdale, *New Jersey Anesthesiologists Win Scope-of-Practice Battle: Physicians Must Supervise Anesthesia During Office-Based Surgeries in New Jersey*, AM. MED. NEWS, Jan. 17, 2005, <http://www.ama-assn.org/amednews/2005/01/17/prse0117.htm> (reporting on the requirement that physicians supervise anesthesia in New Jersey as "one of those scope-of-practice victories that are rare to achieve" (internal quotation marks omitted)); Myrle Croasdale, *Nonphysicians Eager to Pick up Prescription Pad: Empowered by Recent Victories, Nonphysicians Gear Up for 2005 Legislative Efforts to Expand Their Scope*, AM. MED. NEWS, Feb. 7, 2005, <http://www.ama-assn.org/amednews/2005/02/07/prl10207.htm> ("Nonphysicians . . . having seen their colleagues in other states win the right to . . . expand their scope of practice, are expected to push hard for the same authority in more states in 2005. Meanwhile, organized medicine is getting ready to fight their efforts."); Jay Greene, *Physicians Win Big in States Over Scope-of-Practice Issues: Cooperation Between National, State and Specialty Medical Societies Paid off This Year as Dozens of Scope-of-Practice Bills Were Defeated*, AM. MED. NEWS, July 2, 2001, <http://www.ama-assn.org/amednews/2001/07/02/prl10702.htm> ("The 2001 state legislative sessions proved a banner year for physicians as they defeated a slew of scope-of-practice bills . . ."); *News in Brief – Jan. 5, 2004*, AM. MED. NEWS, Jan. 5, 2004, <http://www.ama-assn.org/amednews/2004/01/05/prbf0105.htm> (reporting on the AMA's drafting of model scope legislation).

¹⁷⁷ BUREAU OF LABOR STATISTICS, U.S. DEP'T OF LABOR, OCCUPATIONAL EMPLOYMENT AND WAGES, MAY 2005, <http://www.bls.gov/oes/current/oes290000.htm> (last visited Oct. 17, 2006).

all with scope of practice language.¹⁷⁸ In the process of formation, the practitioners all faced the AMA aggressively seeking to limit their scope of practice such that they could only practice with the permission or control of the medical doctor, often through the authority of the medical doctor to delegate.¹⁷⁹ The AMA was successful in defending its turf, and all non-physician scopes of practice are “carve[] out[s]” from the universal scope of practice.¹⁸⁰ The lesser scopes of practice were “[t]ypically . . . accomplished by focusing on a single part of the body (e.g., podiatrists/feet and dentists/teeth) or on one small subset of functions pertaining to a body part (e.g., optometrists/corrective lens).”¹⁸¹ Health care providers with broader skills—such as nurses—are limited by the requirement that they be supervised by physicians or only act if authority had been delegated.¹⁸² In addition, the universal scope of practice limits what otherwise competent nurses can say.¹⁸³ For example, they can say they “assessed” a patient, not “diagnosed” them, or that they “furnish[ed],” not “prescribe[ed],” drugs.¹⁸⁴

The universal and exclusive scope of practice of the medical doctor has been called “the ‘dark matter’ of the health-care universe.”¹⁸⁵ Starr’s history is that of the distortions in the health care system caused by abuse of the power conferred on the medical profession through licensing acts.¹⁸⁶ “The rules and regulations that govern health care practice are vestiges of the [nineteenth] century.”¹⁸⁷

¹⁷⁸ In 1997, over 1,600 scope of practice bills were introduced. Safriet, *supra* note 150, at 304 n.1.

¹⁷⁹ *Id.* at 307 (quoting ELIOT FREIDSON, *PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE* 47 (1970)).

¹⁸⁰ Safriet, *supra* note 150, at 308.

¹⁸¹ *Id.*

¹⁸² *Id.* at 307–08.

¹⁸³ *Id.* at 308.

¹⁸⁴ *Id.* For more detailed narratives about the problems faced by the nursing professions, see THETIS M. GROUP & JOAN I. ROBERTS, *NURSING, PHYSICIAN CONTROL, AND THE MEDICAL MONOPOLY: HISTORICAL PERSPECTIVES ON GENDERED INEQUALITY IN ROLES, RIGHTS AND RANGE OF PRACTICE* 147–73 (2001); SUSAN M. REVERBY, *ORDERED TO CARE: THE DILEMMA OF AMERICAN NURSING, 1850–1945*, at 126 (1987) (“Few physicians were willing to concede to nursing, through state mandate, what they were unwilling to give up in practice.”).

¹⁸⁵ Safriet, *supra* note 150, at 308; see also Sue A. Blevins, *The Medical Monopoly Protecting Consumers or Limiting Competition?*, *Cato Policy Analysis No. 246* (1995), available at <http://www.cato.org/pubs/pas/pa-246.html> (arguing that because there is no empirical evidence supporting the claim that non-physician providers cannot provide many physician services with comparable outcomes, lower costs, and high patient satisfaction, licensure should be entirely reconsidered in light of its monopolistic, anti-competitive effect).

¹⁸⁶ See STARR, *supra* note 14, at 4–6, 24, 27 (discussing the increased power and authority of the medical profession in relation to licensing laws).

¹⁸⁷ PEW HEALTH PROFESSIONS COMM’N, *RECREATING HEALTH PROFESSIONAL PRACTICE FOR*

A search of “scope of practice” in the AMA Policy Finder results in twenty-five hits.¹⁸⁸ In one, the AMA opposes the appointment of naturopaths to the Medicare Coverage Advisory Committee.¹⁸⁹ In another, the AMA “shall review the circumstances which led to the passage of the clinical psychologist prescribing bill in New Mexico, with the aim of providing the best possible assistance to other states facing similar circumstances” to assist them in preventing such bills.¹⁹⁰ Two of the policies are reproduced below to summarize the foregoing discussion:

D-35.996 Scope of Practice Model Legislation

Our AMA Advocacy Resource Center will continue to work with state and specialty societies to draft model legislation that deals with non-physician independent practitioners’ scope of practice, reflecting the goal of ensuring that non-physician scope of practice is determined by training, experience, and demonstrated competence; and our AMA will distribute to state medical and specialty societies the model legislation as a framework to deal with questions regarding non-physician independent practitioners’ scope of practice.¹⁹¹

D-35.999 Non Physicians’ Expanded Scope of Practice (Laboratory Testing and Test Interpretation)

Our AMA, through appropriate legislative and regulatory efforts, seeks to: (1) ensure that diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO); and (2) limit laboratory test ordering and interpretation of test results solely to licensed physicians (MD/DO) and licensed dentists (DDS/DMD).¹⁹²

Medical doctors argue that their scope of practice is necessary to

A NEW CENTURY: THE FOURTH REPORT OF THE PEW HEALTH PROFESSIONS COMMISSION, at ii (1998), *available at* http://www.futurehealth.ucsf.edu/pdf_files/recreate.pdf.

¹⁸⁸ American Medical Association, Policy Finder, http://www.amaassn.org/apps/pf_new/pf_online (last visited Oct. 17, 2006) (check box for “Select all (1-105);” then type in “scope of practice;” then follow “search” hyperlink [hereinafter Policy Finder]).

¹⁸⁹ *Id.* (check box for “Select all (1-105);” then type in “D-35.995;” then follow “search” hyperlink).

¹⁹⁰ *Id.* (check box for “Select all (1-105);” then type in “D-35.998;” then follow “search” hyperlink).

¹⁹¹ *Id.* (check box for “Select all (1-105);” then type in “D-35.996;” then follow “search” hyperlink).

¹⁹² *Id.* (check box for “Select all (1-105);” then type in “D-35.999;” then follow “search” hyperlink).

protect the public since they are the only health care providers with sufficient education to properly manage health care.¹⁹³ The safety concern is clearly reflected in AMA policies, but it is encompassed by the intention to protect the physicians' exclusive scope of practice. The first policy, D-35.996, indicates that the AMA sees its role as micromanaging the scope of practice debate.¹⁹⁴ An example of how this is done is provided in the second policy statement, D-35.999, in which it seeks to ensure that trained technicians only work under or at the behest of physicians and provide their results only to physicians and dentists.¹⁹⁵ There is no justification for the requirement that technicians, or any other "non-physician" provider, practice only under the supervision of a licensed physician. There would be some justification if it were required that the licensed physician be also trained in the technology (school of medicine, modality, etc.) but this is absent from the AMA policy. Any dangers related to inappropriate use of the technology itself are covered by laws governing the use of medical devices.¹⁹⁶ Furthermore, the division by the AMA of the world into physicians and non-physicians has nothing to do with the training and competencies of the wide range of non-physician health care providers; rather, the division is only concerned with the AMA's agenda to protect its turf.

Non-physician competencies range from anesthesiology (nurse anesthetists) and prescribing (physician's assistants) to massage.¹⁹⁷ There should be a presumption that training and licensure in any health care modality implies competency, but the position of the AMA is that all non-physician providers are only partially competent and in need of supervision by physicians regardless of whether the physician is trained in the modality and regardless of the instrumental danger.¹⁹⁸

¹⁹³ BD. OF TRS., AM. MED. ASS'N, LIMITED LICENSURE HEALTH CARE PROVIDER TRAINING AND CERTIFICATION STANDARDS 4, <http://www.ama-assn.org/ama1/pub/upload/mm/471/bot24A06.pdf> (last visited Oct. 17, 2006) [hereinafter BD. OF TRS., LIMITED LICENSURE]. The AMA refers repeatedly to this as their justification in all scope of practice references. *See id.* at 3–5. Oddly enough, their insistence on overreaching their competencies leads to loss of their professional authority. Schlesinger, *supra* note 109, at 193.

¹⁹⁴ Policy Finder, *supra* note 188 (check box for "Select all (1-105);" then type in "D-35.996;" then follow "search" hyperlink).

¹⁹⁵ *Id.* (check box for "Select all (1-105);" then type in "D-35.999;" then follow "search" hyperlink).

¹⁹⁶ *See generally* 21 U.S.C. § 360c–m (2000) (extensively regulating medical devices).

¹⁹⁷ *See* PEW TASKFORCE REPORT, *supra* note 156, at 23.

¹⁹⁸ *See id.* at 21–23, 26; Safriet, *supra* note 150, at 310–11.

In the 2000 Interim Meeting of the AMA House of Delegates (HOD), the HOD adopted a recommendation that the

AMA continue to support the activities of the Advocacy Resources Center [(ARC)] in providing advice and assistance to specialty and state medical societies concerning scope of practice issues to include the collection, summarization and wide dissemination of data on the training and scope of practice of physicians (MDs and DOs) and nonphysician groups and that our AMA make these issues a legislative/advocacy priority.¹⁹⁹

In 2004, there was evidence that the plan was moving forward with the first mention of a Scope of Practice Partnership (SUPP):

ARC staff have contacted all state and national medical societies, alerting these organizations that staff is available to assist in the opposition of legislative mandates that may lead to inappropriate scope expansions. ARC staff continue to develop the Scope of Practice Partnership as a vehicle to protect the public from potential scope expansions that threaten public welfare.²⁰⁰

By late 2005, the AMA had focused its intentions and resolved: That our American Medical Association, along with the Scope of Practice Partnership and interested Federation partners, study the qualifications, education, academic requirements, licensure, certification, independent governance, ethical standards, disciplinary processes, and peer review of the limited licensure health care providers . . . and limited independent practitioners, as identified by the Scope of Practice Partnership and report back at the 2006 Annual Meeting.²⁰¹

¹⁹⁹ HOUSE OF DELEGATES, AM. MED. ASS'N, MEETING HIGHLIGHTS: AMA POLICIES OF INTEREST TO MEDICAL EDUCATORS THAT WERE ADOPTED BY THE AMA HOUSE OF DELEGATES AT THE 2000 INTERIM MEETING 2-3 (2000), *available at* <http://www.ama-assn.org/ama/upload/mm/44/meetinghighlights.doc>.

²⁰⁰ HOUSE OF DELEGATES, AM. MED. ASS'N, FOLLOW-UP ON IMPLEMENTATION OF RESOLUTIONS AND REPORT RECOMMENDATIONS: AMA HOUSE OF DELEGATES INTERIM MEETING - DECEMBER 4-7, 2004, at 23 (2005), *available at* <http://www.ama-assn.org/meetings/public/interim05/i04status.doc>.

²⁰¹ HOUSE OF DELEGATES, AM. MED. ASS'N, REPORT OF REFERENCE COMMITTEE K 20 (2005), *available at* <http://www.ama-assn.org/meetings/public/interim05/refcomkannotateda05.doc>. This text is a portion of Resolution 814, "Limited Licensure Health Care Provider Training and Certification Standards." *Id.* For the full reprinted text of Resolution 814, see Michael Devitt, *AMA Creates "Partnership" to Limit Other Providers' Scope of Practice: The Next Attempt to "Contain and Eliminate" Chiropractic?*, DYNAMIC CHIROPRACTIC, June 6, 2006,

A 2006 AMA Board of Trustees Report discloses several interesting things about the Scope of Practice Partnership.²⁰² Prior to rolling it out, the AMA sought the advice of its general counsel to make sure that nothing contemplated would violate antitrust, truth-in-advertising, election, or lobbying laws.²⁰³ As a result, all members are required to sign a Statement of Legal Compliance which requires that at all times “the SOPP will have as its goal the protection of the health and safety of patients whose well-being may be threatened by health care practitioners who lack education, training or experience to perform procedures for which they seek licensure.”²⁰⁴

The Report then goes on to the core practices of the SOPP, stating that “involvement in scope of practice ‘campaigns’ would be multi-dimensional.”²⁰⁵ It would become involved in “individual state legislative, regulatory, and judicial advocacy [and] also in programs of information, research and education.”²⁰⁶ In fulfilling these purposes, the initial high priority activities of the SOPP “would focus on discrediting access to care arguments repeatedly made by various allied health professionals when seeking to expand their respective scope of practice, particularly in rural states” and “would concentrate on completing educational/training/licensure comparisons of specific allied health professions and the medical profession.”²⁰⁷

It appears that the AMA is rightfully concerned with the legality of the SOPP since, despite its stated purpose of strengthening public

<http://www.chiroweb.com/archives/24/12/01.html>. Also, in 2005, the Federation of State Medical Boards (FSMB) issued a policy statement on scope of practice that does not question the structure of the existing scope of practice regimes and purports to offer advice to state legislatures on how to properly evaluate requests by nonphysicians for scope of practice creations or expansions. FED. OF STATE MED. BDS., *ASSESSING SCOPE OF PRACTICE IN HEALTH CARE DELIVERY: CRITICAL QUESTIONS IN ASSURING PUBLIC ACCESS AND SAFETY* 2, 13 (2005), available at http://www.fsmb.org/pdf/2005_grpol_scope_of_practice.pdf. FSMB's white paper is consistent with the intentions of the SOPP. It attempts to achieve credibility by citing reports by the Institute of Medicine and the Pew Health Professions Commission, but both of those sources recommend thorough scope of practice reform, not the extension of the status quo recommended by the FSMB and SOPP. *See* COMM. ON THE HEALTH PROFESSIONS EDUC. SUMMIT, INST. OF MED. OF THE NAT'L ACADS., *HEALTH PROFESSIONS EDUCATION: A BRIDGE TO QUALITY* 4, 10, 104, 108 (2003), <http://www.nap.edu/books/0309087236/html/> (citing PEW TASKFORCE REPORT, *supra* note 156).

²⁰² *See* BD. OF TRS., *LIMITED LICENSURE*, *supra* note 193.

²⁰³ *Id.* at 4.

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

health, it intends to achieve this purpose with unrelated activities that are clearly intended to have prejudicial effects. Had the AMA intended to use the SOPP for public health purposes, it would have engaged in an empirical study to determine the validity of arguments by various allied health professionals that scope of practice restrictions urged by AMA unjustly limit access to care. Instead, it intends to discredit the arguments presumably by selective and biased use of evidence. This plan is blatantly unethical and violates the legal constraints placed on it by AMA counsel.

The allied health professional community has responded by forming the Coalition for Patients' Rights (CPR).²⁰⁸ As of July 27, 2006, the CPR had twenty-six members representing primarily nurses' associations, but also including chiropractors, physical therapists, psychologists, and speech therapists.²⁰⁹ The CPR objects to the explicit and implicit assumptions made by the SOPP and to its intentions, noting that the SOPP was formed "to assist various physician organizations facing scope of practice 'battles.'"²¹⁰

The AMA and SOPP imply that patient safety is at risk from increased or new scopes of practice for non-MD health professionals, and they seek to bolster their arguments with studies; however, physician organizations are not objective and thus not the best organizations to conduct balanced and fair assessment of training, competencies, and scope of practice of non-MD health care professions.²¹¹ Instead of resolutions indicating the AMA's intention to escalate inter-disciplinary tensions by "discrediting" other health care professions' arguments for expanded or new scopes of practice, the AMA should be engaging in cooperative efforts to expand access in the United States.²¹² The SOPP's intention to study whether non-MD health care professions really provide increased access in rural and underserved areas is wasteful because this has already been amply demonstrated and ignores the value provided by non-MD health professionals.²¹³ In addition, the language used by the

²⁰⁸ See COALITION FOR PATIENTS' RIGHTS, HEALTH CARE PROFESSIONALS URGE COOPERATIVE PATIENT CARE; OPPOSE SOPP & AMA RESOLUTION 814, <http://www.patientsrightscoalition.org/statement.htm> (last visited Oct. 17, 2006).

²⁰⁹ Coalition for Patients' Rights, List of Coalition for Patients' Rights Members and Contacts, <http://www.patientsrightscoalition.org/news/#coalmembs> (last visited Oct. 17, 2006).

²¹⁰ COALITION FOR PATIENTS' RIGHTS, *supra* note 208.

²¹¹ *Id.*

²¹² See BD. OF TRS., LIMITED LICENSURE, *supra* note 193, at 4.

²¹³ COALITION FOR PATIENTS' RIGHTS, *supra* note 208.

AMA and SOPP begs the question of the competency of non-MD health care professionals. The terms “allied health practitioner,” “limited licensure health care provider,” and “non-physician,” “reflect an anachronistic view of health care professionals who are not physicians.”²¹⁴ The AMA policy that all non-MD health care professionals must be supervised or delegated by an MD is likewise anachronistic and does not comport with the demonstrated fact that non-MD practitioners are competent to act independently within their training and competence.²¹⁵

The legal authority of the practitioner (the scope of practice) should be directly related to the practitioner’s competence (his or her education). This ideal is reflected in the AMA policies, with one glaring exception: the medical doctors themselves. Medical doctors’ legal authority far exceeds their training.²¹⁶ A medical doctor can graduate from medical school and do anything.²¹⁷ To be sure, doctors are constrained by “common sense and decency, professional judgment [if and when acquired], professional ethics, institutional . . . [accrediting] systems, voluntary accreditation standards, malpractice insurance” requirements, and now, a better educated public.²¹⁸

The exclusive universal scope of practice and its defense extract a great cost on the health care system, other health care professions, and the legislatures of each state.²¹⁹ As society’s knowledge of disease, treatment, and wellness has grown, so have the training and skills of all health care providers, but all non-physician

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ See Schlesinger, *supra* note 109, at 198–99.

²¹⁷ Safriet, *supra* note 150, at 311. Medical education conveys specialty training only in residency and post-residency fellowships. American Medical Association, Choosing a Specialty, <http://www.ama-assn.org/ama/pub/category/2375.html> (last visited Oct. 17, 2006). Most physicians specialize in only one field, as residency training can take up to four or more years at the end of medical school, depending on the specialty. *Id.* Physicians are not trained in the myriad of health fields licensed by the states. *Id.*

²¹⁸ *Id.* The role of tort law in restraining medical doctors from practicing beyond their competencies has been bitterly contested for some time as it provides the only mechanism by which the medical profession can be restrained by, among other things, its customers. See Sloan, *supra* note 113, at 907 (“The legal process provides a method for disclosing detailed aspects of the care process as well as consequences of failure to take care, thus reducing the information asymmetry . . .”). See generally GOSTIN, *supra* note 96, at 269–305 (discussing tort law and the public’s health). Evidence that the rhetoric on tort reform is intentionally skewed by the AMA is well-known. See, e.g., U.S. GEN. ACCOUNTING OFF., MEDICAL MALPRACTICE: IMPLICATIONS OF RISING PREMIUMS ON ACCESS TO HEALTH CARE 20–21 (2003), <http://www.gao.gov/new.items/d03836.pdf> (questioning the accuracy of AMA studies).

²¹⁹ See Safriet, *supra* note 150, at 304, 316; PEW TASKFORCE REPORT, *supra* note 156, at ii.

providers—whether in existence for decades or emerging—face bitter battles in the state capitols every time scope of practice issues arise.²²⁰ Legislators must make sense of the bombardment of heavily-financed lobbyists from state and national professional organizations all demanding legislation that will protect and serve the public.²²¹ The proponent of the change in scope of practice will be seeking an expansion: the legal authority to do something they are already training and charging for; the other professions will be seeking to limit that expansion or make their own expansion in response. The system itself—emanating from the exclusive universal scope of practice—could not be designed better to encourage infighting between the professions over the economic monopolies granted by scope of practice language.²²²

State regulatory schemes for the health care occupations should be reformed. There is no “sound empirical evidence that licens[ing] laws have adequately served consumers.”²²³ Legal authority should be commensurate with training, and the regulatory structure should not be responsive to the economic ends of any practitioner group.²²⁴ Regulation should be centered on public safety, not protection of the professions.

For example, Colorado, Ontario,²²⁵ and British Columbia have enacted progressive scope of practice reform that should inform policymakers as they struggle with scope of policy disputes. Colorado consolidated all non-mental health care providers under

²²⁰ Safriet, *supra* note 150, at 309–10.

²²¹ *See id.* at 304; PEW TASKFORCE REPORT, *supra* note 156, at ii.

²²² *See* Safriet, *supra* note 150, at 311 (noting the “built-in inter-professional conflict . . . playground”).

²²³ Sloan, *supra* note 113, at 905.

²²⁴ *See* PEW TASKFORCE REPORT, *supra* note 156, at i; Safriet, *supra* note 150, at 304. The Pew Commission on Health Professions goes so far as to recommend interdisciplinary competence in all health professionals. PEW TASKFORCE REPORT, *supra* note 156, at 27. The confusion on this subject, or perhaps denial, is illustrated by a report on the licensed professions prepared for the department that regulates professions in New York. *See* OFFICE OF THE PROFESSIONS, N.Y. STATE EDUC. DEPT., THE EXPANSION OF THE LICENSED PROFESSIONS (2001), available at <http://www.op.nysed.gov/expprofessions.htm>. In its opening paragraphs, the report acknowledges that “the fundamental reason for licensure is public protection and safety.” *Id.* Soon thereafter it notes the “critical importance of professional regulation to protect the public interest and the *integrity of the professions.*” *Id.* (emphasis added). It lauds itself on complying with a Pew Report suggestion that it have an independent lay board to provide oversight of the professions, yet it ignores the Pew Report recommendations on scope of practice issues and discusses the problems with negotiating scope of practice conflicts later in the report. *See id.*

²²⁵ For general commentary on the Colorado and Ontario reforms, see Safriet, *supra* note 150, at 325–30.

one statutory scheme.²²⁶ With regard to scope of practice, the Colorado statute provides that “no licensee, registrant, or unlicensed psychotherapist is authorized to practice outside of or beyond his or her area of training, experience, or competence” thereby conjoining authority to practice with training.²²⁷ Generally, the experiment has been a success, and it has been recommended that the mental health boards continue until 2013.²²⁸

The Ontario Regulated Health Professions Act²²⁹ is much more comprehensive and covers all health professions. Among other things, the statute defines controlled and authorized acts and defines respective descriptions of what each profession does in terms of those acts.²³⁰ Exclusive scopes of practice were done away with, as two or more professions can be authorized to do the same controlled act.²³¹ Controlled acts include those that, “if not done correctly and by a competent person, have a high element of risk.”²³² Controlled acts are:

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.
3. Setting or casting a fracture of a bone or a dislocation of a joint.
4. Moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
5. Administering a substance by injection or inhalation.

²²⁶ See generally COLO. REV. STAT. § 12-43-101 (2005) (grouping non-mental health care providers together).

²²⁷ *Id.* § 12-43-202.

²²⁸ DIVS. OF REGISTRATIONS, MENTAL HEALTH SECTION, COLO. DEP’T OF REGULATORY AGENCIES, 2003 SUNSET REVIEW 27 (2003), available at <http://www.dora.state.co.us/opr/archive/2003MentalHealth.pdf>.

²²⁹ Regulated Health Professions Act, S.O., ch. 18 (1991) (Can.).

²³⁰ *Id.* ch. 18, §§ 27–29.

²³¹ See *id.* §§ 27–28.

²³² HPRAC – Health Regulations Regulatory Advisory Council (2006), <http://www.hprac.org/english/pageDisplay.asp?webDocID=542>.

6. Putting an instrument, hand or finger,
 - i. beyond the external ear canal,
 - ii. beyond the point in the nasal passages where they normally narrow,
 - iii. beyond the larynx,
 - iv. beyond the opening of the urethra,
 - v. beyond the labia majora,
 - vi. beyond the anal verge, or
 - vii. into an artificial opening into the body.
7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.
8. Prescribing, dispensing, selling or compounding a drug as defined in subsection 117(1) of the *Drug and Pharmacies Regulation Act*, or supervising the part of a pharmacy where such drugs are kept.
9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.
10. Prescribing a hearing aid for a hearing impaired person.
11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.
12. Managing labour or conducting the delivery of a baby.
13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.²³³

The British Columbia Health Professions Act gives authority to the Lieutenant Governor in Council to designate a health profession and to define its scope of practice.²³⁴ The Health Professions Council, formed under authority of the Act,²³⁵ articulated a comprehensive scope of practice policy including recommendations for overlapping scopes of practice.²³⁶ Its list of reserved acts appears

²³³ Regulated Health Professions Act, S.O., ch. 18, § 27(2) (1991) (Can.).

²³⁴ Health Professions Act, R.S.B.C., ch. 183, §§ 12–13.

²³⁵ Health Professions Council, SAFE CHOICES: A New Model for Regulating Health Professions in British Columbia, <http://www.health.gov.bc.ca/leg/hpc/review/index.html> (last visited Oct. 17, 2006).

²³⁶ See HEALTH PROFESSIONS COUNCIL, GOV'T OF BRITISH COLUMBIA, SAFE CHOICES: A NEW MODEL FOR REGULATING HEALTH PROFESSIONS IN BRITISH COLUMBIA pt. 2 (2001), available at <http://www.health.gov.bc.ca/leg/hpc/review/part-ii/index.html#vol2>.

to be based on the Ontario list of controlled acts.²³⁷

Based on the foregoing, regulatory reform is needed in the legal order to address the outdated monopoly in the practice of medicine as it results in unjust treatment of patients, clients, and consumers.²³⁸ Reform supports improved social relations between the doctor and consumer, the conventional medical collective, and other schools of medicine; current regulation may have the opposite effect.²³⁹ Reform is needed in the economic order because informational asymmetries increase costs and require market interventions to restore optimality to the market.²⁴⁰ Existing and proposed CAM legislation is based in the economic order, as the legal order is slower to respond to changed social circumstances.

D. A Constitutional Argument for Scope of Practice Reform

A judicial solution to the problems faced by the homeopathic and CAM communities to the regulatory environment has some merit. Here, I simply outline a constitutional argument for increased access to safe health care modalities, especially safe CAM modalities, without analyzing existing case law. I do this both because an analysis of case law would be tangential to the scope of this Article, and because the argument is based on changed social circumstances, not on a logical extension of an existing line of cases dealing with regulation of health care providers. The argument is grounded in legal realism, not positivism.

The substantive due process argument asserts that the universal exclusive scope of practice of the MPAs infringes on citizens' fundamental right to self-determination and bodily integrity, substantive due process liberty, and privacy rights under the Fourteenth Amendment sounding in autonomy.²⁴¹ One should note

²³⁷ See HEALTH PROFESSIONS COUNCIL, GOV'T OF BRITISH COLUMBIA, SCOPE OF PRACTICE REVIEW pt. 1, vol. 1, <http://www.health.gov.bc.ca/leg/hpc/review/part-i/scope-review.html> (last visited Oct. 17, 2006) (enumerating the acts which involve a significant risk of harm and are reserved based on scope of profession).

²³⁸ See GOSTIN, *supra* note 96, at 255–56.

²³⁹ See generally DOWER ET AL., A MODEL FOR EVALUATING, *supra* note 97, at 12 (noting that some professions have declined to seek regulations due to negative effects).

²⁴⁰ See Sage, *supra* note 93, at 1704–07, 1710 (developing the idea that the information asymmetries in the economic, political, social, and legal orders have different characteristics, and appropriate regulation, especially disclosure laws, intervening to correct the asymmetries must take into account the differences); Sloan, *supra* note 113, at 907, 909.

²⁴¹ See Blevins, *supra* note 185 (analyzing the scope of practice monopoly for the Cato Institute and arguing that the primary right being infringed by the monopoly is the right to contract). Blevins states:

that this is not a right to health,²⁴² nor a right to receive health care, nor a right of access to health care. Because the universal scope-of-practice law restricts access to health care determined to be best for the individual by the individual, it impermissibly interferes with the rights of self-determination and bodily integrity. The informed consent or autonomy arm of the right supports the idea that the citizen is competent to make a decision about what he or she deems to be the best health care.²⁴³

Constitutional arguments asserting a due process liberty interest necessarily implicate historical inquiry and must be supported by social changes.²⁴⁴ There is now a wealth of social history available to support the underlying premises that (1) the universal scope of practice has strong economic motivations and unjust consequences;²⁴⁵ (2) the times have changed with regard to the

Yet the freedom to contract—the right of individuals to decide with whom and for what services they will dispose of their earnings—is one of the fundamental rights of man. As Chief Justice John Marshall said in *Ogden v. Saunders*, “Individuals do not derive from government their right to contract, but bring that right with them into society . . . [e]very man retains [the right] to . . . dispose of [his] property according to his own judgment.” Indeed, legal philosophers and ethicists, such as Roger Pilon, Richard Epstein, and Stephen Mecado, convincingly argue that the rights of property and contract are fundamental rights upon which all others are based.

Id. (alterations in original). For an argument applying the right to contract against Canada’s medical system, see *Chaoulli v. Procureur général du Québec*, [2002] A.C.W.S. (3d) 266.

²⁴² For an understanding of the difficulties in describing a right to health, see Brigit Toebes, *Towards an Improved Understanding of the International Human Right to Health*, 21 HUM. RTS. Q. 661, 662 (1999); M. A. El-Badry, *Health and Human Rights*, Department of Economic and Social Affairs, United Nations Secretariat (Mar. 21, 1989) UN Doc IESA/P/AC.28/9; *The Right to Health as a Human Right*, Economic and Social Council (Nov. 9, 1993) UN Doc E/C.12/1993/WP.17.

²⁴³ See *Lawrence v. Texas*, 539 U.S. 558, 562, 564 (2003) (stating that the liberty interest protected by the Fourteenth Amendment’s Due Process Clause covered an individual’s right to engage in homosexual sodomy); *Vacco v. Quill*, 521 U.S. 793, 800 (1997) (noting a person’s right to refuse medical treatment); *Washington v. Glucksberg*, 521 U.S. 702, 723 (1997) (reaffirming *Cruzan* and emphasizing the difference between medical omissions and commissions); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992) (reaffirming that the “[c]onstitutional protection . . . to terminate . . . pregnancy derives from the Due Process Clause of the Fourteenth Amendment); *Cruzan v. Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990) (“The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.”); *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965) (stating that the privacy protected by several constitutional provisions included the right of married persons to use contraception).

²⁴⁴ See generally *Glucksberg*, 521 U.S. at 721 (“Our Nation’s history, legal traditions, and practices thus provide the crucial ‘guideposts for responsible decisionmaking,’ that direct and restrain our exposition of the Due Process Clause. As we stated recently in *Flores*, the Fourteenth Amendment ‘forbids the government to infringe . . . ‘fundamental’ liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest.” (citation omitted)); GOSTIN, *supra* note 96, at 71 (“[C]onstitutional law reflects culture, society, and politics.”).

²⁴⁵ See *supra* Part IV.C.

omnipotence of the medical profession;²⁴⁶ and (3) there has been an information revolution as a result of the Internet.²⁴⁷ There is a strong social trend to reject the positivist self-serving statements of medical science and technology that underlie the universal scope of practice.²⁴⁸ The utility of medical technology is recognized in certain circumstances, but medical technology has shown not to be the panacea it was once thought to be,²⁴⁹ nor is a medical degree necessary for competence in many medical modalities.²⁵⁰ Many of the advances in mortality and morbidity we enjoy as a society are traceable to the effects of the public health authorities using sanitation, hygiene, and other public health measures.²⁵¹

²⁴⁶ See generally Sara Rosenbaum, *The Impact of United States Law on Medicine as a Profession*, 289 JAMA 1546 (2003); Sage, *supra* note 93, at 1706 (“For physicians, . . . having to give patients direct explanation of risks and benefits meant relinquishing exclusive professional dominion over practice.”).

²⁴⁷ See *supra* Part IV.A; Catherine Pastrokos, *Identity Theft Statutes: Which Will Protect Americans the Most?*, 67 ALB. L. REV. 1137, 1137 & n.2 (2004) (discussing access to information on the Internet).

²⁴⁸ See Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS: J. AM. ACAD. ARTS & SCI. 219, 226–27 (1969) (discussing how individual and societal health care goals may conflict); Schlesinger, *supra* note 109, at 200 tb1.1 (depicting society’s changing perception of medical authority).

²⁴⁹ See generally COMM. ON QUALITY OF HEALTH CARE IN AM., NAT’L ACADS., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 3 (Linda T. Kohn et al. eds., 2000) (“Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.”); Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies*, 279 JAMA 1200, 1202 (1998) (stating that more than 100,000 deaths a year are attributable to adverse drug reactions, making them between “the fourth and sixth leading cause of death in the United States in 1994”). A recent report by the Institute of Medicine indicates that at least 1.5 million serious injuries result from medication errors every year, and a hospital patient is subject to at least one medication error per day. COMM. ON IDENTIFYING AND PREVENTING MEDICATION ERRORS, INST. OF MED. OF THE NAT’L ACADS., PREVENTING MEDICATION ERRORS 3 (Philip Aspden et al. eds. 2007), available at <http://www.nap.edu/catalog/11623.html> (last visited Oct. 17, 2006) (uncorrected copy). The foregoing figures do not take into account errors of omission. *Id.*

²⁵⁰ See Safriet, *supra* note 150, at 305 (noting the “double dichotomy—between legal authority and clinical ability”); Blevins, *supra* note 185 (“Studies have repeatedly shown that qualified nonphysician providers—such as midwives, nurses, and chiropractors—can perform many health and medical services traditionally performed by physicians—with comparable health outcomes, lower costs, and high patient satisfaction.”).

²⁵¹ This idea was first promoted in the first half of the nineteenth century and was placed on a more empirical basis by Thomas McKeown in the 1950s and 1960s. See Bruce G. Link & Jo C. Phelan, *McKeown and the Idea That Social Conditions Are Fundamental Causes of Disease*, 92 AM. J. PUB. HEALTH 730 (2002) (noting and explaining McKeown’s thesis that recent mortality reductions were “due to improved socioeconomic conditions”). See generally GOSTIN, *supra* note 96, at 47 (“The biomedical model of record keeping and the societal need to explain a cause of death with a discrete medical condition distract the public from real contributors to mortality. . . . Seen in this way, the leading causes of death are environmental, social, and behavioral factors.”); John B. McKinlay & Sonja McKinlay, *The Questionable Contribution of Medical Measures to the Decline of Mortality in the United States in the Twentieth Century*, 55 MILBANK MEMORIAL FUND Q.: HEALTH & SOC’Y 405, 426 (1977)

Furthermore, socio-economic status is more highly correlated with the health of the population than either medical care, or access to medical care.²⁵² Science and technology in medicine are inherently dehumanizing, as they are based on a deterministic biochemical model of human life. On the same deterministic theory there can be no human dignity in medical science as a theory of life, and the theory of biology that underlies scientific medicine cannot support the existence of human rights or dignity—concepts that are based on human autonomy. There is widespread social desire to have access to schools of medicine that inherently respect dignity and human rights, are effective health care modalities, and do not require a medical degree to practice safely.²⁵³ This desire is manifested in the widespread use of CAM regardless of local MPAs that potentially illegalize the behavior. Under the universal scopes of practice the MDs are charged with regulating health care modalities—including other entire schools of medicine which they are not trained in—using philosophically dubious standards of evidence—based on unity of science or method claims and other scientific ideology that arose in the Progressive Era.²⁵⁴ Starting in

(writing “to dispel the myth that medical measures and the presence of medical services were primarily responsible for the modern decline in mortality”); *Progress in the Development of Humanitarian Institutions*, reprinted in 2 RUDOLF VIRCHOW, COLLECTED ESSAYS ON PUBLIC HEALTH AND EPIDEMIOLOGY 5 (L. J. Rather ed., Anne Gismann trans., 1985) (1860) (noting the “important requirement [for] the development of effective measures to combat the spread of sickness and suffering”). For a philosophical analysis linking unjust social conditions with health, see Norman Daniels, *Justice, Health, and Health Care*, 1 AM. J. BIOETHICS 2, 2, 6–8 (2001).

²⁵² See, e.g., Norman Daniels et al., *Justice Is Good for Our Health: How Greater Economic Equality Would Promote Public Health*, BOSTON REV., Feb.–Mar. 2000, available at <http://bostonreview.net/BR25.1/daniels.html> (“Health is produced not merely by having access to medical prevention and treatment, but also, to a measurably greater extent, by the cumulative experience of social conditions over the course of one’s life. . . . To avoid vague generalities about justice, we shall advance a line of argument inspired principally by the theory of ‘justice as fairness’ put forth by the philosopher John Rawls. . . . Rawls’s theory of justice as fairness was not designed to address issues of health care. He assumed a completely healthy population, and argued that a just society must assure people equal basic liberties, guarantee that the right of political participation has roughly equal value for all, provide a robust form of equal opportunity, and limit inequalities to those that benefit the least advantaged. When these requirements of justice are met, Rawls argued, we can have reasonable confidence that others are showing us the respect that is essential to our sense of self-worth. Recent empirical literature about the social determinants of health suggests that the failure to meet Rawlsian criteria for a just society is closely related to health inequality.”).

²⁵³ See Goldstein, *supra* note 2, at 926 (discussing the important role CAM has played in the United States and the strong desires Americans have to use CAM). For example, the Summer 2003 edition of the *Journal of Law, Medicine and Ethics*—written from a recent symposium on the topic—was devoted to the persistency of CAM. 31 J.L. MED. & ETHICS (2003).

²⁵⁴ See generally COMM. ON QUALITY OF HEALTH CARE IN AM. INST. OF MED., CROSSING THE

1975, the courts have used antitrust laws to limit the economic authority of the professions including the conventional medical profession.²⁵⁵ While the foregoing social or historical description goes to the due process and equal protection claims, it strongly implicates First Amendment issues as well, especially as informed by Article Eighteen of the International Covenant on Civil and Political Rights.²⁵⁶

The right to self determination or autonomy with regard to bodily integrity—while not a religious right—is of a different character than other rights—such as economic or property rights—as it touches fundamental notions of identity and well-being. Self-identity relates strongly to the body, and bodily well-being affects one’s entire sense of self. Drugs and other interventions are known to be able to influence one’s behaviors and spiritual, intellectual, mental, emotional, and physical self-images.²⁵⁷ That autonomy is circumscribed by one school of thought—the biochemical model of life—in such fundamental matters is inherently unjust and violative of basic human dignity. The forced adherence to one school of medicine by an unjust economic monopoly is no longer justified when measured against autonomy rights.

The right to bodily integrity necessarily includes the right to *maintain* bodily integrity. Autonomy means the right to maintain bodily integrity including the freedom of choice of how to maintain it, which means freedom to choose how to define one’s body and thus which theory to use to maintain it.²⁵⁸ If one sees his or her body as a biochemical event, he or she will choose to maintain it in accordance with conventional medicine. If he or she sees a non-

QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 14 (2001) (noting that it takes “[a]n average of about 17 years . . . for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then application is highly uneven”); Morreim, *supra* note 125, at 224 (“[T]he ‘outcomes studies’ that try to track the actual medical effects of these new technologies in clinical use are sometimes fraught with even greater problems of poor methodology, conflict of interest, and clinical unreliability.”); *supra* note 119.

²⁵⁵ The antitrust drama played itself out primarily in the health care financing and managed care area. *See, e.g.*, *Wilk v. Am. Med. Ass’n*, 895 F.2d 352, 378 (7th Cir. 1990) (holding that the AMA had violated antitrust law by an illegal chiropractor boycott); *Am. Med. Ass’n v. FTC*, 638 F.2d 443, 448 (2d Cir. 1980) (stating that the business acts of the AMA and state medical associations are subject to federal antitrust laws).

²⁵⁶ G.A. Res. 2200A (XXI), 55, U.N. Doc. A/6316 (Dec. 16, 1966).

²⁵⁷ *See generally* *Sell v. United States*, 539 U.S. 166, 185 (2003) (discussing the powerful effects of drugs).

²⁵⁸ *See, e.g.*, Damien Cave, *New York Plans to Make Gender Personal Choice*, N.Y. TIMES, Nov. 7, 2006, at A1; Thomas R. Frieden, Letter to the Editor, *Sex-Change Criteria*, N.Y. TIMES, Nov. 10, 2006, at A30 (“Forty-seven states already change the sex on the birth certificate for transgendered people.”).

reducible mind-body system, then he or she will maintain it using techniques consistent with that idea of body and self.

The universal scope of practice of the MPAs protects both economic and public health interests. Both of these interests should be evaluated by the strict scrutiny standard because the competing interest of self-determination—bodily integrity—is a fundamental right.²⁵⁹ The strict scrutiny standard requires a compelling state interest, that the means for meeting that compelling interest be strictly necessary to meet the end, and that there is no less restrictive alternative.²⁶⁰ Maintaining an economic monopoly for medical doctors is not a compelling state interest because it is not an interest that is truly vital to community well-being.²⁶¹ In fact, the history of the AMA and the state medical associations reveals a long-standing pattern of abuse of the public welfare when it comes between the profession and its economic income.²⁶² If the universal exclusive scope of practice was at one time a justified delegation of authority, an understandable provision of the social contract, it is no longer. Physicians have breached their public trust, their self-adopted but unenforceable ethical duty to the public,²⁶³ by profit-seeking behavior.²⁶⁴ Furthermore, most physicians no longer work for themselves, but are employees subject to contracts and resource distributions in which they do not have primary authority. They are no longer principles in medicine, but agents without the authority to bind their principles to, nor themselves comply with, the ongoing social contract of the scope of practice monopoly. There is no longer a social reason for the physicians' scope of practice to be universal or exclusive. Since all other health worker exclusive scopes of practice are in some way derivative from physicians', the argument can be generalized to conclude no health worker scope of practice should be exclusive.²⁶⁵ Ensuring safe health care practices is arguably a compelling state interest, but the means of providing a

²⁵⁹ See *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (“In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the ‘liberty’ specially protected by the Due Process Clause includes the right[] . . . to bodily integrity . . .” (citations omitted)).

²⁶⁰ *Andrews v. Ballard*, 498 F. Supp. 1038, 1052 (S.D. Tex. 1980).

²⁶¹ See Rosenbaum, *supra* note 246, at 1552–55; RODWIN, *supra* note 160, at 51 (“Despite the AMA’s contention that its code and principles of ethics promote the interests of patients, both were amended to reflect the economic interests of physicians.”).

²⁶² See generally RODWIN, *supra* note 160.

²⁶³ Rosenbaum, *supra* note 246, at 1547–52.

²⁶⁴ See generally RODWIN, *supra* note 160.

²⁶⁵ Professions can be distinguished by titles.

monopoly to conventional physicians is not strictly necessary to ensure public safety. The scope of practice monopoly creates a class of non-physicians that is over-inclusive because competent practitioners are excluded from practicing within the scope of their training. Finally, it is clear there are less restrictive alternatives—such as the regulatory schemes discussed in this paper—in which legal authority is directly commensurate to training.²⁶⁶ The economic interest of the medical profession should fall before the fundamental interest in self-determination.

Justice O'Connor, concurring in *Lawrence*, suggests that the economic underpinning of the MPAs can also be attacked using the Equal Protection Clause:

Laws such as economic or tax legislation that are scrutinized under rational basis review normally pass constitutional muster, since “the Constitution presumes that even improvident decisions will eventually be rectified by the democratic processes.” We have consistently held, however, that some objectives, such as “a bare . . . desire to harm a politically unpopular group,” are not legitimate state interests. When a law exhibits such a desire to harm a politically unpopular group, we have applied a more searching form of rational basis review to strike down such laws under the Equal Protection Clause.

We have been most likely to apply rational basis review to hold a law unconstitutional under the Equal Protection Clause where, as here, the challenged legislation inhibits personal relationships. In *Department of Agriculture v. Moreno*, for example, we held that a law preventing those households containing an individual unrelated to any other member of the household from receiving food stamps violated equal protection because the purpose of the law was to “discriminate against hippies.”²⁶⁷

Rational basis review requires that a regulation fulfill a legitimate government objective and that the means to attain the objective is reasonably related to the end.²⁶⁸ The creation of a monopoly with the exclusive language of the scope of practice statutes does not fulfill a legitimate government objective. The goal

²⁶⁶ See GOSTIN, *supra* note 96, at 77–83.

²⁶⁷ *Lawrence v. Texas*, 539 U.S. 558, 579–80 (2003) (O'Connor, J., concurring) (citations omitted).

²⁶⁸ *Id.* at 579.

of putting CAM practitioners such as chiropractors, naturopaths, and homeopaths out of business for both ideological and economic motives is not a legitimate government objective. The end of public safety is not reasonably met by the creation of a monopoly when it is abundantly clear that many other licensed and unlicensed practitioners can provide some of the restricted practices safely and that the monopoly restricts access to health care and adds tremendous costs to the health care system.

The foregoing is especially true given the increased autonomy rights of competent adults to make significant health care decisions, even if they lead to death, and given the well-documented danger, inefficiencies, and inappropriate paternalism of allopathic medicine²⁶⁹ as well as the extraordinary economic inefficiencies of the allopathic health care markets. Economic arguments are typically scrutinized under the rational basis test, and here—where the interests of the consumer, not the practitioner are being asserted—there is a chance the courts will allow increased access to the health care market by the consumer because there is no rational relationship between the economic restriction imposed by the MPAs and the end of public safety.

It is important to recognize and respect the role federal statutes play in the regulation of medicine. Although the practice of medicine is said to be regulated under the states' police powers,²⁷⁰ the federal government, acting through the Department of Health and Human Services and other governmental departments, plays an enormous role in the day to day regulation of health care providers by establishing standards of care,²⁷¹ regulating drugs,²⁷² and by spending half of every dollar spent in the health care system.²⁷³ The Federal Food, Drug, and Cosmetic Act (FDCA)²⁷⁴ often plays a key role in cases in which the right to self-determination could be

²⁶⁹ See COMM. ON QUALITY OF HEALTH CARE IN AM., *supra* note 254, at 26 (noting the large magnitude of medical inefficiencies and errors).

²⁷⁰ *Gonzales v. Oregon*, 126 S. Ct. 904, 923 (2006).

²⁷¹ For more information on the guidelines and standards enforced by the federal government, see Agency for Health Care Research and Quality, United States Department of Health & Human Services, Effective Health Care, <http://effectivehealthcare.ahrq.gov/aboutUs/index.cfm> (last visited Oct. 17, 2006).

²⁷² See *Gonzales*, 126 S. Ct. at 923 (“Congress regulates medical practice insofar as it bars doctors from using their prescription-writing power as a means to engage in illicit drug dealing . . .”).

²⁷³ Almost half of the total United States' health care budget is funded by the federal government. JUST HEALTH CARE, LABOR PARTY, LABOR PARTY BRIEFING PAPER 2 (2002), available at <http://www.justhealthcare.org/bp02.pdf>; see also Rosenbaum, *supra* note 246.

²⁷⁴ 21 U.S.C. §§ 301–97 (2000).

argued, such as when a health-care provider turns a substance into an unapproved drug by what he or she says about it.²⁷⁵ Although the policy justification for the FDCA is safety²⁷⁶—thus it is subject to the same kind of analysis—a test case would do well to avoid a fact scenario in which drug claims were being made because the use of science to demonstrate safety would be at best a complicated and confusing matter.

*E. Market Regulation and the Health Freedom Movement:
Voluntary Self-Regulation*

Proponents of the market theory of occupation regulation often describe their efforts as “consumer rights” movements for “health freedom.”²⁷⁷ At least eighteen states have “health freedom coalitions” or similar groups seeking to pass legislation that exempts CAM practitioners from the medical practice acts.²⁷⁸ Such

²⁷⁵ See generally *United States v. Rutherford*, 442 U.S. 544, 546 (1979) (presenting the issue of “whether the [FDCA] precludes . . . patients from obtaining . . . a drug not recognized as ‘safe and effective’”).

²⁷⁶ See *United States v. Gen. Nutrition, Inc.*, 638 F. Supp. 556, 561 (W.D.N.Y. 1986) (construing the Act’s “broad purpose” as “the protection of the public” and “to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce” (quoting *AMP, Inc. v. Gardner*, 389 F.2d 825, 829 (2d Cir. 1968))).

²⁷⁷ See, e.g., Kate Birch, Vice-President, North American Society of Homeopaths, President’s Address (Apr. 8, 2006), available at <http://www.homeopathy.org/updatearchives.html> (describing an encounter with a person who “has been helpful in showing [NASH] how to support health freedom rights to protect consumer rights and to best promote the profession of homeopathy”).

²⁷⁸ For a general understanding of different states’ policies, see Arkansas Health Freedom Coalition, <http://www.arhfc.org> (last visited Oct. 17, 2006); California Health Freedom Coalition, <http://www.californiahealthfreedom.com> (last visited Oct. 17, 2006); Colorado Coalition for Natural Health, <http://www.naturalhealth.org/colorado/index.html> (last visited Oct. 17, 2006); Florida Health Freedom Action, <http://www.floridahealthfreedom.org> (last visited Oct. 17, 2006); CAMAction, Inc. – Advocacy, <http://www.camaction.org> (last visited Oct. 17, 2006) (Georgia); Idaho Coalition for Natural Health, <http://www.naturalhealthidaho.org> (last visited Oct. 17, 2006); Iowa Health Freedom Coalition, <http://www.iowahealthfreedom.org> (last visited Oct. 17, 2006); Health Freedom Massachusetts, <http://www.healthfreedommassachusetts.org> (last visited Oct. 17, 2006); Michigan Natural Health Coalition, http://www.mnhc.info/mnhc_001 (last visited Oct. 17, 2006); Minnesota Natural Health Coalition, <http://www.minnesotanaturalhealth.org> (last visited Oct. 17, 2006); New Hampshire Citizens for Health Freedom, <http://www.nhhealthfreedom.org> (last visited Oct. 17, 2006); New Mexico Complementary and Alternative Medicine Project, <http://www.nmcaamp.org> (last visited Oct. 17, 2006); New York Natural & Complementary Practices Project, <http://www.nycpp.org> (last visited Oct. 17, 2006); Citizens for Health Care Freedom, <http://www.citizensforhealthcarefreedom.org> (last visited Oct. 17, 2006) (North Carolina); Health Freedom Coalition of Ohio, <http://www.ohiohealthfreedom.org> (last visited Oct. 17, 2006); Health Freedom Action Network, <http://www.oklahomahealthfreedom.org> (last visited Oct. 17, 2006) (Oklahoma);

efforts to pass legislation have been successful in Minnesota,²⁷⁹ Rhode Island,²⁸⁰ California,²⁸¹ Oklahoma,²⁸² and Idaho.²⁸³ The policy justifications for deregulating CAM practitioners are that (1) the modalities are safe; (2) governmental regulation of health care practitioners is not efficient²⁸⁴ and is unnecessarily intrusive;²⁸⁵ and (3) the market itself provides adequate regulation of quality.²⁸⁶ For a variety of historical and social reasons, a vocal and significant number of unlicensed homeopaths and CAM providers are against licensure—or professionalism—and would prefer to practice in an entirely unregulated CAM market.²⁸⁷

Tennesseans for Health Care Freedom, <http://www.tnhcf.org> (last visited Oct. 17, 2006); Wisconsin Health Freedom Coalition, <http://www.wihfc.com> (last visited Oct. 17, 2006). In addition to those states listed and those with existing legislation, there are unincorporated groups or individuals that have expressed strong interest in such legislation, bringing the total of states with some formalized interest to forty-two.

²⁷⁹ See MINN. STAT. ANN. § 146A.01(4) (West 2006).

²⁸⁰ See R.I. GEN. LAWS § 23-74-1(a)(3) (2005).

²⁸¹ See CAL. BUS. & PROF. CODE §§ 2053.5, .6 (West 2006).

²⁸² See OKLA. STAT. ANN. tit. 59, §§ 480, 492(F), 493.1(M) (West 2006).

²⁸³ See IDAHO CODE ANN. §§ 54-5101 to -5107 (2006).

²⁸⁴ Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Health Care Spending*, 11 YALE J. ON REG. 455, 471 (1994) (“There is very little evidence that licensure provisions have any significant effect on the quality of medical services. Similarly, professional review organizations seem to have little effect on the competence of practitioners. Hence, the whole structure of licensing may impose costs and no benefit.” (footnotes omitted)).

²⁸⁵ See YOUNG, *supra* note 109, at 1 (explaining the negative effects of occupational regulation); Blevins, *supra* note 183 (“Professional licensure laws and other regulatory restrictions impose significant barriers to Americans’ freedom of choice in health care.”); Safriet, *supra* note 150, at 305 (discussing the “wastefulness of many current, overly restrictive laws”).

²⁸⁶ For an introduction to the market model of regulation, see *supra* text accompanying note 134.

²⁸⁷ This conflict is exemplified in the field of naturopathy. There are two kinds of naturopaths. COMM. ON HEALTH CARE, FLA. H.R., SUNRISE REPORT ON PROPOSED LICENSURE OF NATUROPATHIC PHYSICIANS (2004) (Interim Project Rep.), *available at* <http://www.naturowatch.org/licensure/flasunrise2004.html>. One kind, who refer to themselves as “[n]aturopathic physicians” (NPs), attend four year post-baccalaureate colleges of naturopathy and seek to be licensed as primary care physicians. *Id.*; American Association of Naturopathic Physicians, Licensed States and Licensing Authorities, http://naturopathic.org/about_licensing.htm (last visited Oct. 17, 2006) [hereinafter AANP Licensing]. Fourteen states have licensing acts for NPs. AANP Licensing, *supra*. The second kind of naturopaths may or may not have attended a formal school and do not seek licensing. COMM. ON HEALTH CARE, *supra*. They refer to themselves as “[t]raditional naturopaths” and actively oppose licensing because it causes confusion in the eyes of consumers and because the modalities that require licensing are not proper naturopathy. *Id.* For more information on their position, see The Coalition for Natural Health, Licensing Natural Health Is Bad Medicine, <http://www.naturalhealth.org/agenda/license.html> (last visited Oct. 17, 2006). The State of Florida recently completed a report on the request for licensing by the NPs and came down on the side of the unlicensed naturopaths because naturopathy, among other things, is not dangerous. COMM. ON HEALTH CARE, *supra*. On March 8, 2005, the NPs reintroduced

For example, the traditional naturopaths and nutritional counselors oppose licensure of naturopathic physicians and dietitians for the following reasons:

Licensing makes the practices of traditional naturopathy and holistic nutrition counseling illegal.

An NP's education is accredited academically, not by the medical profession and their accrediting body, the American Medical Association's Liaison Committee on Medical Education (LCME).

Naturopathic physicians mix naturopathic and allopathic medicine without any sufficient medical training, hospital experience, or trauma education.

Licensed naturopathic physicians seek the status of primary care physicians without sufficient medical training. Dietitians seek the status of nutrition counselors without sufficient education in holistic nutrition.

Naturopathic physicians and dietitians advocate diagnostic care; traditional naturopaths and holistic nutrition counselors emphasize healthy lifestyle choices and wellness care.

Elevating NPs to primary care status will distort the practice and philosophy of true naturopathy, and will elevate the cost of consultation and natural substances to that of traditional medical pricing.

Consumers will no longer have access to traditional naturopathy consultants. Choices will be increasingly limited to special interest groups and low-tech, insufficiently-trained

their bill to the Florida legislature. H.R. 695, 2005 Leg., Reg. Sess. (Fla. 2005) (as originally filed), *available at* http://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?FileName=_h0695_.doc&DocumentType=Bill&BillNumber=0695&Session=2005. Another example that illustrates the antagonism towards positive regulation is occurring in the health freedom movement in New York. In the 2001 legislative session, the New York Natural & Complementary Practices Project, Inc. introduced Minnesota-style legislation to exempt CAM practitioners from the New York Medical Practices Act, in which an office within the department of health was created, and there were reporting and other requirements, including minimum disclosures; this was not successful. In 2003, the next legislative session, the group introduced California-style legislation; this was not successful. For the 2005 legislative term, the group introduced a registration bill under the department that would regulate state businesses. *See* S.B. 4790, 228th Leg. Sess. (N.Y. 2005). Vociferous opposition to the bill was voiced from homeopaths in many other states and Canada, and the National Health Freedom Coalition removed the New York group from its website. The opposition is based on the deep-seated mistrust held by three vocal community leaders of any government oversight. In time, the opposition prevailed and the proponent of the legislation reformed the bill by removing the registration requirements.

medical doctors.

Licensing dietitians as nutrition counselors will severely limit public access to such personal choices as macrobiotic foods, vegetarianism, organic and whole foods diets, and Ayurvedic nutrition.²⁸⁸

But in the text immediately before this list, the traditional naturopaths, represented by the Coalition for Natural Health (CNH), say that “[h]ealth freedom is about consumer choice, expanding existing scope of practice laws, and obtaining holistic insurance coverage.”²⁸⁹

The CNH and the National Health Freedom Coalition, advocacy groups and lobbying organizations, refer to consumers on their websites, but appear to work most closely with CAM providers.²⁹⁰ Consumer choice and the freedom to practice one’s way of making a living are economic concerns, but they are treated much differently under the law. Consumer choice can be understood to involve the fundamental constitutional right to self-determination and to bodily integrity. This makes it a very powerful concept when contemplating overthrowing existing or contemplated regulatory schemes because the strict scrutiny standard of review is triggered. On the other hand, the right of a person to practice a certain livelihood is based on an economic right—which tends to only trigger the rational review standard—rarely resulting in the regulation being overturned.²⁹¹

Health freedom movement rhetoric is atomistic and philosophically libertarian. The market for safe health practices, left to itself, will result in the maximum quality for the best price. Ignored by its advocates are the effects of competition on quality and the growth of the professions. There are several factors that could lead to loss of quality. First, if competition reduces profits, providers may respond by lowering standards because they are less involved in professional activities and lagging in professional knowledge. Second, less involvement in professional activities may erode collective agreements that are the basis of professional standards and undercut professional culture. Third, even if profits

²⁸⁸ The Coalition for Natural Health, *Licensing Natural Health Is Bad Medicine*, <http://www.naturalhealth.org/agenda/license.html> (last visited Oct. 17, 2006).

²⁸⁹ *Id.*

²⁹⁰ *See generally* The Coalition for Natural Health, *Mission*, <http://www.naturalhealth.org/about/> (last visited Oct. 17, 2006); National Health Freedom Coalition, <http://www.nationalhealthfreedom.org/> (last visited Oct. 17, 2006).

²⁹¹ *See supra* Part IV.D.

remain strong, market pressures could create incentives for specialization increasing fragmentation and undercutting the professional culture.²⁹²

The clearest example of the implementation of the market model is the California alternative healing arts practices legislation passed in 2003. The California Medical Practices Act was amended by addition of the following language defining the unlawful practice of medicine:

§ 2053.5. Actions that constitute unlawful practice of medicine

(a) Notwithstanding any other provision of law, a person who complies with the requirements of Section 2053.6 shall not be in violation of Section 2051 or 2053 unless that person does any of the following:

- (1) Conducts surgery or any other procedure on another person that punctures the skin or harmfully invades the body.
- (2) Administers or prescribes X-ray radiation to another person.
- (3) Prescribes or administers legend drugs or controlled substances to another person.
- (4) Recommends the discontinuance of legend drugs or controlled substances prescribed by an appropriately licensed practitioner.
- (5) Willfully diagnoses and treats a physical or mental condition of any person under circumstances or conditions that cause or create a risk of great bodily harm, serious physical or mental illness, or death.
- (6) Sets fractures.
- (7) Treats lacerations or abrasions through electrotherapy.
- (8) Holds out, states, indicates, advertises, or implies to a client or prospective client that he or she is a physician, a surgeon, or a physician and surgeon.

²⁹² White, *supra* note 132, at 857–58. For an argument based on free market principles against fundamental aspects of Canada’s universal health care system that was successful, see *Chaoulli c. Québec*, [2005] S.C.R. 791, ¶ 158 (“[T]he prohibition on obtaining private health insurance, while it might be constitutional in circumstances where health care services are reasonable as to both quality and timeliness, is not constitutional where the public system fails to deliver reasonable services. Life, liberty and security of the person must prevail.”).

(b) A person who advertises any services that are not unlawful under Section 2051, 2052, or 2053 pursuant to subdivision (a) shall disclose in the advertisement that he or she is not licensed by the state as a healing arts practitioner.²⁹³

This statute redefines the practice of medicine in California to be the undertaking of any of the listed actions which certainly makes sense.²⁹⁴ The listed actions are all instrumentally dangerous. On the other hand, properly labeled CAM practices are widely known to be safe, and this Act—properly evaluating and using this safety information—allows their practice by unlicensed providers. The combination of existing fraud and illegal practice of medicine laws with patient autonomy and increased access to medical information is a sufficient regulatory force. Other scopes of practice are still in place, and CAM practitioners cannot hold themselves out to be licensed in an area in which they do not hold licenses or to undertake practices subject to other exclusive scopes of practice, such as certain kinds of chiropractic adjustments, acupuncture, eye-care, veterinary practices, etc.

Unfortunately, legislative solutions to the scope of practice problem are few and the manifest unjustness of the imposition of economic motives into public health regulation continues to burden the health care system.

In the market model, lack of government-approved credentials could prevent entry of the practitioners into managed care markets.²⁹⁵ On the other hand, managed care represents a loss of autonomy for the practitioner. This is significant not only because of the avoidance of possible infringement on professional judgment, but also because many CAM modalities—especially homeopathy—cannot easily be shoehorned into statistical models or the conceptual models utilized in clinical practice guidelines.²⁹⁶

²⁹³ CAL. BUS. & PROF. CODE § 2053.5 (West 2006).

²⁹⁴ Compare this list with the list of controlled acts in the Ontario legislation which can be found in Part IV.C above.

²⁹⁵ See Eisenberg et al., *supra* note 18, at 971 (“More uniform . . . standards for licensing and credentialing of CAM providers could help . . . translate CAM therapies into standardized diagnostic and therapeutic codes for billing purposes.”).

²⁹⁶ See Practice and Policy Guidelines Panel, National Institutes of Health Office of Alternative Medicine, *Clinical Practice Guidelines in Complementary and Alternative Medicine: An Analysis of Opportunities and Obstacles*, 6 ARCHIVES FAM. MED. 149, 149 (1997) (“[C]AM practices currently are unsuitable for the development of evidence-based practice guidelines, in part because of the lack of relevant outcomes data from well-designed clinical trials. Moreover, the notions of standardization and appropriateness, inherent in guideline

The longest experience with the market model comes from Minnesota, which passed its health freedom legislation in 2000.²⁹⁷ The regulation established an Office of Unlicensed Complementary and Alternative Health Care Practice in the Department of Health to handle complaints.²⁹⁸ State officials have recently talked about closing the office because, in spite of rapidly growing use of CAM modalities, there have only been sixty-three complaints since 2001, and it costs \$65,000 a year to keep the office open.²⁹⁹ This suggests that claims of safety are empirically supported; however, the strength of the conventional medical profession's construction of the idea that CAM is unsafe is reflected by the comment of a nurse when interviewed on the potential closing of the office: "It's time to revisit [regulation of CAM], knowing that there are a lot of patient safety issues and that we have a huge population of people that are using these therapies," said Lori Knutson, director of Abbott Northwestern Hospital's Institute for Health and Healing in Minneapolis."³⁰⁰

Absent from the rhetoric of the health freedom proponents are the informational asymmetries first analyzed by Arrow that disadvantage the consumer.³⁰¹ The consumer in the formulations of the health freedom movement is the perfect rational maximizer of his or her utility.³⁰² Although it seems clear that Arrow's picture of the consumer—as someone not well-informed about health and medical care, having uncertain and infrequent demand for health services, a class of goods and services about which little can be learned because they are often one-time purchases (credence goods), who experiences non-health related externalities, and whose risk is only partially insurable—has evolved among contemporary

development, face challenging methodologic problems when applied to CAM, which considers many different treatment practices appropriate and encourages highly individualized care. Due to different belief systems and divergent theories about the nature of health and illness, CAM disciplines have fundamental differences in how they define target conditions, causes of disease, interventions, and outcome measures of effectiveness." For an introduction to the language of clinical practice guidelines, see generally National Guideline Clearinghouse, Glossary, <http://www.guideline.gov/resources/glossary.aspx> (last visited Oct. 17, 2006).

²⁹⁷ MINN. STAT. ANN. § 146A.01 (West 2006).

²⁹⁸ See *id.* § 146A.02.

²⁹⁹ See Lohn, *supra* note 98, at B11.

³⁰⁰ *Id.*

³⁰¹ See Jacobson, *supra* note 133, at 1165. See generally Arrow, *Uncertainty*, *supra* note 136 (discussing the informational asymmetries).

³⁰² See, e.g., Blevins, *supra* note 185 (stating how consumers rationally seek "the best deal for their dollar" in health care).

economists,³⁰³ the basic informational asymmetry has not disappeared for three kinds of health care and for at least one type of health care consumer: the patient.

Three types of health care have been distinguished:

- (1) [S]ervices that are purchased relatively frequently by most households, such as pediatric care, normal deliveries, prescription drugs for common conditions, and routine care for persons with chronic conditions;
- (2) services a typical provider produces relatively frequently but that a typical consumer can consume relatively infrequently, perhaps once a lifetime, such as gallbladder surgery;
- and (3) services that a typical producer produces and a typical consumer consumes relatively infrequently, which include experimental and unusual procedures, including most care undertaken in medical emergencies.³⁰⁴

Most health care services are of the first type and are purchased by consumers and clients. Medical services of the second and third types (credence goods) are ones in which the information asymmetry is strongest and suggest the need for some kind of market intervention.

Since Arrow's time, two major revolutions have coincided to change the characteristics of the consumer dramatically. The first is the emphasis on autonomy: the creation of a legal standard that recognizes patients as clients, if not consumers.³⁰⁵ The second is in the availability of information to support the client or consumer as an autonomous decision-maker.³⁰⁶ This, however, still leaves a certain area in which it is arguable that some kind of regulatory market intervention is required in the provision of dangerous or emergency care for life-threatening conditions.

Arrow understood the code of conduct to be part of the market response.³⁰⁷ If so—if it is the natural order to move from code of conduct to statutory self-regulation—then there is an argument that licensure is part of the market response to information asymmetry.

³⁰³ See Sloan, *supra* note 113, at 899–901, 906–09.

³⁰⁴ *Id.* at 904 (citing Mark V. Pauly, *Is Medical Care Different?*, in *COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE* 11–13 (1978) (Warren Greenberg ed., 1978)).

³⁰⁵ Informed consent supported by medical malpractice suits as a sanction for non-compliance with informed consent standards. See Sloan, *supra* note 113, at 906–07.

³⁰⁶ This includes the Internet, mandated disclosures by managed care organizations, and direct-to-consumer advertising. *Id.* at 908–09.

³⁰⁷ Jacobson, *supra* note 133, at 1166.

If this is the case, surely it is title licensure and non-exclusive scopes of practice that allow the conventional medical profession to maintain its monopoly causing even worse information asymmetries to prejudice the consumer.

The foregoing problems with continued information asymmetries suggest the pure market theory for health care does not work—all things considered—and thus, if the health freedom movement were seeking the removal of all regulation of health care providers, then there is a problem.³⁰⁸ But the health freedom movement, in its current form, is not seeking complete scope of practice reform, but merely the right of currently unlicensed practitioners of safe health care modalities to practice. This desire is consistent with existing policy justifications based on public safety, and, perhaps most importantly, it does not seek to remove any existing limits or regulations of health care providers. It maintains the safety mechanisms already at play in society for dangerous or emergency health care; however, for the professions under its umbrella, health freedom does not provide any incentives for quality control or improvement. This is not satisfactory for whole medical systems such as homeopathy,³⁰⁹ and at least a few occupations are actively

³⁰⁸ There are also persuasive arguments that market regulation of health care on a global scale not only does not work, but is a positive force for widespread violations of human rights and humanitarian norms. See, e.g., PAUL FARMER, *PATHOLOGIES OF POWER: HEALTH, HUMAN RIGHTS, AND THE NEW WAR ON THE POOR* 176–77 (2004) (“In the name of ‘cost-effectiveness’ we cut back health benefits to the poor, who are more likely to be sick than the nonpoor. . . . But how can we glibly use terms like ‘cost-effective’ when we see how they are perverted in contemporary parlance? . . . A compelling lexicon of social medicine must be linked to a return to social justice”); Edmund D. Pellegrino, *The Commodification of Medical and Health Care: The Moral Consequences of a Paradigm Shift from a Professional to a Market Ethic*, 24 *J. MED. & PHIL.* 243, 252 (1999) (“In a market-driven economy, commodities are fungible In this view of health care, physicians and patients become commodities, too. . . . The ‘quality’ of any group of patients is then measured by their profitability”).

³⁰⁹ There is something vaguely amoral and unacceptable about the atomism of pure market regulation, especially concerning something like health care that is intimately tied to socio-economic conditions. See Sloan, *supra* note 113, at 902–03. At least one economist has argued that because consumers are not rational and they do not make intellectually consistent decisions to maximize their utility, market intervention is required, and the best model for intervention is universal health care rather than a system based on individual provision of health services. See THOMAS RICE, *THE ECONOMICS OF HEALTH RECONSIDERED* 2–3 (1998) (arguing against the majority of American health economists who privilege market based health policies and contending that “one of the main reasons for the belief that market-based systems are superior stems from a misunderstanding of economic theory as it applies to health”). Altruism—the defining characteristic of the doctor-patient relationship—is considered an externality. Sloan, *supra* note 113, at 900. The socially desirable result from a market-oriented perspective is perfectly self-interested actors purchasing the products they most value, and manufacturers providing only those goods in the most cost-efficient manner. Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*,

seeking scope of practice legislation for their occupations.³¹⁰

The struggle between the pure market and professional models of regulation of health care providers is unlikely to go away or be resolved in the foreseeable future. There are no preparations at this time for a judicial solution, and at the current rate of legislative change it could take decades to pass exemptions from medical practice acts for unlicensed practitioners; although, there is some hope the key states of New York and Florida will have legislation passed within the next few years.

V. VOLUNTARY SELF-REGULATION BY HOMEOPATHIC COMMUNITIES

The homeopathic community is in a quandary. Many practitioners are forced to practice without the benefit of legal certainty because the community has simply not reached critical mass to attain enough political power or will to seek regulated status even as unlicensed CAM providers.³¹¹ This makes it hard to attract new practitioners and leads to perpetuation of the status quo.³¹² Voluntary self-regulation is the best option for the community.³¹³ This Article provides guidance to the community on

66 MO. L. REV. 341, 367 (2001).

³¹⁰ See, e.g., H.B. 44, 79th Leg. Sess. (Tex. 2005) (proposing regulation of clinical nutritionists).

³¹¹ Note that a group of homeopaths in Arizona, led by a medical doctor, are investigating opening a homeopathic medical school modeled on the larger naturopathic medical schools and is seeking legislation that would allow its graduates to be licensed to practice homeopathy in Arizona. See TODD ROWE & THELMA ROWE, WE HAVE A DREAM: THE GROWTH OF A HOMEOPATHIC PROFESSION: WATCHING HOMEOPATHY GROW (2004), available at <http://www.weppracticehomeopathy.com/library/We%20have%20a%20dream.pdf>.

³¹² Kelner et al., *supra* note 126, at 86 (discussing the problems associated with the “lack of cohesion [among and between CAM groups which] constitutes a significant obstruction to integrating CAM therapies into the overall system of health care”). *But see id.* at 82 (“Recognition by the state has often required reduction or modification of the profession’s original goals or modes of practice, medicalization of their approach, or acceptance of a limited or subordinate role in the system of health care.”).

³¹³ Another option for the homeopathic community would be to seek federal legislation similar to that passed with regard to mammography. Congress has established national quality standards for mammography. 42 U.S.C. § 263b(b)(1) (2000). Congress mandates that facilities who provide mammography services after October 1, 1994 be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services. *Id.* The Secretary is authorized to delegate its authority to approve accreditation bodies, certify facilities, and establish quality standards. *Id.* § 263b(a), (d), (e). The homeopathic community could seek a congressional act in which the Secretary is authorized to accredit those who use homeopathic drugs. This authority could be delegated to the Homeopathic Pharmacopœia of the United States (HPUS). HPUS could in turn use the certificate issued by CHC as the qualification for using homeopathic drugs. This would not confer the authority to practice medicine under state law, but since homeopathic remedies are instrumentally safe and the model of homeopathic treatment is so different from allopathy that it does not fit

how to organize.

Voluntary self-regulation has well-described advantages and disadvantages.³¹⁴ In general, proponents like its “ability to form and communicate values, to reflect current knowledge, and to foster voluntary compliance” while critics “maintain that professional standards are too often a guise for self-protection . . . that enforcement . . . is lax” and that there is the “possibility of selective enforcement, bias, and double standards.”³¹⁵

Each CAM modality, especially homeopathy, should work towards having one voluntary self-regulatory organization in each state, although it is better to have multiple organizations rather than none, and, for low population states, it may make sense to begin with regional organizations.³¹⁶ The organizations should strive for the following characteristics:

- i. A single independent registering body funded by registration fees.
- ii. A governing council made up of a balance between members of the profession democratically elected by their peers and appointed non CAM or lay members to supplement the skills of the professional members and represent the views and needs of consumers. The lay members should comprise at least one third of total membership.
- iii. Agreed standards of training and minimum levels of clinical competence.
- iv. Evidence of continuing professional education and development as a prerequisite for continued retention on the register.
- v. Evidence of adequate levels of professional indemnity insurance should be required for maintaining annual renewal of registered status.
- vi. Publication, dissemination and enforcement of an appropriate code of practice and ethical guidelines which set

under some MPAs, it would confer enough authority to satisfy state and public concerns for informational safety.

³¹⁴ See Priest, *supra* note 136, at 268–74 (explaining the advantages and disadvantages of voluntary self-regulation).

³¹⁵ Agrawal, *supra* note 309, at 400–01.

³¹⁶ The Prince of Wales’ Foundation for Integrated Health has recommended that “[a] single, lead, voluntary, self-regulatory body should be established for each of the CAM professions and therapies.” UK Healers, Integrated Health Care: A Way Forward for the Next Five Years?, <http://www.ukhealers.info/Press1.htm> (last visited Oct. 17, 2006).

out a practitioner's responsibilities and duty of care to patients.

vii. Publication and dissemination of disciplinary procedures and establishment of appropriate fitness to practice mechanisms including investigation, professional conduct, health and appeals jurisdictions.

viii. Provisions for professional conduct committee hearings normally to be held in public.

ix. An accessible, supportive and published mechanism for dealing sympathetically and effectively with complaints about practitioners from members of the public.

x. Provision of effective enforceable disciplinary sanctions and publication of the findings of professional conduct committees.

xi. The publication of patient information leaflets explaining the scope and limitations of the particular treatments or therapies together with an explanation of what standards of care patients should expect from practitioners.

xii. Publication of an annual report setting out the organisation's main activities and audited accounts.³¹⁷

In addition to the aforementioned, there should be a mechanism to ensure that providers outside of the practitioner community who use the regulated modality be trained to minimum levels of competence as determined by the profession, perhaps through an ancillary certification.³¹⁸

The aforesaid recommendations occur in a regulatory environment in which there are structures for increased governmental involvement in the voluntary self-regulation model and are clearly designed for a larger group. Nonetheless, they set an inspirational standard for any voluntary self-regulating community of CAM practitioners.

As manifested in the United States, such an organizational structure directly references two other types of organization: (1) a certifying body; and (2) an accrediting body for schools and educational programs. As mentioned, the CHC—the certifying body—is fulfilling its purpose well, but the Council for Homeopathic Education—the accrediting body—is hobbled.

³¹⁷ *Id.*

³¹⁸ *Id.*

The situation with a national trade organization is somewhat more complicated. Ideally, a trade organization that represents all practitioners, regardless of training, is desired for the purposes of identifying, developing, and expressing the political will of the community; however, there are no existing trade organizations that fit the bill.

The National Center for Homeopathy (NCH) has the greatest membership without regard to training, but it does not see itself as a trade organization. Rather, NCH sees itself as serving an educational and outreach function to all persons—practitioners or not.³¹⁹ It is organized as a 501(c)(3) tax exempt organization,³²⁰ which is not optimal for a trade organization.

The CHC—a 501(c)(3) tax exempt organization—although functioning as the dominant certifying body, has some trade organization functions.³²¹ This is understandable in the absence of a national trade organization; however, it represents potential areas of conflict with a trade organization that will have to be resolved. It does not see its primary function as a trade organization.

NASH—a 501(c)(6) “business league” type of organization³²²—was formed to represent the interests of the unlicensed homeopaths in the tradition of the registry system found in the United Kingdom.³²³

³¹⁹ See National Center for Homeopathy, Welcome! to the NATIONAL CENTER FOR HOMEOPATHY, <http://homeopathic.org/index.html> (last visited Oct. 17, 2006).

³²⁰ 501(c)(3) organizations cannot lobby, whereas other 501(c) organizations can. INTERNAL REVENUE SERV., U.S. DEP'T OF TREASURY, TAX-EXEMPT STATUS FOR YOUR ORGANIZATION 17 (2005), available at <http://www.irs.gov/pub/irs-pdf/p557.pdf>.

³²¹ See generally Council for Homeopathic Certification, Our Mission, <http://www.homeopathicdirectory.org/mission.php> (last visited Oct. 17, 2006) (presenting the CHC's mission which resembles those of trade organizations).

³²² The 501(c)(6) “business league” type of organization is for trade organizations. See Internal Revenue Service, Business Leagues, <http://www.irs.gov/charities/nonprofits/article/0,,id=96107,00.html> (last visited Oct. 17, 2006). For more information on 501(c)(6) organizations, see JOHN FRANCIS REILLY ET AL., IRC 501(c)(6) ORGANIZATIONS (2003), available at <http://www.irs.gov/pub/irs-tege/eotopick03.pdf>.

³²³ The homeopathic community in the United Kingdom is undergoing a consolidation process “within the wider context of a European and world-wide emergence of a new profession of homeopaths.” COUNCIL OF ORGANISATIONS REGISTERING HOMEOPATHS, THE STORY SO FAR: REGULATION: THE HOMEOPATHY PERSPECTIVE 1, available at <http://www.corh.org.uk/pubs/TheStorySoFar.pdf> (last visited Oct. 17, 2006). Except for licensed practitioners who have homeopathy in their scope of practice, homeopathy in the United Kingdom is regulated under the common law. *Id.* There are currently nine registries in the United Kingdom for unlicensed and licensed non-physician homeopathic practitioners. *Id.* at 4. In a November 2000 report on CAM, the House of Lords Select Committee on Science and Technology recognized that homeopathy was one of “the big 5” that was eligible for statutory self-regulation. *Id.* at 2. It further recommended that, in the interest of better regulation, each therapy should have a single voluntary self-regulatory body. *Id.* With regard to that end, the homeopathic community and its existing organizations formed the

It immediately was in conflict with CHC as a certifying body. In time, NASH adopted the CHC certification as the educational qualifier for membership and opened its doors to licensed practitioners; however, there continues to be deep suspicion of the licensed community among a significant number of unlicensed practitioners. This is reflected in the membership and politics of NASH, which still sees itself as primarily an organization for unlicensed practitioners.³²⁴ Its yearly conferences are poorly attended; as of September 2006, only seventy-five votes were counted in an election that included—as one of its key issues—the question of whether the reinstatement fee for lapsed registered voters should be reinstated.³²⁵

NASH has other impediments to serving as a national trade organization. As a national organization, it does not “see” its members as citizens of states each with a different regulatory process. Although some proposed health freedom legislation includes provisions to expand the scope of practice of licensed practitioners to include the modalities covered in the bill, NASH has aligned itself with the health freedom movement which does not directly benefit licensed practitioners.³²⁶ None of this legislation has been enacted, though. If NASH is to be the trade organization for the community, then it must have policies to address and allocate resources between licensed and unlicensed practitioners, each with their different legal needs. It must also recognize that each state regulates health care differently and that one policy does

Council of Organisations Registering Homeopaths which has received significant help from the Prince of Wales’ Foundation for Integrated Health. *Id.* at 1, 4. The Foundation helped place a highly experienced executive in the Council to assist its efforts. *Id.* at 4. Although there have been some predictable roadblocks related to membership status for those with less education, to date, the Foundation has made considerable progress in establishing a unified registry for homeopaths. *Id.* NASH operates in a regulatory and social environment radically different from that found in the United Kingdom, and without significant soul-searching NASH will never develop as an effective organization.

³²⁴ See North American Society of Homeopaths, Directory of NASH Registered Homeopaths (2006), <http://www.homeopathy.org/directory.html>.

³²⁵ North American Society of Homeopaths, NASH Member Update (2006), <http://www.homeopathy.org/update.html>. “In December 1998, NASH ha[d] only 60 registered members.” WINSTON, *supra* note 16, at 496.

³²⁶ NASH’s website states its political agenda is to “[l]egitimize homeopathy as a profession through a strong political voice.” North American Society of Homeopaths, Our Goals (2006), <http://www.homeopathy.org/goals.html>. New leadership has just been installed and the new president, Manfred Mueller, has a history of working for health freedom legislation, suggesting the policy with regard to legislative priorities will continue in the same vein. North American Society of Homeopaths, NASH Board Members, <http://www.homeopathy.org/board.html> (last visited Oct. 17, 2006).

not fit all. NASH has not done—and does not have—any of these things.

There are no other trade organizations with open membership. The American Institute of Homeopathy is for MDs, DOs, dentists, advanced practice nurses, and physician's assistants.³²⁷ It is not perceived to be a strong organization, and its yearly conferences are poorly attended. The Homeopathic Academy of Naturopathic Physicians likely has more than thirty naturopathic doctor members and is not considered to be a national trade organization.³²⁸ The membership of the veterinarian organization³²⁹ is not open to all and has small memberships.

I recommend that the community—rather than focusing on building a national trade organization—focus on organizing state-wide 501(c)(6) trade groups. In this model of voluntary self-regulation, the organizations model that of a licensed profession, but there would be no delegation of authority by the state to the organization. The organization would require its members to agree to the code of ethics and standards of practice—including continuing education and a complaint procedure—adopted by the organization.³³⁰

There is a tremendous variation in the training of providers who call themselves homeopaths,³³¹ but for an initial period of time everyone who called themselves a homeopath would be invited to join. Since the standards of practice call for annual continuing education of certain standards, in time, members would move towards having the same minimum competencies. After the initial period, guidelines for membership should be developed based on minimum competencies that are less than CHC certification. The diversity of training of members could be handled by encouraging

³²⁷ American Institute of Homeopathy, About the AIH, <http://www.homeopathyusa.org/> (last visited Oct. 17, 2006).

³²⁸ See HOUGH ET AL., PROFILE OF A PROFESSION, *supra* note 77, at 77 & n.19, 80 & tbl.21 (depicting the national professional trade associations and stating that the number of naturopaths is tough to calculate).

³²⁹ There are about thirty-six veterinarians certified by the Academy of Veterinary Homeopathy. See The Academy of Veterinary Homeopathy, Certified Veterinarians, <http://www.theavh.org/referral/certifieds.php> (last visited Oct. 17, 2006).

³³⁰ Annex A to this Article is a model code incorporating the concepts described herein.

³³¹ Compare American Medical College of Homeopathy, <http://schools.naturalhealers.com/disch> (last visited Oct. 17, 2006) (stating that the American Medical College of Homeopathy offers a three year program, with a full one-third of the training dedicated to clinical study), with Institute of Classical Homeopathy, <http://schools.naturalhealers.com/instch> (last visited Oct. 17, 2006) (stating that the Institute of Classical Homeopathy's program entails four years of study with a heavy concentration on the philosophy of the classical practitioners).

specialty groups within the organization. The goal is that within a certain period of time—four or five years—the public and the state could be assured that members of the state organization have minimum competencies that can be determined from the website and from the disclosures required in the informed consent statement signed by all clients.

The standards of practice include a complaint procedure. Currently, there is no readily discernable complaint process in place by any national organization. NASH and CHC have codes of ethics—and their bylaws provide for a complaint process—but there is no enforcement of these standards, the complaint process is not available on any website, and there is no requirement it be disclosed to the client.³³² In fact, the health freedom advocates have argued against a complaint process when it is contained in proposed health freedom legislation.³³³

Not having a clearly articulated complaint process is unwise. This sends a message to the public and the state that homeopaths are not organized and, although there are standards of competency through CHC certification, there are no ethics or standards of practice. If there is a state-wide organization and it has a complaint procedure, then only the most serious complaints would make it into the judicial or administrative systems where they belong.³³⁴

³³² See Council for Homeopathic Certification, Certification Exams (2005), <http://www.homeopathicdirectory.com>; North American Society of Homeopaths, Code of Ethics and Rules of Practice (1999), http://www.homeopathy.org/CodeofEthics_Jan99_May04.doc.

³³³ See generally North American Society of Homeopaths, NASH Member Update (2005), <http://www.homeopathy.org/updatearchives0905.html> (explaining that NASH opposes any legislation that restricts its members' rights to practice).

³³⁴ For example, I recently heard a story in Texas about an unlicensed practitioner who had several customers that were unhappy about their records and billing habits. The clients had all ended up complaining to a health activist in the city where the clients and practitioner lived. The activist heard these complaints from several clients, but had no ability to do anything and ended up complaining to the local police department. The police department has an investigator that only handles medical complaints. Shortly after the complaint was made to the police department, I, as President of the Texas Society of Homeopathy, heard from one of the clients. I questioned the client about the problem, called the activist, and questioned them about the complaints. I determined that the complaints were not about medical issues, and, in fact, the clients were pleased with the health services they had received. They were unhappy with aggressive billing policies and with the refusal to give copies of the records to the client so they could go to another practitioner. After determining the nature and scope of the problem, I suggested to both of them that I try resolving the complaint, but without the threat of police action. The activist agreed and left the investigator a message and explained that the community was going to handle the problem itself. I called and left a message explaining the same thing. I then called the practitioner and explained the situation and my intentions to resolve the problem without police intervention. The practitioner was very grateful and resolved the problems within two days.

This model is for use if there is health freedom legislation or not, since health freedom legislation typically only allows the practice and requires minimal disclosures. It leaves regulation of the professions to the practitioners themselves.

The state is the natural level of organization for political work. Practitioners within a state have more in common than practitioners of the same credentials in different states because they practice in the same legal environment, their resources for education of the public and lawmakers will be more efficiently joined, and they are geographically and culturally part of the same community. This will move the focus of attention of the communities away from national and international teachers³³⁵ and toward local resources and concerns for the community. It will enable the identification of political or legislative goals, the development of political will, and the manifestation of community spirit in the larger health care and social environments. In addition, it will serve to protect public health by promoting the adoption of standards of practice, care, and ethics—the formal articulation and adoption of which will promote vigilance in adherence. Further, it will protect the community of practitioners from law enforcement, as the departments of health and other agencies with investigative powers will have a well-defined community with which to interact.

With regard to accreditation of schools and educational programs, although standards have been promulgated within the national community, they have not been disseminated or adopted widely in the educational community.³³⁶ Until CHE begins to function, each state organization should accept CHC certification as evidence of sufficient education for its certificate holders. A grandfathering period of two to five years should give enough time and experience for state organizations to determine an appropriate policy in the event CHE is not functioning. State organizations can pressure NASH and the national unlicensed community to support the

No word has been heard from local authorities.

³³⁵ The development of the “guru-mentality” interferes with homegrown educational programs and business. WINSTON, *supra* note 16, at 395. Famous homeopaths from abroad come into a community, give multi-day seminars, and book patients at rates much higher than they are able to charge in their country of residence. *Id.* at 393. They contribute nothing to the development of local communities of practitioners or clients. *See id.* at 397 (explaining some of the problems associated with homeopaths from abroad).

³³⁶ *See* HOUGH ET AL., PROFILE OF A PROFESSION, *supra* note 77, at 45 (stating that the U.S. Department of Education does not currently recognize any “accrediting body for naturopathic medicine programs”).

functions of CHE and, ideally, it will begin to function in the next few years.

With the exception of the CHC, reorganization on a state-by-state basis will take resources from national organizations. This is as it should be, since the resources will work harder for the homeopath at the state level. As state organizations get stronger and income improves as a result, stronger, better focused national organizations will result.

VI. CONCLUSION

From the point of view of regulation of the professions, CAM can be called “common-law medicine.” It is instrumentally safe and—at least in the legal order—the issues surrounding efficacy are more a red herring for the “therapeutic reformers” of conventional medicine than anything else.

Is any kind of statutory regulation called for? Absent widespread scope of practice reform, minimal regulation is necessary to remove the threat of criminal action in states that do not have health freedom-type legislation. The threat of criminal action with regard to CAM practitioners is purely a result of the economic motivations of the conventional doctors and their lobbying organizations—especially the AMA. Doing away with this aspect of the medical practice acts will only benefit society as it frees markets and brings the regulatory system in line with what is happening on the street thus conferring legal authority on the tens of thousands of CAM practitioners that are practicing without statutory protection. It must be remembered that minimal regulation—in the form of a California-style exemption from the medical practice act—would be occurring in the context of many regulated health professions. In addition, such legislation would not serve to introduce any instrumentally dangerous modalities nor lead to CAM practitioners seeing patients in life-threatening emergencies. Rather, CAM practitioners would see consumers, clients, and competent patients. In addition, incompetent or very vulnerable patients would be routed to appropriate care by health care providers licensed for that appropriate care.

Of the three regulatory models—market regulation, self-regulation, and bureaucracy—it is clear bureaucracy is inappropriately absent from a universal health care system. The pure market approach has merit. What empirical data exists from the five states that have some kind of health freedom legislation

suggests there are very few complaints, and Minnesota is considering closing its complaint office because there are not enough complaints to justify the expense.³³⁷ The market approach can be implemented by a California-style exemption from the medical practice act that includes a requirement for disclosure to offset information asymmetries. However, the pure market approach does not adequately address quality issues—especially with regard to more established whole health systems—as it encourages an atomistic libertarian philosophy. This thereby obviates the benefits that flow from communal activities of practitioners, such as standard setting and other acts that would serve to make the public confident in the professions. The pure market approach may be appropriate for some CAM modalities, but I suggest it is detrimental to such whole medical systems as homeopathy.

Self-regulation comes in essentially two flavors: statutory and voluntary. Statutory regulation for CAM practitioners has been rejected by some states—for example Florida—because it is instrumentally safe.³³⁸ However, some CAM groups are currently seeking licensure so they can practice legally or so they can practice modalities—such as surgery—that are not instrumentally safe.³³⁹ Apart from the professionals that want to practice dangerous modalities, the drive for statutory protection must be attributed to the existence of the universal exclusive scope of practice of the conventional physicians. If medical pluralism is to be valued, then most groups that want licensure should seek title protection only, and not a monopoly-making act with an exclusive scope of practice.³⁴⁰

I believe that for homeopathy the value of statutory self-regulation as a policy goal must be evaluated on a state-by-state basis. In most states there are not enough homeopaths, organization, political will, or resources to pass a title act. On the other hand, in both health freedom states and states that already regulate homeopathy, there may be some justification for considering a title bill. This is occurring in Arizona.³⁴¹

³³⁷ See Lohn, *supra* note 98, at B11.

³³⁸ See COMM. ON HEALTH CARE, *supra* note 287.

³³⁹ HOUGH ET AL., PROFILE OF A PROFESSION, *supra* note 77, at 4, 33.

³⁴⁰ For example, in Texas, the “clinical nutritionists” have filed bills regularly for the past few years seeking an exclusive scope of practice for “clinical nutrition” that is drafted so broadly it would stop many other groups from giving nutritional advice, a staple of many different kinds of CAM. See H.B. 44, 79th Leg. Sess. (Tex. 2005).

³⁴¹ See Rowe & Rowe, *supra* note 311.

California is another state in which title licensure could be justified. The justification stems from grounds that title licensure enhances the reputation of the profession and opens doors to increased involvement of homeopaths in the larger health care system. As of today, however, there is no movement in that direction. This is because homeopaths have had legal authority to practice in California for almost two years. It should be considered a natural development—if homeopaths were a cohesive community—since it does not harm health freedom and it confers benefits on all practitioners. It may be that there has not been enough time for the community of homeopaths to grow strong enough; however, I suggest there is more fundamental impediment: a lack of community.

There is much talk and identification of the value of community, but in the struggle between libertarian self-centered practice and the sacrifice of the individual desires of communal life, the libertarian goal wins out. I do not see this as a moral failing, but rather as a socially-determined mind-set arising from the intense “scientific” and “medical” discrimination against homeopathy. This discrimination stems from the mindset that (1) homeopathy is a non-technological modality that can be well-learned by any intelligent person regardless of licensure or academic training; (2) doctors—given legal independence—tend to be individualists; and (3) the legacy of Hahnemann, a notoriously difficult personality.

I think an important part of the development of the homeopathic community, and other similarly situated CAM communities, is voluntary self-regulation on a state-by-state basis. Optimally, it would occur within the context of an exemption from the medical practice acts, but this is currently impossible in forty-five states. Homeopaths should simply begin self-regulating by contracting among themselves to practice according to agreed-on norms. In states in which there is no explicit legal authority to practice voluntarily, self-regulation can only be viewed as an attempt to fulfill the policy requirements of the state. This all occurs with regard to regulation of a similarly situated occupation in the absence of distortions in the regulatory environment caused by scope of practice monopolies.

The information asymmetries—regardless of whether they are considered from the legal, political, social, moral, or economic orders—must be addressed. Health freedom advocates do not explicitly address them and seem to suggest that a complete

absence of regulation is acceptable. I disagree with this strong libertarian position. As a matter of fact, no exemption from a medical practices act has been passed or proposed that does not include mandatory disclosure as a condition of the exemption. The disclosure mandates are both appropriate and sufficient given the safety of the regulated conduct. Although there may be thousands of unregulated practitioners practicing “bare” in many states, in states where there is no exemption, there is likewise no mandated correction to the information gap.

Codes of conduct are an appropriate response by the community to the information disparity. Whether one argues that voluntary self-regulation is a result of market pressures or is a paternalistic move by a profession that aims for full statutory self-regulation, there can be no argument that it would not increase public confidence and serve a valuable public health function. Because voluntary self-regulation is not in wide use, it may be appropriate to include provisions in the disclosure mandates of health freedom legislation that encourage—or require—communities of CAM practitioners to organize around a code of conduct. For example, the mandate could require that within a reasonable time after the enactment of the statute, the informed consent statement must include the disclosure of membership in a trade organization that requires compliance with a code of conduct, a complaint resolution procedure, and continuing education as conditions of membership. In addition, a phone number that handles complaints for members of the trade organization should be in place. Such a mandate puts the entire burden of self-regulation on the community. The checklist developed by the Prince of Wales’ Foundation for Integrative Health—although developed in a somewhat different regulatory environment—provides a thorough and reasonable norm for a fully functioning, voluntary, self-regulating profession.³⁴²

CAM practitioners should pursue a two-pronged approach to achieving professional standing. In all cases they should engage in voluntary self-regulation, organizing and adopting a code of conduct, including a transparent complaint process and educational and competency standards. This is especially true of homeopathy, as it is the only major whole medical system that is not well-organized. Unlicensed practitioners should seek California-style exemptions from the medical practice acts in their states, but

³⁴² See UK Healers, *supra* note 316.

should understand that voluntary self-regulation is an important aspect of providing quality health care and engendering trust and respect from society. Licensed CAM practitioners should seek changes to their scope of practice acts, or seek riders in the California-style exemptions that would expand all scopes of practice to include CAM for trained practitioners.

The particular analysis of how best to integrate unlicensed practitioners into the health care system illustrates how the different values of the economic order and the social or moral order come into conflict because they each represent different linguistic, moral, and normative functions. They are incommensurate in means and ends although they meaningfully inform each other.³⁴³

The movement of the person seeking health care from status as a patient to that of a consumer gives rise to ethical and thus legal dilemmas. Clearly a physician owes a patient a fiduciary duty: an obligation to act only in the patient's best interest respecting the vast knowledge disparity between physician and patient. However, what about the consumer with one or more chronic conditions who shops around for the least expensive doctor for routine care that is well understood by the consumer? Should the physician be considered anything other than a merchant with regard to that consumer? The same can be said for persons who seek enhancement of their physical or mental states: they are consumers—not clients or patients—seeking heavily advertised services on the open market. Is advertising alone enough of a measure to treat the purchaser of medical care as a consumer?

As the doctor-patient relationship moves from the social order to the economic order, do the outcomes of ethical analysis change? Is there a need to overlay the fiduciary duty on the provider in that case, or will ordinary contract or fraud principles suffice? The ends of economic activity are profits, whereas the ends of social or moral medical activities are altruistic. The incursion of the economic order—the profit motive—into the social or moral order results in very serious issues for individual physicians,³⁴⁴ managed care

³⁴³ The dichotomy or incommensurability described here echoes that found in other domains. In science, it references the problem of how to relate the statistical law of the group to the individual seeking health care, the unity of science problem, and reductionism. Philosophically, it is the problem of the one and the many, of rationalism versus empiricism, or the problem of induction. Ethically, it is the problem of utilitarian versus deontic principles. In legal theory, it is related to positivism versus natural law theory.

³⁴⁴ See generally *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (stressing the importance of having a physician reveal his or her “personal interests unrelated

organizations,³⁴⁵ and governmental institutions.³⁴⁶ Should the system be reformed into clearly defined types of provider or medical care along axes of instrumental or informational danger, for patients, clients, or consumers being treated by individual providers or managed care organizations? A move in this direction has started with self-care for consumers with chronic disease,³⁴⁷ but more clarification is certainly needed. Analysis along these lines may lead to new solutions to the distributive justice problem arising from limited health care resources.

In the social order, duties are imposed on the health care provider as a result of ethical analysis of the doctor-patient relationship. But the ethical analysis and legal duties are based on the safety and power disparities of a relationship structure that was formalized in its strongest form in the 1950s. The ethical status of the person seeking health care started changing in the late 1960s, and now that person is autonomous and no longer the automaton. Also, in the meantime, the social status of the physician has undergone transformation as new social institutions—such as Medicare, managed care, and CAM—have asserted themselves. They not only have considerable regulatory, political, and economic power, but their jurisdiction over health care in many significant areas is stronger than and overlaps that of the physician. It may not be that physicians have lost power as a result of these large institutions vis-à-vis the patient, but their relative power has been significantly diminished. As a result of the new social institutions and the increased autonomy, new categories of persons seeking health care have arisen. The relationship of clients and consumers to physicians—conventional, corporate, and CAM—is not covered by the conventional ethical analysis of the doctor-patient relationship. Doctor Welby—if he ever existed—is certainly deceased now.

Economics and the law and economics movement have informed a stream of ethical analysis based on utilitarian ethical principles applied to the non-existent—but overworked—rational maximizer of

to the patient's health, whether research or economic, that may affect the physician's professional judgment").

³⁴⁵ See generally Clark C. Havighurst, *Starr on the Corporation and Commodification of Health Care: The Sequel*, 29 J. HEALTH POL. POL'Y & L. 947, 948–49 (2004) (identifying money as a large factor in the corporatizing of American medicine).

³⁴⁶ See generally Ned Feder, *NIH Must Tell Whole Truth About Conflicts of Interest: Little Has Yet Been Disclosed About a Consulting Spree That Has Left a Legacy of Harm*, 434 NATURE 271, 271 (2005) (discussing the problems associated with United States National Institute of Health scientists "serving as paid consultants to private companies").

³⁴⁷ See White, *supra* note 132, at 858, 862.

utility, the consumer, the producer of goods and services, and the health care merchant.³⁴⁸ Arrow identified many complicating factors that characterize the consumer's weaknesses in the market—his inutilities—but these factors were based on the now limited doctor-patient relationship of the 1950s. Sloan, Jacobson, and other commentators have worked at the problem of updating Arrow, but the nuance of their arguments is hindered by not considering market models based on consumers, clients, and scope of practice reform. That is, although there is recognition of the consumer and discussion of the meaning of the consumer, there continues to be a conceptual unity in categorizing the person who seeks health care. They are either consumers or they are patients. Unless the distinctions between the types of people seeking health care are recognized and the rhetoric of the conventional doctors that makes all non-conventional physicians second-class providers is neutralized, realistic consideration of scope of practice reform does not make much sense. The rhetoric and the propaganda of the conventional medical profession are so powerful that many in the academy continue to question the safety and efficacy of CAM. Thus, these academics never reach a consideration of alternatives to the economic monopoly of the conventional physicians and its profound impact on the practice and cost of health care provisioning.

It is not necessarily so that having a conviction that CAM is safe and effective is important. Rather, what is important is having a platform that is not part of the structures imposed on the system by the AMA from which to consider conventional medical care. When these factors are subjected to an ethical analysis in the economic order, it is apparent that the scope of practice monopoly of the conventional doctors should be a target of economic reform in the health care sector. This is so because it perpetuates significant informational asymmetries for clients and consumers.

Many of the arguments used by proponents of market regulation in the early 1980s to justify the managed care revolution³⁴⁹ can be

³⁴⁸ Competition in unregulated markets is held up as the ideal economic state for all businesses by neo-liberal economic theorists; however, significant players in the health care market compete on factors other than cost, making direct comparisons to normal markets very difficult. For example, the health insurance industry competes on the basis of risk selection, not cost. Paul Krugman, Op-Ed., *Passing the Buck*, N.Y. TIMES, Apr. 22, 2005, at A23.

³⁴⁹ The revolution has generated different theses and antitheses. The emphasis in managed care has now shifted from management of health care to management of costs. See White, *supra* note 132, at 861.

applied as modified by the distinctions drawn in this Article. There have been proposals to empower consumers by giving them the opportunity to evaluate corporate providers' clinical and financial performance; however, these are accompanied by proposals that limit self-directed medical care to non-major illnesses,³⁵⁰ suggesting that an explicit distinction between patient and consumer would be helpful.³⁵¹

³⁵⁰ *Id.* at 865.

³⁵¹ *See* Havighurst, *supra* note 338, at 966 ("By refusing to let health care become truly commodified—in the sense of letting people decide for themselves, beyond a reasonable margin established by public subsidies, what more and better coverage or services they wanted for themselves—the American legal/political system, revealing again the high degree of cognitive dissonance that characterizes public attitudes towards health care, eventually frustrated the realization of a revolutionary vision [based on a market theory]." (citations omitted)).