Complementary and Alternative Medicine and the Law
Syllabus

Summer 2009
Professor Tovino
Hamline University School of Law

General Course Information

Course: Complementary and Alternative Medicine and the Law
Credits: 2
Classroom: Law 103
Day: Monday, Tuesday, Wednesday, and Thursday, June 22, 23, 24, 25
Time: 9:00 a.m. – 12:00 p.m.; 12:30 – 4:00 p.m.
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Contacting me: Please do not hesitate to contact me with any questions or concerns. The best (fastest) way to contact me is on my BlackBerry at the cell number or email address listed immediately above.

Course Description and Objectives

Welcome to Complementary and Alternative Medicine and the Law! This course will examine the legal, ethical, and policy issues raised by the delivery of complementary and alternative medicine (CAM). Special attention will be given to the definitions, theories, and practice of major CAM therapies, including chiropractic, acupuncture, homeopathy, naturopathy, massage therapy, dietary supplementation, herbal medicine, and various cancer therapies; the role of evidence-based medicine in evaluating CAM therapies; the licensure, regulation, and certification (or lack thereof) of CAM providers; the historical bias of allopathic physicians and health insurance companies against CAM providers; legal issues relating to collaboration with CAM providers, including credentialing, medical staff membership, clinical privileges, ordering, and referrals; informed consent to CAM therapies and CAM research; CAM malpractice; other civil and criminal law issues cases involving CAM providers; truth-in-advertising by CAM providers; and public and commercial insurance coverage of CAM.
Course Description and Objectives (continued)

The objectives of this course include: (1) familiarizing students with the major legal, ethical, and policy issues raised by the delivery of CAM; (2) exploring the reasons for CAM use and the health conditions for which CAM is used by different genders, racial and ethnic groups, religious traditions, and socio-economic status groups; (3) obtaining the knowledge and research skills necessary to confront biomedicine’s exclusive claim to being scientific in relation to other competing epistemologies in medicine; and (4) introducing students to non-legal (i.e., medical, scientific, public health, ethics, and sociology) literature that bears on the evaluation of CAM therapies.

Readings are drawn from a range of primary and secondary legal sources, including statutes, regulations, judicial opinions, attorney general opinions, law review articles, legal news articles, and legal blogs, as well as the relevant medical, scientific, public health, health policy, ethics, and sociology literature.

Course Materials

Your course materials include: (1) this syllabus; (2) the readings posted to our Course Blog; and (3) my PowerPoint presentations, which also will be posted to our Course Blog. Students may access the Course Blog at http://camseminarsummer09.blogspot.com/. The PowerPoint presentations are designed to structure class discussions and assist on-call students with class preparation.

I will post our class readings to our Course Blog at least three weeks prior to the first day of class so that students have ample time to download and read the material before class. I will post our PowerPoints to our Course Blog at least one week prior to the first day of class so that students have ample time to download the PowerPoint before class. I will not distribute paper copies of the readings or the PowerPoints during class.

Course Evaluation

Course grades shall be based on one anonymous, final examination, which shall include thirty multiple-choice questions.

Course Attendance

At the beginning of each class session, I will distribute a class roster for students to sign. Students who are absent for more than 20% of our total in-class minutes will be treated as “excessively” absent in accordance with the Hamline University School of Law Academic Rules.
Background Information

I will provide background information regarding CAM during our first week of class. However, it may be helpful for students to review this background information as our course progresses or before beginning the seminar paper. I think that the best summary of the development of CAM is provided by Professor Michael H. Cohen, J.D., M.B.A, M.F.A., a prominent Boston attorney and prolific scholar who has appointments at Harvard Medical School and Harvard School of Public Health and who founded the CAM Law Blog, available at http://www.camlawblog.com/. The following summary is from Professor Cohen’s many writings and online resources:

In the late-nineteenth century, what we now call “scientific medicine,” “biomedicine,” or “allopathic medicine” began to dominate patient care as well as the regulation of patient care. The growing power of the biomedical community resulted in: (1) the passage of medical licensing laws that broadly defined the “practice of medicine” and prohibited the unlicensed practice of medicine by non-medical providers, including homeopaths, naturopaths, and chiropractors; (2) the establishment of medical and professional society rules and regulations that limited membership to medical providers; and (3) the adoption of ethical and other standards that prohibited professional association between allopathic physicians and non-medical providers.

By the 1960s and 1970s, increasing patient interest in therapies such as chiropractic, naturopathy, massage therapy, acupuncture and traditional oriental medicine, nutritional and herbal medicine, folk medicine, and mind-body therapies resulted in greater attention to “holistic health care.” Very generally, holistic health care approaches treatment in terms of its effect on the whole person, including the physical, mental, emotional, spiritual, and environmental dimensions.

In 1992, Congress created a tiny office within the National Institutes of Health (NIH) known as the Office for Unconventional Medical Practices. In 1993, David M. Eisenberg, M.D., et al., published an article in the New England Journal of Medicine describing the field of “alternative medicine” and including within that field many therapies not commonly used in U.S. hospitals or taught in U.S. medical schools, including the therapies listed in the previous paragraph. In Europe, the term “complementary medicine” was gaining currency to describe the same therapies. The Office for Unconventional Medical Practices later was renamed the Office of Alternative Medicine and, even later, the National Center for Complementary and Alternative Medicine (NCCAM), http://nccam.nih.gov/.

The NCCAM currently defines CAM as covering “a broad range of healing philosophies (schools of thought), approaches, and therapies that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available.” The NCCAM further explains: “A few of the many CAM practices include the use of acupuncture, herbs, homeopathy, therapeutic massage, and traditional oriental medicine to promote well-being or
treat health conditions. People use CAM treatments and therapies in a variety of ways. Therapies may be used alone, as an alternative to conventional therapies, or in addition to conventional, mainstream therapies, in what is referred to as a complementary or an integrative approach. Many CAM therapies are called holistic, which generally means they consider the whole person, including physical, mental, emotional, and spiritual aspects.” Although the NCCAM’s definition is neither universally accepted nor authoritative, it does represent a starting point for thinking about what distinguishes (or fails to distinguish) CAM therapies from conventional care.

State (not federal) law governs much of CAM practice. During class, we will explore several Iowa and other state statutes, regulations, and common laws relating to professional licensure, scope of practice, and malpractice that are representative of most states’ laws governing CAM providers and the provision of CAM therapies. With respect to licensure, each state has enacted a medical licensing act that technically prohibits the unlicensed practice of medicine and thereby criminalizes activity by unlicensed CAM providers who offer medical services to patients. We also will examine the application to CAM of malpractice, which you learned about in your first year Torts course and may be defined as an unreasonable practice that fails to conform to the standard of care in the profession and causes injury.

Although state law controls much of CAM practice, a significant federal role exists in the regulation of dietary supplements. The federal Food and Drug Administration (FDA) regulates foods, drugs, and cosmetics in interstate commerce. No new “drug” may be introduced into interstate commerce unless proven “safe” and “effective” for its intended use, as determined by FDA regulations. “Foods,” however, are subject to different regulatory requirements, and need not go through trials proving safety and efficacy. The growing phenomenon of consumer use of vitamins, minerals, herbs, and other “dietary supplements” has challenged the historical divide between drugs and foods. The federal Dietary Supplements Health Education Act (DSHEA) has allowed manufacturers to distribute dietary supplements without having to prove safety and efficacy, so long as the manufacturers have made no claims linking the supplements to a specific disease.

CAM law and policy is constantly evolving. Three recent and significant developments include: (1) approval of final guidelines, by the Federation of State Medical Boards, to govern physician integration of CAM therapies; (2) a final report, issued to Congress by the White House Commission on Complementary and Alternative Medicine, making recommendations for federal legislation and policy regarding CAM; and (3) a Complementary and Alternative Medicine report issued by the Institute of Medicine in 2005. All three of these documents are included in the readings below. These developments are likely to influence future efforts at regulating CAM therapies both at the federal level, where possible, and across states, as well as through the efforts of professional healthcare organizations. Clinical pathways and laws governing CAM will continue to evolve as new evidence accumulates regarding safety and efficacy (or lack thereof) of specific CAM therapies.
Course Schedule; Readings

PLEASE NOTE: YOU WILL NOT BE REQUIRED TO READ ALL, OR EVEN MOST, OF THE FOLLOWING READINGS. At least three weeks prior to the first day of class, I will assign just a few of the readings listed under each date/topic below. These readings will be posted to our Course Blog. In the list below, I am simply identifying a very broad range of relevant readings should you, in the future: (1) choose to write a paper on a particular CAM topic and like a head start on your research; and/or (2) be interested in reading more about a particular CAM topic. The Director of the Health Law Institute, Professor Lucinda Jesson, has in her office six bound volumes that contain each and every one of the readings listed below. Please feel free to make an appointment with Professor Jesson to look through the volumes.

Volume I: Introduction to CAM

- NCCAM, Acupuncture, Get the Facts.
- Acupuncture, Consumer Reports, 54-58 (January 1994).
- The Nuts and Bolts of Needling, Consumer Reports 58 (January 1994).
- Acupuncture and Oriental Medicine Association of Minnesota, About.
- NCCAM, An Introduction to Naturopathy, Backgrounder.
- NCCAM, Questions and Answers about Homeopathy, Research Report.
- NCCAM, Massage Therapy as CAM, Backgrounder.
- Andrew Vickers, Herbal Medicine, 319 British Medical Journal 105-1053, 1422 (October 16, 1999).
- Office of Dietary Supplements, Dietary Supplements: Background Information.
- NCCAM, Cancer and Complementary and Alternative Medicine, Get the Facts.
• NCCAM, Meditation for Health Purposes, Backgrounder.
• Jon A. Astin, Why Patients Use Alternative Medicine: Results of a National Study, 279(19) JAMA 1548 (May 20, 1998) and responsive Letters to the Editor.
• Alternative Therapies: Beyond the Myths, Consumer Reports on Health 8 (January 2007).
• David B. Larson and Susan S. Larson, Spirituality in Clinical Care: A Brief Review of Patient Desire, Physician Response, and Research Opportunities.
• Stephen E. Straus, Complementary and Alternative Medicine: Challenges and Opportunities for American Medicine, 75(6) American Medicine 572 (June 2000).
• Ralph Snyderman et al., Integrative Medicine: Bringing Medicine Back to Its Roots, 162 Archives of Internal Medicine 395 (2002).
• Minnesota Statutes Chapter 146A, Complementary and Alternative Health Care Practices.
• Catherine Zollman et al., Uses and Practitioners of Complementary Medicine, 319 British Medical Journal 836-838 (September 25, 1999).
• Susan Smith, Who Uses Complementary Therapies?
• Catherine Zollman et al., Complementary Medicine in Conventional Practice, 319 British Medical Journal 901-904 (October 2, 1999).
• White House Commission on Complementary and Alternative Medicine Policy
• Federation of State Medical Boards, Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice (April 2002).

Volume II: CAM, Empirical Research, and Evidence-Based Medicine

• Bonnie B. O’Connor, Personal Experience, Popular Epistemology, and Complementary and Alternative Medicine Research, in Callahan, supra.
• Loretta M. Kopelman, The Role of Science in Assessing Conventional, Complementary, and Alternative Medicines, in Callahan, supra.
• Howard Brody, The Placebo Effect: Implications for the Study and Practice of Complementary and Alternative Medicine, in Callahan, supra.
• Tom Whitmarsh, The Nature of Evidence in Complementary and Alternative Medicine: Ideas from Trials of Homeopathy in Chronic Headache, in Callahan, supra.
• Paul Root Wolpe, Medical Culture and CAM Culture: Science and Ritual in the Academic Medical Center, in Callahan, supra.
• Phil B. Fontanarosa et al., Alternative Medicine Meets Science, 280(18) JAMA 1618 (November 11, 1998).
• Victor S. Sierpina et al., Need for Scholarly, Objective Inquiry into Alternative Therapies, 76(9) American Medicine 9 (September 2001).
• Tom Delbanco et al., Complementary and Alternative Therapies and the Question of Evidence, 16 Advances in Mind-Body Medicine 244 (2000).
• AHRQ, Routine Vitamin Supplementation to Prevent Cancer and Cardiovascular Disease, AHRQ Pub. No. APPIP03-0012 (June 2003).
• National Cancer Institute, Tea and Cancer Prevention: Fact Sheet.
• Charles E. Lewis et al., The Recipients and Results of Acupuncture, 14(3) Medical Care 255-262 (March 1976).
• National Cancer Institute, Garlic and Cancer Prevention: Fact Sheet.
• Perspectives on the Placebo Phenomenon, 14(4) Medical Anthropology Quarterly 3, 16(19 (August 1983).
• David S. Sobel, Mind Matters, Money Matters: The Cost-Effectiveness of Mind/Body Medicine, 284(13) JAMA 1705 (October 4, 2000).
• Food and Drug Administration, FDA Issues Information for Consumers about Claims for Green Tea and Certain Cancers, FDA News (June 30, 2005).
• Michael Cohen, Pet Therapy: The Evidence, CAM Law Blog.
• Michael Cohen, Acupuncture Helped Osteoarthritis Patients, CAM Law Blog.
• Michael Cohen, Tai Chi May Help Prevent Shingles, CAM Law Blog.
• R.J. Ignelzi, Meditation ‘Fools the Brain’ in a Threatening World, Greater Paramus News and Lifestyle Magazine.
• Michael Cohen, Mixed Efficacy Found for CAM Approaches to Treating Chronic Pain, CAM Law Blog.
- Molly Glentzer, Desperate Measures, 222(1) Good Housekeeping 84 (January 1996).
- The Mainstreaming of Alternative Medicine, Consumer Reports 17-25 (May 2000).
- E. Ernst et al., Ethical Problems Arising in Evidence Based Complementary and Alternative Medicine, 30 Journal of Medical Ethics 156-159 (2004).

**Volume III: Licensure; Scope of Practice Limitations**

- New York State Education Law, Article 155, Massage Therapy.
- Vermont Administrative Rules for Licensed Acupuncturists.
- Nevada Revised Statutes, Chapter 630A, Homeopathic Medicine.
- California Senate Bill No. 577 (2002).
- Coalition for Natural Health, Mission and State-by-State.
- Natural Healers, Massage Therapy Law and Licensure; States Regulating Massage.
- Legal Issues in Homeopathy.
- National Center for Homeopathy, Homeopathy in the Law.
- Ann Richtman, Minnesota Natural Health Coalition, A Slice of Law and Medicine.
- Minnesota Statutes, Chapter 147B, Acupuncture Practitioners.
- Minnesota Board of Medical Practice, Acupuncturist Fact Sheet.
- Minnesota Board of Chiropractic Examiners, Requirement for Licensure to Practice.
- Minnesota Board of Chiropractic Examiners, Reciprocity/Endorsement.
- Minnesota Board of Chiropractic Examiners, Reciprocity, and Minn. Rules 2500.0800.
- Minnesota Board of Chiropractic Examiners, Chemical Dependency/Other Disabilities.
- Minnesota Board of Chiropractic Examiners, The Authority of Chiropractors to Perform Certain Physical Examinations.
- Minnesota Board of Chiropractic Examiners, Overview of the Complaint Review Process.
- Minnesota Board of Chiropractic Examiners, Questions and Answers about the Board of Chiropractic Examiners Complaint Review Process.
- Crees v. California State Board of Medical Examiner, 28 Cal. Rptr. 621 (1963).
- Oosterveen v. Board of Medical Examiners, 246 P.2d 136 (1952).
- David M. Eisenberg et al., Credentialing Complementary and Alternative Medical Providers, 137(12) Annals of Internal Medicine 965 (December 17, 2002).
- Minnesota Board of Chiropractic Examiners, Newsletter, Spring/Summer 2006.
- Minnesota Board of Medical Practice, Fee List.

**Volume IV: Advertising; Unfair Competition; Marketing; Labeling; Patients’ Rights**

- Minnesota Rules 2500.0510, Advertising.
- Minnesota Rules, 2500.0550, Professional Designations.
- Minnesota Rules, 2500.0600, Board Certification Advertising.
- People v. Hoang Chiropractic
- Minnesota Board of Chiropractic, Decompression Therapy … Be very careful!!! (Fall/Winter 2006)
● Dare v. Board of Medical Examiners, 136 P.2d 304 (1943).
● Oosterveen v. Board of Medical Examiners, 246 P.2d 136 (1952).
● National Council Against Health Fraud, Wikipedia entry.
● National Council Against Health Fraud v. Aroma Vera.
● National Council Against Health Fraud v. King Bio Pharmaceuticals.
● Office of Dietary Supplements, Botanical Dietary Supplements: Background Information.
● Sample Client Bill of Rights (BOR).

Volume IV (cont.): Other Civil and Criminal Law Issues: Sexual Misconduct

● David M. Studdert, Medical Malpractice Implications of Alternative Medicine, 280(18) JAMA 1610 (November 11, 1998).
● Michael Cohen, Informed Consent in Complementary and Alternative Medicine, CAM Law Blog.
● Edzard Ernst, Informed Consent in Complementary and Alternative Medicine, 161 Archives of Internal Medicine 2288 (October 22, 2001).
● Michael Cohen, Legal Boundaries and Ethics in Energy Work During the Clinical Encounter, CAM Law Blog
• Illinois Attorney General Press Release, Madigan Sues Mediation and Acupuncture Teacher Accused of Defrauding his Students in a Real Estate Investment Scheme (November 16, 2006).
• Minnesota Rules, 2500.6050, Sexual Misconduct.
• Minnesota Board of Chiropractic Examiners, Sexual Misconduct.

Volume V: Collaboration with CAM Practitioners; Antitrust Issues

• The Wilk Case: Table of Contents, Chiro.org
• Wilk v. American Medical Association, 719 F.2d 207 (7th Cir. 1983).
• Wilk v. American Medical Association, 895 F.2d 352 (7th Cir. 1990).
• Kelly Safreed Harmon, Naturopath Puts a New Spin on Board Diversity, Trustee 26 (September 1999).
• Jason W. Busse et al., Disclosure of Natural Product Use to Primary Care Physicians: A Cross-Sectional Survey of Naturopathic Clinic Attendees, Mayo Clinic Proceedings 616-623 (May 2005).
• Michael Cohen et al., Pediatric Use of Complementary Therapies: Ethical and Policy Choices, CAM Law Blog
• Moshe Frenkel et al., The Growing Need to Teach about Complementary and Alternative Medicine: Questions and Challenges, 76(3) Academic Medicine 251 (March 2001).
• Harold G. Koenig, Religion, Spirituality, and Medicine: Application to Clinical Practice, 284(13) JAMA 1708 (October 4, 2000).
**Volume VI: Insurance, Workers’ Compensation, and Reimbursement Issues**


**Volume VI (cont.): Diversity and CAM**

- Gregory Juckett, Cross-Cultural Medicine, 72(11) American Family Physician 2267 (December 1, 2005).
- Moon S. Chen, Informal Care and the Empowerment of Minority Communities: Comparisons between the USA and the UK, 4(3) Ethnicity and Health 139-151 (1999).
● Deepa Rao, Choice of Medicine and Hierarchy of Resort to Different Health Alternatives among Asian Indian Migrants in a Metropolitan City in the USA, 11(2) Ethnicity & Health 153-167 (May 2006).
● Lorraine Culley, Transcending Transculturalism? Race, Ethnicity and Health-Care, 13(2) Nursing Inquiry 144-153 (2006).
● Laura Howell, Use of Herbal Remedies by Hispanic Patients: Do They Inform Their Physician, 19(6) JABFM 566-578 (November-December 2006).
● David J. Hufford, CAM and Cultural Diversity: Ethics and Epistemology Converge, in Callahan, supra.

Volume VI (cont.): Midwifery

● Minnesota Board of Medical Practice, Traditional Midwife Fact Sheet.
• Rose Weitz et al., The Politics of Childbirth: The Re-Emergence of Midwifery in Arizona, 33 Social Problems 163-175 (February 1986).
• Lesley M. Barclay, Midwifery in Australia and Surrounding Regions: Dilemmas, Debates, and Developments 6(11) Reproductive Health Matters 149-156 (May 1998).