Complementary and Alternative Medicine and the Law
Syllabus

Spring 2008
Professor Tovino
Hamline University School of Law

General Course Information

Course: Complementary and Alternative Medicine and the Law Seminar
Credits: 3
Classroom: 240A
Day: Saturday
Time: 1:15 – 3:15 p.m.
Professor: Stacey A. Tovino, J.D., Ph.D.
Office: 232 East Law/Grad
Office Hours: Saturdays, 3:15 -4:15 p.m.; other times by appointment.
Office Phone: (651) 523-2118
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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 seminar 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; CAM malpractice; other civil and criminal law issues cases involving CAM providers; truth-in-advertising by CAM providers; and 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 traditional legal sources, including statutes, regulations, judicial opinions, attorney general opinions, law review articles, and legal blogs, as well as the relevant medical, scientific, public health, health policy, ethics, and sociology literature. Although we will focus on the most popular CAM therapies during class, students are free to examine in their seminar papers the legal, ethical, and policy issues raised by other “not-necessarily-traditional-medical” therapies and health care modalities such as meditation, energy work, hydrotherapy, pet therapy, prayer, midwifery, shamanism, etc.

Course Materials

Your course materials include: (1) a required packet of materials; and (2) my PowerPoint presentations. You may access our PowerPoint presentations through our LexisNexis Web Course, as discussed in the paragraph below. The PowerPoint presentations are designed to structure class discussions and assist on-call students with class preparation. Additional material available through our LexisNexis Web Course includes: (1) a list of students who will be on call for each class; and (2) the most current version of this syllabus.

I will post each week’s PowerPoint presentation to our LexisNexis Web Course by the preceding Monday so that you have ample time to download and use the material for class preparation. I will not distribute paper copies of the PowerPoint presentations in class. To access the PowerPoints and other course materials through our Web Course: (1) Go to your LexisNexis Web Course home page (http://www.lexisnexis.com/lawschool/webcourses/); (2) click on the light gray “Launch Web Courses” button near the top of the page; (3) click on the red “Courses” tab at the top of the page; (4) click on the “Browse Course Catalogue” link on the right hand side of the page; (5) click on the “Hamline University” link; (6) scroll down and locate our class (“CAM Law—Spring 2008”) and click on the “Enroll” button. Once you have enrolled in our course, “CAM Law” (and any other Web Courses in which you have enrolled) will show up under the “My Courses” box that appears after you enter the LexisNexis Web Course home page.
Course Evaluation

I will base eighty-five percent (85%) of your course grade on your seminar paper, which shall be, exclusive of any cover page, thirty (30) or more pages of double-spaced, page-numbered, Times New Roman 12-point font, with top and bottom margins equal to 1” and left and right margins equal to 1.25.” Adequate footnote (not endnote) support shall be provided in accordance with the method of documentation and citation you learned in your Legal Research & Writing course. One e-mail copy of your paper is due to stovino01@gw.hamline.edu by 11:59:59 p.m. CST on Wednesday, May 14, 2007. Your paper grade will drop one half of a letter grade (e.g., from an A to an A-, from an A- to a B+, from a B+ to a B, and so on) for each day that your paper is late. For example, B+ papers received in my in-box on May 16, which would be two days late, will receive a B- grade.

I will base the remaining fifteen percent (15%) of your course grade on: (1) the presentation of your paper or work-in-progress that you will make sometime between April 5 and April 19; as well as (2) your participation during the day(s) in which you are on call.

Course Attendance

At the beginning of each class, I will distribute a class roster for you to sign. If you are absent for more than two classes, your absences will be treated as “excessive” in accordance with Hamline University Academic Rule 1-110.

Background Information

I will provide background information regarding CAM during our first two class sessions. However, it may be helpful to review this background information as our course progresses or before you begin your 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/](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 Minnesota 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. Two weeks prior to each class, I will assign just a few of the readings listed under each tab/date/topic below. These assignments will be posted to our Lexis Nexis Web Course. Here, I am simply identifying relevant readings should you: (1) choose to write a paper on that particular CAM topic; (2) need a head start on your research; and/or (3) be interested in reading more about a particular CAM topic.

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<thead>
<tr>
<th>Tab/Date</th>
<th>Topic</th>
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<tr>
<td><strong>Tab 1</strong></td>
<td><strong>Introduction to CAM</strong></td>
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<tr>
<td><strong>Jan. 19</strong></td>
<td>● Catherine Zollman et al., ABC of Complementary Medicine, 319 British Medical Journal 693-696 (September 11, 1999).</td>
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<td>● Stephen E. Straus, Complementary and Alternative Medicine: Challenges and Opportunities for American Medicine, 75(6) American Medicine 572 (June 2000).</td>
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● Ralph Snyderman et al., Integrative Medicine: Bringing Medicine Back to Its Roots, 162 Archives of Internal Medicine 395 (2002).
● NCCAM, Cancer and Complementary and Alternative Medicine, Get the Facts.
● 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).
● Acupuncture, Consumer Reports, 54-58 (January 1994).
● NCCAM, Acupuncture, Get the Facts.
● Acupuncture and Oriental Medicine Association of Minnesota, About.
● Heather Caunt, The History and Present Day Practice of Acupuncture (June 30, 2000).
● NCCAM, An Introduction to Naturopathy, Backgrounder.
● NCCAM, Questions and Answers about Homeopathy, Research Report.
● NCCAM, Massage Therapy as CAM, Backgrounder.
● Massage Therapy: The Healing Touch, Consumer Reports on Health (July 2005).
● Andrew Vickers, Herbal Medicine, 319 British Medical Journal 105-1053, 1422 (October 16, 1999).
● 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.
● David B. Larson and Susan S. Larson, Spirituality in Clinical Care: A Brief Review of Patient Desire, Physician Response, and Research Opportunities
● 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).

Tab 2

**CAM, Empirical Research, and Evidence-Based Medicine**

**Jan. 26**

● 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.
● Paul Root Wolpe, Medical Culture and CAM Culture: Science and Ritual in the Academic Medical Center, in Callahan, supra.


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.

National Cancer Institute, Garlic and Cancer Prevention: Fact Sheet.


David S. Sobel, Mind Matters, Money Matters: The Cost-Effectiveness of Mind/Body Medicine, 284(13) JAMA 1705 (October 4, 2000).


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).

Tab 3
Licensure; Scope of Practice Limitations
Feb. 2
• 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 Attorney General Opinion, 1975 Minn. AG Lexis 9 (March 10, 1975).
• Minnesota Board of Chiropractic Examiners, Requirement for Licensure to Practice.
• Minnesota Board of Chiropractic Examiners, Reciprocity/Endorsement.
• Minnesota Statutes, Chapter 147B, Acupuncture Practitioners.
• Minnesota Board of Medical Practice, Acupuncturist Fact Sheet.
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• Minnesota Board of Chiropractic Examiners, Reciprocity/Endorsement.
• Minnesota Statutes, Chapter 147B, Acupuncture Practitioners.
• Minnesota Board of Medical Practice, Acupuncturist Fact Sheet.
- 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, 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 Chiropractic Examiners, Overview of the Complaint Review Process.
- Minnesota Board of Medical Practice, Fee List.

### Tab 4

**Advertising; Unfair Competition; Marketing; Labeling; Patients’ Rights**

**Feb. 9**

- Minnesota Rules 2500.0510, Advertising.
- Minnesota Rules, 2500.0550, Professional Designations.
- Minnesota Rules, 2500.0600, Board Certification Advertising.
- People v. Hoang Chiropractic.
- 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, Dietary Supplements: Background. Information.
- Office of Dietary Supplements, Botanical Dietary Supplements: Background Information.
- Sample Client Bill of Rights (BOR).

**Tab 5 Other Civil and Criminal Law Issues: Sexual Misconduct**

**Feb. 16**
- Michael Cohen, Legal Boundaries and Ethics in Energy Work During the Clinical Encounter, CAM Law Blog
- Edzard Ernst, Informed Consent in Complementary and Alternative Medicine, 161 Archives of Internal Medicine 2288 (October 22, 2001).
- David M. Studdert, Medical Malpractice Implications of Alternative Medicine, 280(18) JAMA 1610 (November 11, 1998).
- 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.
Collaboration with CAM Practitioners; Antitrust Issues

Tab 6
Feb. 23

- 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

Mar. 1

Work on Papers

Tab 7

Mar. 8

Insurance, Workers’ Compensation, and Reimbursement Issues

- E. Ernst et al., Ethical Problems Arising in Evidence Based Complementary and Alternative Medicine, 30 Journal of Medical Ethics 156-159 (2004).
- Kenneth R. Pelletier, Current Trends in the Integration and Reimbursement of Complementary and Alternative Medicine by Managed Care Organizations

**Tab 8**

**Diversity and CAM Use**
- 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.

Mar. 22  No Class: Mid-Term Break
Tab 9  Midwifery
Mar. 29
- Minnesota Board of Medical Practice, Traditional Midwife Fact Sheet.
- Lesley M. Barclay, Midwifery in Australia and Surrounding Regions: Dilemmas, Debates, and Developments 6(11) Reproductive Health Matters 149-156 (May 1998).

Apr. 5  Rough Drafts Due; Student Presentations
Apr. 12  Student Presentations
Apr. 19  Student Presentations
May 14  Final Paper Due by email to stovino01@gw.hamline.edu by 11:59:59 midnight CST. Your paper grade will drop one half of a letter grade (e.g., from an A- to a
B+) for each day that your paper is late. For example, B+ papers handed in on May 16, which is two days late, will receive a B- grade.