Patients Access to Integrative Heathcare Act of 2020

TESTIMONY BEFORE THE MARYLAND SENATE
EDUCATION, HEALTH, AND ENVIRONMENTAL AFFAIRS COMMITTEE
Maryland Society of Integrative Medicine, Inc.
Alan Dumoff, JD, MSW
CV in attached materials

In addition to testifying before you today we have had the privilege of meeting with the Maryland Board of Physicians ("Board"), the Department of Health and MedChi who have all made good faith efforts to understand our concerns and the operation of the bill. A few of the objections raised simply evidence the same negative reactions to integrative medicine that underlie the need for this bill, but many are legitimate questions about how the bill would operate. We hope to continue these constructive conversations, but I intend to address 6 misconceptions about the bill as best I can in the next few minutes.

1) Misconception: The bill prevents proper disciplinary action against physicians misusing integrative techniques.

The Board of Physicians has expressed concern that Section 1 of the bill would carve out special exemptions that would prevent the Board from taking appropriate disciplinary actions against integrative physicians. The Board is apparently reading Section 1 as if it says it may not take action IF a practitioner's practice is integrative in nature. The language is in fact that the Board may not take action BECAUSE a practice is integrative in nature. If a peer reviewer qualified by training and experience in a well-founded minority viewpoint similar to that of the respondent physician finds the respondent was in error, the Board could bring an action based on improper use of integrative methods under Section 2. This would NOT be an action taken BECAUSE the practitioner used integrative methods, but rather because a properly qualified peer reviewer found the integrative methods were not valid or used responsibly. Seeking discipline in such a case would not violate Section 1.

What the language in Section 1 would accomplish is to ensure that the Board does not discipline a physician because he or she uses integrative medicine, in other words, by imposing standards of care that are contrary to methods that have been developed by the integrative or other minority medical communities. For the Board to do that would be to take action BECAUSE the physician used integrative methods. This gives effect to our intent that the standards and evidence supporting integrative work not be ignored but applied by at least one reviewer.

The bill would also allow discipline, as has been the consistent approach in other states, where the methods used present a risk not outweighed by the potential benefits and where informed consent was not adequate.

An important instance are areas where there are unresolved differences in professional viewpoint, such as determining whether continuing symptoms in Lyme patients are a post-Lyme syndrome or result from ongoing persistent infection. We understand, for example, that Johns Hopkins and Stanford medical schools have sharp disagreements over the Lyme controversies. The Board of Physicians should not take sides in such disputes, nor discourage innovative, emerging, or established minority medical viewpoints by choosing reviewers from only one side of such disputes or where there are differences in the paradigm for care.

2) Misconception: The bill creates a separate disciplinary track for integrative medicine.

The bill does not create a different disciplinary track for integrative physicians nor treat them differently; it merely requires that, like any other physician, respondents be viewed according to the standards or evidence-base for their practice. That there is only one standard of care is in many cases a misconception that ill-fits the complexity of medicine as art and science. What the bill does is restore the concept of review by an actual peer.

Current law requires that a reviewer be board certified in the matter at hand and also have special expertise. Health Occupations § 14-401.1(e)(2). We have litigated the meaning of this language in the context of orthomolecular psychiatry, a form of integrative medicine which focuses on nutrients that affect neurologic function. We argued before the Baltimore Circuit Court that the statutory additional requirement for special expertise required a reviewer versed in orthomolecular expertise, not simply a psychiatrist, but the Court held that being boarded in psychiatry was sufficient, making a legislative fix necessary. Note that the then President of the Maryland Psychiatric Society testified at the hearing at which the charges in this case were dismissed that these charges never should have been brought because of differences in standards of care, which is exactly our point.

3) Misconception: "Integrative medicine" is not sufficiently defined.

The proposed obligation on the Board to respect standards of practice or evidence-base for integrative medicine does not turn on its definition. While we understand the nature of the concern, note as context that of the 13 states that have passed similar laws, only three attempt a definition and none of those definitions add to what is contained in SB103, these statutes merely define it in contrast to conventional methods. The field is highly varied and includes emerging therapies as evidence becomes available. While there are common elements such as an holistic approach, a focus on nutritional medicine and the evidence-based use of herbs, among other aspects, whether a practice under scrutiny clearly fits within or without an integrative model is not a legal standard that can be directly applied.

The actual issue is whether a physician's methods have a rational basis properly applied as indicated in part by professional and evidence-based support. There are a number of professional associations that teach, research and support integrative practice, noted in the attached materials, which are a place to begin but the actual question should be about the basis for a therapy that takes into account that patients should have access to different paradigms of practice.

4) Misconception: The bill is not about access but physician protection.

As an attorney representing many integrative physicians in Maryland, I frequently have to counsel physicians who ask whether they can perform certain therapies with legal safety that,

even though the learned about these therapies at established conferences there could be real disciplinary risk. We cannot go to the Board for declaratory rulings and have to base advice on dozens of cases in which physicians have been reprimanded or their licenses suspended or revoked. The chilling effect of possible board action limiting physicians ability to use innovative approaches is a major bar to access to this care and this is our central concern.

5) Misconception: Because few cases have addressed integrative medicine, it is not a significant problem.

Understanding that one of our concerns is Lyme Disease, the Board reviewed their records and found 27 of 27,000 cases reported involved Lyme Disease. Of those 27, I handled 3 cases, one leading to probation solely on record keeping because the reviewers were unable to recognize the use of pulsed antibiotics under ILADS guidelines. One of the others was dismissed on its face and one because I insisted and the Board accepted the peer review we seek be established in law. This does not often happen in other cases.

More to the point, I alone have handled over a dozen other cases and seen a dozen others in which charges were filed that raised a wide number of integrative medicine matters, aside from Lyme, and action against one doctor can affect the willingness of many other physicians to provide what they consider legitimate treatments.

6) Misconception: Integrative medicine is not evidence-based.

As we have highly qualified physicians and researchers testifying I will just make a few observations. Integrative methods have been taught for years in coursework with Category 1 CME credit at medical conferences that have been ongoing for over 40 years with thousands of participating physicians. The field has board certification in the American Board of Integrative Medicine (ABOIM), recognized by the American Board of Physician Specialties (ABPS) with over 20 fellowship programs feeding the board qualification. Integrative physicians have lead many developments in medicine, stressing the importance of diet and food beginning some 40 years ago. Immunotherapies for cancer began as an integrative medical idea that was initially scorned. Herbal and nutritional approaches can make available well-researched interventions that are effective and can be safer than pharmaceutical options that may be widely prescribed even with black box warnings. As but one resource, Harvard Medical School compiled a database of over 15,000 citations to clinical studies for natural medicines now available through a pay site at https://naturalmedicines.therapeuticresearch.com to assist doctors in making evidence-based choices. John's Hopkins has published research, for example, suggesting that garlic may be more effective against the Lyme spirochete than antibiotics. (*See* attached exhibits). There are peer-reviewed journals, medical textbooks, and other substantial resources of which a few are listed in our exhibits.

Patients who see integrative physicians have usually exhausted conventional means, particularly for chronic disease for which treatments are limited. There is also a mythology that conventional medicine is largely evidence-based, but repeated studies have found estimates more on the order of 20% are in fact evidence-based, as in the 2017 BMJ article included in our exhibits.

Additional Background

The Maryland Board of Physicians (Board) has taken the position that responsible use of such therapies may be performed with patient informed consent, but the policy does not work well in practice because 1) the Board relies on peer reviewers who are largely only versed in conventional standards of care and critique physicians based upon a lack of information and a presumption against schools of thought in which they are not trained, 2) this unfamiliarity with other protocols gives rise to critiques of diagnosis, treatment and documentation that reflect the reviewers lack of understanding, not error on the part of the respondent, and 3) the views of informed consent and scientific evidence are not consistently applied by the Board.

Patient harm is rarely alleged in these cases and the presumption that nonstandard therapies present an unreasonable risk of harm reflect untested conventional viewpoints that are often not valid. The Board often expresses concern about the avoidance of conventional treatments, but these patients have generally already exhausted conventional care before seeking out an integrative physician.

The disciplinary process is largely dictated by peer reviewer findings; the bill requires that at least one of two peer reviewers is trained in the methods at issue. If a physician is investigated for an approach that is disengaged from a respectable minority of physicians and, as a result, a peer trained in that view is legitimately unavailable, the Board may use any reviewer with some training in integrative medicine. Peer reviewers would be guided by the standard that the methods must pose no greater risk than conventional medicine not outweighed by potential benefits. If a CAM therapy that may be generally appropriate is incompetently applied, the reviewer trained in such methods would be in a position as a peer to form a proper basis for an adverse finding. Further, if it can be shown that a physician was acting in bad faith rather than a genuine healing effort, this bill would provide no protection. In any event, in order to use nonconventional approaches a physician must have documented proper informed consent by the patient.

Closing Thought

Contemplating the importance of this bill I am reminded of work I did as a clinical social worker before engaging in my 30-year legal career working with integrative physicians. I was a family therapist at a residential facility for adolescent drug offenders and the young men we worked with generally went on one of two paths; they were either identified as the sick one and went into

psychiatric inpatient care where the purpose was to "fix" the child, or they stayed with us where we identified the entire family as in need of assistance and worked to address the family dysfunction that manifested in the young man's symptoms. Hospitalization was 10 times the cost, but more to the point the life path of these young men and their families was deeply affected by this choice. Joining the parents in assigning blame to the child was not always in anyone's best interest. The manner in which we define medical problems sets the stage for how we resolve them. Fortunately, no regulator was imposing one view over the other in the name of "standard of care."

Many integrative/CAM therapies once scorned have now become accepted. There is often not one static, clear standard of care, particularly for complex, chronic diseases that are too often not well-managed with conventional care alone. Allowing functional and emerging views of medicine to be used in practice with informed patients per the standards laid out in this bill would provide a proper balance of access and safety.

Thank you for your consideration.

The Patient's Access to Integrative Healthcare Act of 2020

Formerly Known as The Patient's Right to Choose Act

In Plain Language

1. A health occupations board shall not revoke, fail to renew, suspend or take any action against a health care provider's license because the licensee's methods of diagnostic evaluation or treatment are integrative, complementary, alternative or nonconventional if the licensee has disclosed the nature of the test or treatment including that it is considered integrative, complementary, alternative or nonconventional and obtained informed consent from the patient (or responsible party) unless the board can establish that the diagnostic evaluation or treatment method has a significant risk greater than conventional methods not outweighed by the potential benefits.

2. If a statute authorizes a health occupations board to use a system of peer review, one of the two peer reviewers selected for review of methods described in this Chapter shall have demonstrated training, competence and experience in integrative medicine, and, if available, in the same methods under review, unless a good faith inquiry by the Board finds that such methods have not been adopted by any professional organization, taught in a CME Category 1 program, the subject of favorable peer-reviewed publication or other indication of acceptance by a minority community of physicians. Charges shall only be brought in cases governed by this Chapter where there is agreement between the two peer reviewers.

3. The Department of Health may not take action against a health care provider's Medicare or Medicaid certification based on the health care provider's use of diagnostic or treatment methods consistent with this Chapter.

4. An official, employee, or agent of the State may not block or attempt to block a patient's access to a diagnostic or treatment method delivered in a manner consistent with this Chapter.

5. That a treatment uses a drug, device, biologic or method that has not been approved by the US Food and Drug Administration shall not be a basis for a disciplinary action pursuant to the provisions of the MD Health Occupations Article against a licensee if the provisions of # 1 (above) are met by the licensee.

6. The requirements for coordination of care, referral to a medical specialist or other manner of managing patient care shall be no greater for a licensee practicing consistent with the provisions of this Chapter than for any other licensee. A licensee shall not be found to have violated record-keeping, billing, or other regulatory requirements for acts or omissions that arise as a result of professional differences in training or opinion where the licensee has acted in good faith in a manner consistent with the intent of such requirements and the licensee has not acted in a way that is false or misleading.

7. The protections provided in this Chapter do not apply in a case in which it can be shown by clear and convincing evidence that the health care provider knew that the diagnostic or treatment method did not have a reasonable basis and was intended to defraud the patient.

Patient's Access to Integrative Healthcare Act
Examples of Professional Resources and Evidence-Based Materials
Submitted by the Maryland Society of Integrative Medicine, Inc.

Integrative medicine and its various fields is highly developed professionally. The following collects some of the major organizations that have been providing CME credits or other training in the field; it would take some time just to explore and get a sense of all of the materials supporting these practices.

Demonstrating that there is a considerable evidence-base for integrative therapies is difficult to do simply as much of the work crosses boundaries and is done under more specific headings, such as environmental or herbal medicine or are developments within each of the medical specialties, such as infectious disease, orthopaedics or cancer treatment. However, the following lists the websites of organizations that offer education and certification, selected textbooks in the field, journals and online resources.

Education and Certification

The following well-established organizations have been offering continuing medical education for decades, have conferences at least annually and extensive on-line learning. Some offer board or other certification programs. This covers many of the major organizations but is by no means a complete list, the field is extensive and there are hundreds of educational programs in more specific methods.

The Academic Consortium for Integrative Medicine & Health
(comprised of most of the major medical schools)
List of upcoming workshops and events
https://imconsortium.org/events/upcoming-integrative-medicine-health-events/
There are 23 Fellowship Programs in Integrative Medicine
https://imconsortium.org/training-jobs/fellowships/

Fellowships can lead to a recognized board certification, Diplomate in Integrative Medicine
https://www.abpsus.org/integrative-medicine

Academy of Integrative Health & Medicine (AIHM)
Conference coursework
https://conference.aihm.org/annual/2019/all_education.cfm
Education and elearning
https://www.pathlms.com/aihm/

American Academy of Environmental Medicine
Recent conference coursework
http://aaemconference.com/fall/congress.php
Education and elearning
https://www.aaemonline.org/online_ed.php
American College for Advancement in Medicine

Upcoming Conference
https://www.acam.org/page/Events
elearning Integrative Medicine Academy
https://www.acam.org/mpage/BootcampRegister

International Lyme and Associated Disease Society
https://www.ilads.org/ilads-conference/boston-2019/
Physician training program
https://iladef.org/physician-training-program/

Institute for Functional Medicine
Certification Program
https://www.ifm.org/certification-membership/certification-program/
Conference
https://www.ifm.org/learning-center/2020-annual-international-conference/
Education and elearning
https://www.ifm.org/learning-center/

International College of Integrative Medicine
Conference
https://icimed.com
On line education, available to members only

University centers of integrative medicine offer their own conferences, for e.g.:
University of Maryland Center for Integrative Medicine
https://cim.umaryland.edu/Education/

Andrew Weil Center for Integrative Medicine
https://integrativemedicine.arizona.edu/education/index.html

Duke University Integrative Medicine
https://dukeintegrativemedicine.org; https://dukeintegrativemedicine.org/programs-training/

There are numerous other organizations hosting conferences, for e.g.
https://www.townsendletter.com/conferencecalendar.htm

Some private conference organizations host integrative medicine conferences, for example:
Kaerwell
https://kaerwell.com/events/events_page/index/2

Sample Textbooks

Alan Gabby (Nutritional Medicine) https://www.amazon.com/Nutritional-Medicine-Second-Alan-Gaby/dp/1532322097/ref=sr_1_1?crid=2BNLCGB7H4IA1&keywords=alan+gaby+nutritional+medicine&qid=1575824104&sprefix=alan+gaby+%2Caps%2C127&sr=8-1

David Rakel (Integrative Medicine)
https://www.amazon.com/Integrative-Medicine-David-Rakel-MD/dp/0323358683/ref=sr_1_1?keywords=david+rakel+%28integrative+medicine%29&qid=1575824186&sr=8-1

Benjamin Kligler (Integrative Medicine: Principles for Practice, which also has a CME study guide)
https://www.amazon.com/Integrative-Medicine-Principles-Benjamin-Kligler/dp/007140239X/ref=sr_1_fkmr0_1?keywords=benjamin+race+%28integrative+medicine%29&qid=1575824129&sr=8-1-fkmr0

Spencer and Jacobs (Complementary and Alternative Medicine: An Evidence-Based Approach)
https://www.amazon.com/Complementary-Alternative-Medicine-Evidence-Based-Approach/dp/0323020283/ref=sr_1_1?keywords=spencer+and+jacobs+complementary+and+alternative&qid=1575824261&sr=8-1

Lyn Freeman (Mosby's Complementary & Alternative Medicine: A Research-based Approach)
https://www.amazon.com/Mosbys-Complementary-Alternative-Medicine-Research-Based/dp/0323053467/ref=sr_1_2?keywords=%28Mosby%27s+Complementary+%26+Alternative+Medicine%3A+A+Research-based+Approach&qid=1575824286&sr=8-2

Marc S. Micozzi (Complementary and Integrative Medicine in Cancer Care and Prevention)
https://www.amazon.com/Complementary-Integrative-Medicine-Cancer-Prevention-ebook/dp/B0084Z27RC/ref=sr_1_1?keywords=Complementary+and+Integrative+Medicine+in+Cancer+Care+and+Prevention&qid=1575824368&sr=8-1

Sidney Baker (Textbook of Functional Medicine)
https://www.amazon.com/Textbook-Functional-Medicine-Sidney-MacDonald/dp/0977371301/ref=sr_1_3?keywords=Textbook+of+Functional+Medicine&qid=1575824413&sr=8-3

Leonard A. Jason (Handbook of Chronic Fatigue Syndrome)
https://www.amazon.com/Handbook-Chronic-Fatigue-Syndrome-Leonard/dp/047141512X/ref=sr_1_3?keywords=Handbook+of+Chronic+Fatigue+Syndrome&qid=1575824459&sr=8-3

Peer Reviewed Journals

There are a wide range of peer-reviewed journals in the field. A few examples include:

The Journal of Alternative and Complementary Medicine: Paradigm, Practice, and Policy Advancing Integrative Health
https://home.liebertpub.com/publications/the-journal-of-alternative-and-complementary-medicine/26

Alternative and Complementary Therapies
https://home.liebertpub.com/publications/alternative-and-complementary-therapies/3

Evidence-based Complementary and Alternative Medicine
https://www.hindawi.com/journals/ecam/

Resources

There are numerous well-established databases on-line that provide evidence-based research for clinicians. Many of these require paid access so the ability to review these will be limited. To list just a few:

Harvard Maintains a collection of evidenced-base data. Note this also lists books, articles and other resources:
https://guides.library.harvard.edu/CAM

The Research Company Natural Medicines Database.
https://trchealthcare.com/natural-medicines/ $

Examine.com
https://examine.com

Only 18% of clinical recommendations are evidence-based

Cara Livernois | *June 22, 2017* | *Business Intelligence*

Advising patients on decision making with input based on evidence should be the minimum for primary care physicians. But according to a new *BMJ* study, only 18 percent of clinical recommendations are based on high-quality evidence.

The study used Essential Evidence, an online platform with evidence-based medical references, to compile 721 chapters of recommendations. Researchers then used the Strength of Recommendations Taxonomy (SORT) system to grade the recommendations as A, B or C. SORT A recommendations included consistent, high-quality evidence; SORT B included inconsistent or limited quality evidence; and SORT C included expert opinion or recommendations that rely on intermediate outcomes.

“This finding highlights the need for more research in primary care and family medicine,” said Mark Ebell, lead author on the study and professor of epidemiology at University of Georgia. “The research done in the primary care setting, which is where most outpatients are seen, is woefully underfunded and that's part of the reason why there's such a large number of recommendations that are not based on the highest level of evidence."

In total, 3,251 recommendations were analyzed. Findings included the following:

- Overall, 18 percent of recommendations were graded A, 34 percent B and 49 percent were C.
- Therapy was the most common A recommendations, diagnosis were least common.
- Categories with the most A graded recommendations included pregnancy and childbirth, cardiovascular, and psychiatric care.
- The A categories least mentioned covered information on hematological, musculoskeletal and rheumatological, and poisoning and toxicity.
- 51 percent of recommendations were based on studies examining patient outcomes like morbidity, mortality, quality of life or symptom reduction.

“Filling in the gaps for evidence-based, patient-oriented primary care research should matter to patients as well as their health care providers,” said Ebell. "You would want your care to be guided by studies that have demonstrated that what the physician recommends will help you live better or longer. We should all want that kind of information to guide care."

State Freedom of Medical Practice Legislation
Currently exist in at least Fourteen States

Alaska

Alaska Statute, Section 08.64.326(a)(8)(A).

Professional incompetence, gross negligence, or repeated negligent conduct; the board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient.
[Enacted June 14, 1990]

California

§ 2234.1. Circumstances in which physician or surgeon not to be disciplined for alternative or complementary treatment or advice

(a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine, including the treatment of persistent Lyme Disease, if that treatment or advice meets all of the following requirements:
(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.
(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices.
(3) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.
(4) It does not cause death or serious bodily injury to the patient.
(b) For purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.
(c) Since the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases, particularly those that are not yet broadly recognized in California.
[Enacted in 2004, amended 2006, effective date January 1, 2006]

Cal. Bus. & Prof. Code § 2500. Responsibilities of boards.

The boards acknowledge the significant interest of physicians and patients alike in integrating preventative approaches and holistic-based alternatives into the practice of medicine, including, but not limited to, biopsychosocial techniques, nutrition, and the use of natural supplements to

enhance health and wellness. The boards shall establish specific policies in this regard and shall review statutes and recommend modifications of law, when appropriate, in order to assure California consumers that the quality of medicine practiced in this state is the most advanced and innovative it can be both in terms of preserving the health of, as well as providing effective diagnosis and treatment of illness for, the residents of this state.

Cal. Bus. & Prof. Code § 2501. Disciplinary processes and procedures

In fulfilling their responsibilities under this article, the boards shall, on or before July 1, 2002, establish disciplinary policies and procedures to reflect emerging and innovative medical practices for licensed physicians and surgeons. The boards shall solicit the participation of interested parties in the development and preparation of these policies and procedures and shall consult technical advisors as necessary to fulfill the purposes of this article. In preparing these policies and procedures, the boards shall consult with professional medical associations and review the need for any changes in the boards' services, procedures, and activities. The boards shall also assess the need for:
(a) Specific standards for informed consent, if any, in order for patients to be able to understand the risks and benefits associated with the range of treatment options available.
(b) Standards for investigations to assure competent review in cases involving the practice of any type of alternative medicine, including, but not limited to, the skills and training of investigators.
[Enacted September 26, 2000]

Colorado

Colorado General Statute, Section 12-36-117. Unprofessional Conduct.

a) For purposes of this section, "alternative medicine" means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of such methods. A licensee who practices alternative medicine shall inform each patient in writing, during the initial patient contact, of such licensee's education, experience, and credentials related to the alternative medicine practiced by such licensee. The board shall not take disciplinary action against a licensee solely on the grounds that such licensee practices alternative medicine.

(b) Nothing in paragraph (a) of this subsection (3) prevents disciplinary action against a licensee for practicing medicine, practicing as a physician assistant, or practicing as an anesthesiologist assistant in violation of this article.
[Enacted July, 1989]

Florida

Section 1. Section 456.41, Florida Statutes, is created to read: 456.41 Complementary or alternative health care treatments.--

(1) Legislative Intent.--It is the intent of the Legislature that citizens be able to make informed choices for any type of health care they deem to be an effective option for treating human disease, pain, injury, deformity, or other physical or mental condition. It is the intent of the Legislature that citizens be able to choose from all health care options, including the prevailing or conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing or conventional treatment methods. It is the intent of the Legislature that health care practitioners be able to offer complementary or alternative health care treatments with the same requirements, provisions, and liabilities as those associated with the prevailing or conventional treatment methods.

(2) Definitions.--As used in this section, the term:
(a) "Complementary or alternative health care treatment" means any treatment that is designed to provide patients with an effective option to the prevailing or conventional treatment methods associated with the services provided by a health care practitioner. Such a treatment may be provided in addition to or in place of other treatment options.
(b) "Health care practitioner" means any health care practitioner as defined in § 456.001(4).

(3) Communication of Treatment Alternatives.--A health care practitioner who offers to provide a patient with a complementary or alternative health care treatment must inform the patient of the nature of the treatment and must explain the benefits and risks associated with the treatment to the extent necessary for the patient to make an informed and prudent decision regarding such treatment option. In compliance with this subsection:
(a) The health care practitioner must inform the patient of the practitioner's education, experience, and credentials in relation to the complementary or alternative health care treatment option.
(b) The health care practitioner may, in his or her discretion, communicate the information orally or in written form directly to the patient or to the patient's legal representative.
(c) The health care practitioner may, in his or her discretion and without restriction, recommend any mode of treatment that is, in his or her judgment, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of his or her license.

(4) RECORDS.--Every health care practitioner providing a patient with a complementary or alternative health care treatment must indicate in the patient's care record the method by which the requirements of subsection (3) were met.

(5) EFFECT.--This section does not modify or change the scope of practice of any licensees of the department, nor does it alter in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care and

which prohibit fraud and exploitation of patients.
[Enacted May 31, 2001]

Illinois

The Department shall not revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action against the license or permit issued under this Act to practice medicine to a physician based solely upon the recommendation of the physician to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device.

225 Ill. Comp. Stat. Ann. 60/22 (LexisNexis, Lexis Advance through P.A. 100-575 of the 2017 Regular Legislative Session)

Massachusetts

Massachusetts General Law Annotated, Chapter 112, Section 7.

Section two to six, inclusive, and section eight shall not be held to discriminate against any particular school or system of medicine.
[Enacted in 1901]
(Unlike similar old non-discrimination statutes in California and Texas, the Massachusetts law has been and continues to be upheld as a health freedom law.)

Minnesota

146A.065 Complementary and Alternative Health Care Practices by Licensed or Registered Health Care Practitioners

(a) A health care practitioner licensed or registered by the commissioner or a health-related licensing board, who engages in complementary and alternative health care while practicing under the practitioner's license or registration, shall be regulated by and be under the jurisdiction of the applicable health-related licensing board with regard to the complementary and alternative health care practices.
(b) A health care practitioner licensed or registered by the commissioner or a health-related licensing board shall not be subject to disciplinary action solely on the basis of utilizing complementary and alternative health care practices as defined in section 146A.01, subdivision 4, paragraph (a), as a component of a patient's treatment, or for referring a patient to a complementary and alternative health care practitioner as defined in section 146A.01, subdivision 6.
(c) A health care practitioner licensed or registered by the commissioner or a health-related

licensing board who utilizes complementary and alternative health care practices must provide patients receiving these services with a written copy of the complementary and alternative health care client bill of rights pursuant to section 146A.11.
(d) Nothing in this section shall be construed to prohibit or restrict the commissioner or a health-related licensing board from imposing disciplinary action for conduct that violates provisions of the applicable licensed or registered health care practitioner's practice act.
[Enacted May 21, 2014]

New York

Education Law, Section 6527(4)(e).

(4) This article [Article 131.] shall not be construed to affect or prevent the following:
(e) The physician's use of whatever medical care, conventional or non-conventional, which effectively treats human disease, pain, injury, deformity, or physical condition.

and

Public Health Law, Section 230, Subdivision 1.

A state board for professional medical conduct is hereby created. . . not fewer than 2 of whom shall be physicians who dedicate a significant portion of their practice to the use of non-conventional medical treatments who may be nominated by New York state medical associations dedicated to the advancement of such medical treatments. . .

and

Public Health Law. Section 230, Subdivision 10(a) Investigation. (ii) If the investigation of cases referred to an investigation committee involves issues of clinical practice, medical experts shall be consulted. Experts may be made available by the state medical society of the state of New York, county medical societies and specialty societies, and by New York state medical associations dedicated to the advancement of non-conventional medical treatments.
[Enacted July 26, 1994]

(Note: New York utilizes legislative intent to clarify terms of laws, in this case, effectively treats is clarified to mean "has been shown to be effective but has not yet gained general acceptance in the United States.")

North Carolina

North Carolina General Statute, Section 90-14(a)(6).

Unprofessional conduct. . . The Board shall not revoke the license of or deny a license to a person solely because of that person's practice of a therapy that is experimental, nontraditional, or that departs from acceptable a prevailing medical practices unless, by competent evidence, the Board can establish that the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective.
[Enacted June 29, 1993]

Oklahoma

Oklahoma Statute Title 59, Section 493.1(M).

The Board shall not deny a license to a person otherwise qualified to practice allopathic medicine within the meaning of this act solely because the person's practice or therapy is experimental or nontraditional.
[Enacted November 1, 2013]

and

Oklahoma Statute Title 59, Section 509.1(D)(2).

The Board may take disciplinary action . . . . The Board shall not revoke the license of a person otherwise qualified to practice allopathic medicine within the meaning of this act solely because the person's practice is experimental or nontraditional.
[Enacted July 1, 2009]

Oregon

Oregon Revised Statutes, Section 677.190, Subsection (1) Unprofessional Conduct. Grounds for suspending, revoking or refusing to grant license, registration or certification; alternative medicine not unprofessional conduct.

(b) For purposes of this subsection, the use of an alternative medical treatment shall not by itself constitute unprofessional conduct. For the purposes of this paragraph:

1. "alternative medical treatment" means:
(i) A treatment that the treating physician, based on the physician's professional experience, has an objective basis to believe has a reasonable probability for effectiveness in its intended use even if the treatment is outside recognized scientific guidelines, is unproven, is no longer used as

a generally recognized or standard treatment or lack approval of the United States Food and Drug Administration;
(ii) A treatment that is supported for specific usages or outcomes by at least one other physician licensed by the Board of Medical Examiners; and
(iii) A treatment that poses no greater risk to a patient than the generally recognized or standards treatment.

(B) "Alternative medical treatment" does not include use by a physician of controlled substances in the treatment of a person for chemical dependency resulting from the use of controlled substances.
[Enacted May 30, 1995]

Texas
Texas enjoys protection in three forms: A constitutional provision, a law, and as of October 24, 1998, a regulation.

Constitution of the State of Texas. Article 16, §31.

The Legislature may pass laws prescribing the qualifications of practitioners of medicine in this state, and to punish persons for malpractice, but no preference shall ever be given by law to any schools of medicine.
[Enacted in 1846]
("Schools of medicine" has been settled by the Texas Criminal Court of Appeals to mean "system, means, or method employed or schools of thought accepted by practitioner" Ex parte Halsted, 182 S.W.2d 479, 1944.)

and

Texas Medical Practices Act: TMPA §3.06

Construction. (a): Nothing in this act shall be construed so as to discriminate against a school or system of medical practice. . . [Enacted in 1907]
(This act consolidated multiple state medical boards. Therapeutic distinctions of homeopathy, eclectic and naturopathy were considered to be additions to the basic allopathic "science" required of all licensees.)

and

Texas Administrative Code: 22 TAC §§200.1-200.3

Standards for Physicians Practicing Integrative and Complementary Medicine

§200.1. Purpose. The purpose of this chapter is to recognize that physicians should be allowed a

reasonable and responsible degree of latitude in the kinds of therapies they offer their patients. The Board also recognizes that patients have a right to seek integrative or complementary therapies.

§200.2. Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Integrative and Complementary Medicine- Those health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods.

(2) Conventional Medicine - Those health care methods of diagnosis, treatment, or interventions that are offered by most licensed physicians as generally accepted methods of routine practice, based upon medical training, experience and review of the peer reviewed scientific literature.

§200.3. Practice Guidelines for the Provision of Integrative and Complementary Medicine. A licensed physician shall not be found guilty of unprofessional conduct or be found to have committed professional failure to practice medicine in an acceptable manner solely on the basis of employing a health care method of integrative or complementary medicine, unless it can be demonstrated that such method has a safety risk for the patient that is unreasonably greater than the conventional treatment for the patient's medical condition. The Texas State Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates the Medical Practice Act, §§3.08(4), 3.08(4)(E), and 3.08(18) in regard to providing complementary and integrative medical treatment.

(1) Prior to offering advice about complementary health care therapies, the physician shall undertake an assessment of the patient. This assessment should include but not be limited to, conventional methods of diagnosis and may include non-conventional methods of diagnosis and shall be documented in the patient's chart. Such assessment shall include the following listed in subparagraphs (A)-(E) of this paragraph:
(A) adequate medical records as defined in §165.1 of this title (relating to Medical Records);
(B) documentation as to whether conventional medical treatment options have been discussed with the patient and referral input, if necessary;
(C) documentation as to whether conventional medical options have been tried, and if so, to what effect or a statement as to whether conventional options have been refused by the patient;
(D) if a treatment is offered which is not considered to be conventional, documentation of at least a verbal informed consent for each treatment plan must be included (including documentation that the risks and benefits of the use of the treatment were discussed with the patient or guardian);
(E) documentation as to whether the complementary health care therapy could interfere with any other ongoing conventional treatment.

(2) The physician may offer the patient complementary and integrative treatment pursuant to a documented treatment plan tailored for the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives such as pain relief and/or improved physical and/or psychosocial function. Such a documented treatment plan shall consider pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals, or the use of other treatment modalities.

(3) The physician may use the treatment subject to documented periodic review of the patient's care by the physician at reasonable intervals in view of the individual circumstances of the patient in regard to progress toward reaching treatment objectives which takes into consideration the treatment prescribed, ordered or administered, as well as any new information about the etiology of the complaint.

(4) Complete and accurate records of the care provided including the elements addressed in paragraph (1)(A)-(E) of this section should be kept.

(5) If the provisions set out in paragraphs (1)-(4) of this section are met, and if all treatment is properly documented, the board will presume such practices are in conformity with the Medical Practice Act, §§3.08(4), 3.08(4)(E), and 3.08(18).[Adopted October 24, 1998]
(Board's intent is discussed the Preamble to Agency Rules)

Washington (State)

Washington Revised Code Annotated, Section 18.130.180(4).

Incompetence, negligence or malpractice. . . . The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.
[Enacted May 21, 1991]

Lyme Only Statute

Iowa Code § 147.56

A person licensed by a board under this subtitle shall not be subject to discipline under this chapter or the board's enabling statute based solely on the licensee's recommendation or provision of a treatment method for Lyme disease or other tick-borne disease if the recommendation or provision of such treatment meets all the following criteria:

1. The treatment is provided after an examination is performed and informed consent is received from the patient.

2. The licensee identifies a medical reason for recommending or providing the treatment.
3. The treatment is provided after the licensee informs the patient about other recognized treatment options and describes to the patient the licensee's education, experience, and credentials regarding the treatment of Lyme disease or other tick-borne disease.
4. The licensee uses the licensee's own medical judgment based on a thorough review of all available clinical information and Lyme disease or other tick-borne disease literature to determine the best course of treatment for the individual patient.
5. The treatment will not, in the opinion of the licensee, result in the direct and proximate death of or serious bodily injury to the patient.

Health

Garlic holds promise in treating lingering Lyme disease, Johns Hopkins research finds

By Meredith Cohn · Contact Reporter
The Baltimore Sun

DECEMBER 3, 2018, 1:30 PM

Oils from garlic and other common herbs and medicinal plants are showing promise in the lab for treating the bacteria that causes Lyme disease, and may prove especially useful in treating the those who continue to have symptoms after antibiotic treatment, Johns Hopkins University researchers have found.

The findings, still in the early stages, come just after the U.S. Centers for Disease Control and Prevention released data showing that tick-borne diseases such as Lyme are on the rise nationwide. Last year, state and local health departments reported 59,349 cases, up from 48,610 the years before. The case numbers have been rising for years to last year's record, though the reasons are unknown.

Maryland reported 1,887 cases of Lyme last year, 13 more than in 2016, according to the state Department of Health.

Related

Ask the expert: With Lyme disease on the rise, here's how you can protect yourself

Cases are not always diagnosed, and Hopkins researchers say there are likely 300,000 new cases of Lyme annually in the United States. For most people, a course of doxycycline or other antibiotic clears up the infection in a few weeks.

But 10 percent to 20 percent experience lasting symptoms that include fatigue and joint pain.

Some researchers have speculated that this persistent Lyme infection, or post-treatment Lyme disease, may be a new disorder triggered by the initial infection. The Hopkins researchers also say the Lyme bacteria, Borrelia burgdorferi, can enter a stationary or slow-growing phase, and so-called persister cells from the bacteria are more resistant to antibiotics.

Related

Lyme disease research in Howard County seeks best ways to reduce tick populations

The oils from garlic and other herbs may prove better than antibiotics at tackling those cells, according to the new Hopkins study, published Oct. 16 in the journal Antibiotics.

The research included lab-dish tests of 35 essential oils, pressed from plants or their fruits. Ten of these, including oils from garlic cloves, myrrh trees, thyme leaves, cinnamon bark, allspice berries and cumin seeds, showed the strongest killing activity against the Lyme persister cells.

"We found that these essential oils were even better at killing the persister forms of Lyme bacteria than standard Lyme antibiotics," said study senior author Dr. Ying Zhang, professor in the department of molecular microbiology and immunology in the Hopkins Bloomberg School of Public Health.

Zhang previously found that antibiotic combinations and drugs used to treat resistant bacteria, such as MRSA, work better than standard antibiotics in treating Lyme disease. He plans to test the oils in animals and later in humans.

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This article is related to: Diseases and Illnesses, Essential Oils, U.S. Centers for Disease Control and Prevention

Alan Dumoff
Doctor of Law
Master of Social Work

Curriculum Vita

Health care attorney with extensive experience on matters of law, practice management, program design, public policy, credentialing and research dedicated to furthering the responsible practice of integrative medicine.

SUMMARY

Legal Practice– Thirty years of experience and in-depth understanding of the legal aspects of integrative medicine practice and its regulation, including medical board discipline; risk management; food, drugs, devices and dietary supplements; Medicare/insurance reimbursement; laboratory requirements; practice management. Consultation on a wide range of legal, management, business and clinical aspects of practice. Representation before U.S. Supreme Court, extensive appellate and administrative experience.

Lobbying– National and state lobbying and drafting of legislative solutions to problems in integrative health care delivery.

Public Policy Leadership– Board advisor, Integrative Medicine Consortium; former board member of Integrative Healthcare Policy Consortium; extensive volunteer contributions to national collaborative efforts toward integrative health policy.

Clinical/Program Design and Research Skills– Ten years well-rounded care delivery as a social worker, experience including facilitation of a multidisciplinary health care team, delivery of family therapy/psychotherapy services to over 500 families; assisted in design and management of social programs. Development of IRB approved research, post-graduate clinical psychology training in research design.

Certification/Board Development– Former Executive Director of National Commission for the Certification of Acupuncture and Oriental Medicine (NCCAOM); counsel to The Academy of Integrative Health and Medicine (AIHM), former American Board of Integrative & Holistic Medicine (ABIHM).

Extensive Publications/Presentations– Over 90 articles, anthology chapters, and conference presentations on integrative health topics, including co-chair of two national integrative medicine conferences and an international presentation addressing a wide variety of legal and policy issues regarding integrative/CAM practice.

Awards: Jonathan Forman Award, 2019, for making the most significant contribution to the field of environmental medicine by the American Academy of Environmental Medicine.

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LEGAL SKILLS

Notable Achievements:

- United States Supreme Court, Counsel on *Hercules v. United States*, 516 U.S. 417 (1996), *sub nom. Wm.Thompson v. United States*, 26 Cl. Ct. 17 (1992), *aff'd* 24 F.3d 188 (Fed. Cir. 1994); drafted successful petition for certiorari in government contract matter involving Vietnam war Agent Orange damages.
- Submitted FDA Citizen's Petition seeking reconsideration of restrictions on compounding natural ingredients on behalf of integrative and naturopathic professional organizations.
- Vacated summary suspension of medical license by D.C. Board of Medicine *In the Matter of Ahmed Ali, M.D.,* Case No. DH-B-06-8000032 (2006).
- Obtained, with co-counsel Jacques Simon, dismissal after full hearing of disciplinary charges against orthomolecular psychiatrist in *Maryland Board of Physicians v. Alice Lee-Bloem, M.D.*, DHMH-SBP-71-08-08596 (2008).
- Temporarily vacated summary suspension of dental license by D.C. Board of Dentistry in In the Matter of Robert. B. Johnson, DMD, 2014-DOH-00007; obtained remand from D.C. Court of Appeals in *Johnson v. D.C. Dep't of Health*, 163 A.3d 746 (D.C. 2017).
- Successfully curtailed numerous Board investigations against integrative physicians and complementary and alternative (CAM) practitioners.
- Successfully inserted Congressional conference report language to protect CAM practice in the Health Insurance Portability and Accountability Act.
- Obtained reversal of FDA barring sale of Shealy Relaxmate™ as an unapproved medical device.
- Assisted new homeopathic company with FDA drug establishment registration and state drug licensure.
- Drafted Quality of Life Study approved by IRB for Insulin Potentiation Therapy.
- Obtained $9,000 jury award, negligent injury by unlicensed massage therapist.
- Obtained $250,000 contested award for vaccine-related injury.
- Reduced Medicare overpayment demand from $266,000 to $27,000.
- Assisted in overturning Medicare overpayment demand of $1.7 million.
- Assisted not-for-profit organization in obtaining and planning for implementation of integrative health care center funded at $30 million level.
- Obtained dismissal of million-dollar contract dispute against health care center.
- Successful criminal appellate practice; obtained reversal of conviction–*Jones v. Unites States*, 779 A.2d 357 (D.C. 2001) due to coercive statements from the bench; remand in *Haley v. United States*, 799 A.2d 1201 (D.C. 2002); and release from prison in *Lawrence v. United States,* No. F-7791-89 (D.C. 2002).

Other Published Opinions:

- *Faulkenstein v. Board of Medicine*, 727 A.2d 302 (D.C. 1999).
- *Hall v. Henderson*, 627 A.2d 1047 (D.C. 1996).
- *Singer v. D.C. Board of Medicine*, 631 A.2d 1232 (D.C. 1993).
- *Weaver v. Grafio*, 595 A.2d 983 (D.C. 1991).

Diverse and Skilled Legal Services:

- *Health law practice*–Legal audits and protection of health care practice, including practitioner discipline, licensure, credentialing, malpractice; insurance and Medicare claims, fraud and abuse, Stark and anti-kickback requirements; telemedicine; drug, medical device, dietary supplement, food labeling, laboratory regulation, IRBs and legal aspects of clinical research; HIPAA regulations; practice structure, including concierge practice; practice sales; vaccine injury claims; Child Protective Service matters involving the use of CAM therapies: extensive knowledge of medical practice, policy issues of complementary and alternative medicine, functional medicine, clinical delivery, managed care, mental health matters.
- *Diverse practice*–Transactional, litigation and appellate practice covering tort and contract matters; trademark, business development, employment discrimination, real estate, insurance, criminal matters, attorney sanctions.
- Extensive *litigation* and *appellate* experience as principal/sole counsel before the U.S. Supreme Court, federal and state trial and appellate courts, including full evidentiary hearings before medical boards, other administrative bodies.
- *Solo Practitioner with Firm Experience* – Co-managed cases with Anderson, Kill, Olich & Ochinsky; Sidley & Austin; four years with Swankin & Turner.

LEADERSHIP CONTRIBUTIONS TO DEVELOPMENT IN THE FIELD

Notable Achievement: Acknowledged by White House Commission on Complementary & Alternative Medicine Policy for contributions to Final Report.

- Legal advisor to the Integrative Medicine Consortium, composed of the American Academy of Environmental Medicine (AAEM), American Association of Naturopathic Physicians (AANP), American College for Advancement in Medicine (ACAM), International College of Integrative Medicine (ICIM), International Hyperbaric Medical Association (IHMA), International Organization of Integrative Cancer Physicians (IOIP).
- General Counsel, The Academy of Integrative Health and Medicine (merger of the American Board of Integrative Holistic Medicine and American Holistic Medical Association).
- Co-founder, Maryland Society of Integrative Medicine, www.mism-info.org.
- Extensive *pro bono* contributions to the CAM community, such as legislative efforts on conversion of Office of Alternative Medicine at NIH to the National Center for Complementary and Alternative Medicine.
- Co-Chairman, Design Principles for Healthcare Renewal Working Group, a project of the Collaboration for Healthcare Renewal Foundation.
- Executive Committee Member, Integrated Healthcare Policy Consortium, which created the National Policy Dialogue between 60 universities, conventional and CAM professional organizations.
- Taught integrative methods to Washington, D.C. CAM practitioner network.

INSURANCE PANELS

Panel attorney for professional disciplinary defense for:

- Fairway Physicians Insurance Company, all covered states, Agoura Hills, CA.
- NAS Insurance Services, Inc., national panel, Encino, CA.

LOBBYING SKILLS

Notable Achievement: Successfully achieved changes in legislative history of the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) to protect the practice of complementary/alternative medicine and physician autonomy.

- Drafted and successfully lobbied in the District of Columbia for the *Qualified Massage Therapists Act of 1994*; assisted in regulatory development of Act.
- Assisted the Acupuncture Society of the District of Columbia with proposed revisions to the regulations governing acupuncture.
- Testified before United States House Committee on Oversight and Government Reform regarding dietary supplement policy.
- Testified before United States Food and Drug Administration regarding dietary supplement regulation.
- Testified before National Committee on Vital and Health Statistics, Department of Health and Human Services, on coding issues affecting CAM practice.
- Assisted New Jersey Association of Medical Acupuncture as registered lobbyist to counter unfavorable legislative changes.

SUBSTANTIVE EXPERTISE

Notable Experience: Former Director and General Counsel, National Commission for the Certification of Acupuncturists and Oriental Medicine.

- Strong substantive knowledge of *medicine* and *alternative health care* legal, clinical and practice management matters.
- Experienced provider of individual and family therapy; expertise in *psychiatric* and *psychotherapeutic* matters.
- Doctorate level training in *research methods*, *experimental design* and *certification* issues.

TEACHING EXPERIENCE

Adjunct Professor: American University—Department of Justice, Law & Society; undergraduate courses in juvenile law, violence in America, and criminal behavior.

- Workshops offered to general public on "How to Choose and Work with an Alternative Practitioner," courses on meditation and other topics.
- Training for CAM practitioners in Alternative Medicine Referral Service.
- Guest lecturer at Georgetown Masters Program in Physiology with CAM specialization.

CLINICAL EXPERIENCE

- Developed integrative methodology based on over 100 hours of facilitation of volunteer bimonthly multidisciplinary clinical meeting reviewing cases with various medical specialists, acupuncturists, chiropractors, homeopaths, nurses, nutritionists, physicians from various specialties, psychologists, and others; provided consultations for selected patients as learning exercise; produced clinical grand round presentation and draft guidelines for integrative clinical practice.
- Led mental health treatment team staffed by psychiatrist, other therapists.
- Delivered family therapy services to over 500 families, individual and couples therapy to numerous clients; facilitated group psychotherapy, working groups.
- Worked closely on clinical issues with acupuncturists, chiropractors. homeopaths, nutritionists, holistic physicians and other practitioners.

COUNSEL RELATIONSHIPS

Informal Relationships, Former "Legal Quartet" - Legal team comprised of Al Augustine, Esquire (Chicago), Rick Jaffe, Esquire (New York, Houston), Jacques Simon, Esquire (New York) and myself; a group of independent attorneys supporting integrative health practice, 2007-2012.

Of counsel to Law Office of Michael H. Cohen, formerly of Harvard University and Harvard Medical School.

PUBLICATIONS

Chapters in Anthologies:

- *Legal and Regulatory Barriers to Accessing Complementary and Alternative Cancer Treatments*, in Complementary and Alternative Therapies in Cancer, Micozzi, M. (ed.), Springer Publishing (2007).
- *The Legal Issues: Liability and Regulatory Concerns Interacting with Chiropractors*, Integrative Chiropractic: An Invitation to Collaborate, Michael Minke, D.C. (ed.) Elsevier Publishing (publication date TBD).
- *Legal and Ethical Issues in Integrative Practice*, in Integrative Medicine, Ben Kligler, M.D., M.P.H. and Roberta Lee, M.D., McGraw-Hill (eds. From Albert Einstein College of Medicine and Beth Israel Medical Center) (2004).
- *Complementary and Alternative Medicine,* Best Practices in Medical Management, Kongstvedt and Plocher (eds.), Aspen Press (Fall, 1998).
- *Chiropractic and the Law*, Current Controversies in Chiropractic, Redwood (ed.) Churchill-Livingstone (1997)(2nd ed. 2004).

Published Articles (note that ACM titles refer to Alternative/Complementary Medicine):

- *FDA Restrictions on Drug Compounding: Needed Medications are Going to Disappear. A Call for Intervention.* Integrative Medicine: A Clinician's Journal, June/July 2018; http://www.imjournal.com
- With Weeks, J. *The Move to Gain ABPS-Recognition of Board Certification in Integrative Medicine*, The Integrator, theintegratorblog.com, July 1, 2012.
- *Further Developments in the Battleground Over Lyme Disease Standards: The Connecticut Attorney General Investigates the Infectious Disease Society of America.* Alternative/Complementary Therapies, 2007; 1(2).
- *Research Under Institutional Review Board Approval: A Clinical Means to Legal End.* Alternative/Complementary Therapies, 2006; 12(6).
- *The Umbrella Stand: A Professional Defense Project of the American Association for Health Freedom.* Alternative/Complementary Therapies, 2006; 12(5).
- *Ethical Considerations: Lessons from One Professional's Journey.* Alternative/Complementary Therapies, 2006; 12(4): 190-198.
- *The Ins and Outs, Pros and Cons of Non-licensed Practice: Report and Commentary on the Health Freedom Movement,* Alternative/ Complementary Therapies, 2006; 12(3): 136-142.
- *Diagnosing Lyme Disease: A Case Study in Complications Arising in Standards of Care*, Alternative/Complementary Therapies, 2006; 11(5).
- *The Institute of Medicine's Report on ACM: A Review & Commentary,* Alternative/Complementary Therapies, 2005; 11(4).
- *The Institute of Medicine's CAM Report: A Step in The Right Direction*, Seminars in Integrative Medicine, Elsevier Publishing, 2005.
- *Dealing With Difficult Patients: Therapeutic and Legal Suggestions*, Alternative/Complementary Therapies, 2005; 11(3): 155-160.
- *Current Practice Terminology (CPT) Coding and the Practice of Integrative Medicine,* Seminars in Integrative Medicine, Elsevier Publishing, (2005).
- *The Institute of Medicine's Report on ACM: A Review & Commentary,* Alternative/Complementary Therapies, 2005; 11(2): 94-99.
- *Asset Protection as Defense Against a Malpractice Judgment? A Very Brief Primer*, American College for the Advancement of Medicine - Newsletter, Jan (2005).
- *Over the Transom: A Poi Pori of Legal Issues*, Alternative/ Complementary Therapies, 2005; 11(1):41-45.
- *Decoding the Codex Threat: Are Limits on Access to Dietary Supplements Looming?* Alternative/Complementary Therapies, 2004; 10(6): 343-349.
- With Cohen, M. *Advising from a Distance: The Legality of Web-Based Clinical Consultations, Parts I & II.* Alternative/Complementary Therapies, 2004; 10(4/5): 231, 234; 289, 293.
- *Legal Issues Presented by Integrative Practice*, Seminars in Integrative Medicine, Elsevier Publishing, 2(1) March, 2004.

- *Recognizing and Working With Legal Issues: A Legal Audit for Integrative Practices and CAM Practitioners*, *Parts I & II* Alternative/ Complementary Therapies, 2004; 10(2/3):109-115, 175-179.
- *Interview with Michael Cohen, JD, MBA, MFA.* Alternative/ Complementary Therapies 2003; 10(1):46-51.
- *Squandering the Promise of Collaboration: Invoking the Tower of Babel By Using and Touting Unproven Therapies,* Alternative/ Complementary Therapies 2003; 9(6):283-288.
- *Where the Danger Lies: The Imposition of Informed Consent as a Bias in Physician Regulation,* Alternative/Complementary Therapies 2003; 9(5):268-273.
- *Left to Our Own Devices? Understanding the Ill-Fitting Nature of BioEnergy Product Regulation,* Alternative/Complementary Therapies 2003; 9(3):202-207.
- *National Developments in ACM Policy: A Report on a Maturing Field,* Alternative/Complementary Therapies 2003; 9(2):93-97.
- *ACM: An International Perspective*, Alternative/Complementary Therapies 2003; 9(1):45-48.
- *Minimizing Malpractice Risk (A Review)*, Integrative Medicine Consult 2002; 4(8):88-89.
- *Coding System for Alternative and Complementary Therapies: It's Not as Easy as ABC,* Alternative/Complementary Therapies 2002; 8(4):246-252.
- *New Codes for CAM: HHS Review Could Make Them A Reality*, Alternative Therapies in Health and Medicine 2002; 8(4):32-36.
- *The Federation of State Medical Boards' New Guidelines for ACM Practice: Improvements and Concerns,* Alternative/Complementary Therapies 2002; 8(5):303-309.
- *New FSMB CAM Guidelines: Significant Steps in the Right Direction*, The Integrative Medicine Consult 4(9):97, 102-103.
- *Protecting ACM Physicians from Undeserved Discipline: Legislative Efforts in Maryland,* Alternative/Complementary Therapies 2002; 8(2):120-126.
- *A Collision Between Principles and Law: A Case Study in Why Integration is So [Damn] Difficult,* Alternative/Complementary Therapies 2002; 8(1):8-9.
- *Is It Merck or is it Pharmanex? The Regulatory Tale of Lovastatin and Cholestin,* Alternative/Complementary Therapies 2001; 7(5):310-314.
- *Legal Aspects of Integrative Medicine: A Brief Look at LifeWorks Wellness Center,* Alternative/Complementary Therapies 2001; 7(4):244-245.
- *Creating the New Medicine: Harmonizing Diverse Viewpoints*, Alternative/Complementary Therapies 2001; 7(3):174-179.
- *Balancing Experience Versus Paradigm: Moving Toward the New Medicine*, Alternative/Complementary Therapies 2001; 7(2):112-116.
- *An Open Letter to the White House Commission of Complementary and Alternative Medicine Policy, Part 1: Suggestions for Federal Policy & Part 2: Suggestions for State Policy*, Alternative/ Complementary Therapies 2000; 6(5):249-257 & 6(6):355-357.
- *State Medical Board Prohibitions on Physician Sale of Supplements,* Physician Consult, Fall, 2000.

- *Medical Board Prohibitions Against Physician Supplement Sales,* Alternative/ Complementary Therapies 2000; 6(4):226-236.
- *CPT Coding for ACM Services: A Short Course,* Alternative/ Complementary Therapies 2000; 6(3):152-161.
- *Defining"Disease:" The Latest Struggle for Turf in Dietary Supplement Regulation*, Alternative/Complementary Therapies 2000; 6(2):95-104.
- *Regulating Professional Relationships: Kickback and Self-Referral Restrictions on Collaborative Practice*, Alternative/Complementary Therapies 2000; 6(1):41-46.
- *Understanding the Kassebaum-Kennedy Health Care Act: Addressing Legitimate Concerns and Irrational Fears*, Alternative/ Complementary Therapies 1997; 3(4):309-313.
- *Legislation versus Self-Regulation in the Somatic Practices Field: Comments from the Editor*, Alternative/Complementary Therapies 1997; 3(3):220-222.
- *Expanding the Office of Alternative Medicine into the Center for Integrative Medicine and Creating Access to Medical Treatment; Two Agendas for the 105th Congress*, Alternative/ Complementary Therapies, 1997; 3(1):59-63.
- *Protecting Your Practice: Myth v. Fact*, Alternative/ Complementary Therapies 1996; 2(3):186-191.
- *Malpractice Liability of Alternative/Complementary Health Care Providers: A View From the Trenches*, Alternative/Complementary Therapies, 1995; 1(4):248-253 & 1(5):333-334.
- *Including Alternative Providers in Managed Care—Managing the Malpractice Risk (Part I & II)*, Medical Interface (May & June, 1995).
- *Private Right of Action*, Administrative Law, Stein, *et al.* (1987) (Unattributed Note).

Former Editorial: Senior Professional Editor, legal/business section IntegrativMedicine (http://www.onemedicine.com).

- Editorial Board, The Integrator: for the Business of Alternative Medicine, IMC Publishing.
- Editorial Board, Journal of Alternative & Complementary Therapy, Liebert Publishing.

CONFERENCE CHAIRMANSHIPS AND PRESENTATIONS

National conferences on alternative medicine, health law topics, the majority for Category 1 CME credits, including—

- "Regulating (and Surviving) Professional Differences of Opinion: FDA Compounding and Functional Medicine, American Academy of Enivronment Medicine, Louisville, KY (October, 2019).
- "Top Ten Legal Mistakes Made by Integrative Medicine Physicians," Heal Thy Practice: Transforming Primary Care, Long Beach, CA (November, 2012).
- "Legal Issues in Delivering IV Therapies" and "Legally Safe Practice of Integrative Medicine," Joint Conference of the American College for Advancement in Medicine and American Association of Environmental Medicine, Portland, OR (November, 2011)

- "Medicolegal Issues in Integrative Medicine," Heal Thy Practice: Transforming Primary Care, Long Beach, CA (November, 2011).
- "Legally Safe Practice of Integrative Oncology," Integrative Oncology Program of the American Association for Anti-Aging Medicine, Dallas, TX (September, 2011).
- Medicolegal Issues in Integrative Medicine" and "Board Investigations and Negotiations," iMosaic Conference, Integrative Medicine Consortium, Minneapolis, MN (April, 2011).
- "Preventive Measures in Practicing Integrative Medicine," "Meet the Lawyer, a Q&A Period," Holistic Primary Care, Charlotte, NC (June 2010).
- "Legally Safe Integrative Medicine Practice," Clinical II track, Autism Research Institute, Baltimore, MD (April, 2010).
- "Legal Safety and Reimbursement Issues in Integrative Medicine Practice," North Carolina Integrative Medicine Society, Statesville, NC (March, 2010).
- "Legally Safe Integrative Medicine Practice," Clinical II track, Autism Research Institute, Tampa Florida (via webcam), (February, 2010).
- "Legal Issues in Integrative Practice," Autism Research Institute, Clinical I and Clinical II track, Dallas, TX (October, 2009).
- "The Legal Landscape: Issues, Alerts and Solutions for Integrative Medicine Practitioners," Heal Thy Practice, Holistic Primary Care Publication, Phoenix, AZ (June, 2009).
- Various presentations, American College for Advancement in Medicine, Las Vegas, NV (November, 2008).
- "IV Therapies in Naturopathic Practice: Basic Training and Clinical Applications from the Experts (and a lawyer!)" Bastyr University, Seattle, Washington (February, 2008).
- "Legal Issues Affecting Collaboration: Physician/Patient Originated Studies in CAM Cancer Methods," Cancer Researchers and CAM Practitioners: Fostering Collaborations; Advancing the Science, Office of Cancer and Complementary and Alternative Medicine, National Institutes of Health, Bethesda, Maryland (October, 2007).
- "Announcing the 'Quartet:' Team Legal Approach to Integrative Medicine, American College for Advancement of Medicine, Phoenix, AZ (April, 2008).
- "The Legal Quartet: Review of Legal Needs for Integrative Physicians," American College for Advancement in Medicine, Orlando, Florida (October, 2007).
- "Report from the Trenches: Legal Case Studies in Defending Integrative Practitioners," East International Complementary and Natural Healthcare Conference and Expo (CAMEXPO), InnoVision Communications, Continuum Center for Health and Healing, Beth Israel Medical Center (February, 2007).
- "Defending and Making the Case for Integrative Physicians," American College for Advancement in Medicine. Palm Springs, CA (November, 2006).
- "Institutional Review Boards and Insulin Potentiation Therapy," Elka Best Foundation Fourth Annual Conference, Atlanta, GA (October, 2006).
- "Avoiding and Defending Medical Board Actions," at *Building Bridges to Advance Healthcare,* American College for Advancement in Medicine Dallas, TX (May, 2006).

- "Credentialing and Legal Issues in Complementary and Alternative Medicine" and "Legal Issues for Physicians Delivering Integrative Medicine" at *Bringing the Entire Complementary and Natural Healthcare Community Together*, International Complementary and Natural Healthcare Conference and Expo (CAMEXPO), InnoVision Communications (March, 2006).
- "Credentialing and Legal Issues in Complementary and Alternative Medicine" as a pre-conference and seminar, *Integrative Medicine for Healthcare Organizations Conference,* American Hospital Association/Health Forum, in San Diego, CA (January, 2006).
- "Legal Issues in the Delivery of Complementary and Alternative Medical Care," at *A Blast to the Future: Emerging Concepts in Immunology* sponsored by American College for Advancement in Medicine San Diego, CA (November, 2004).
- "Credentialing & Legal Issues," Pre-Conference at *Second Annual Integrative Medicine for Healthcare Organizations* co-sponsored by American Hospital Association/Heath Forum and InnoVision Communications, LLC San Diego, (January, 2004).
- "Separating Promising Therapies from Wishful Thinking: Choosing and Working with CAM Practitioners: A Professional and Patient-Centered Perspective," *Mini-Med School, Georgetown Medical Center*, March 2003.
- "Credentialing & Privileging Complementary and Alternative (CAM) Practitioners in Health Organizations," presented with Andrew Sparber, R.N., M.S., C.S. *Integrative Medicine for Healthcare Organizations: Business Strategies, Practical Tools, and Best Practices,* co-sponsored by American Hospital Association/Heath Forum and InnoVision Communications, LLC San Francisco, January, 2003.
- "National Policies and Regulations on Integration," *Integration of CAM and Modern Medicine*, the Islamic Organization for Medical Sciences in collaboration with World Health Organization Eastern Mediterranean Regional Office and the Islamic Educational, Scientific and Cultural Organization, Cairo, Egypt, October, 2002.
- Conference Co-chair, *Fourth Annual Congress on Complementary & Alternative Medicine*; Plenary Panel Moderator, "The Complex Patient: Grand Round Case Presentation;" Moderator, "Townhall on Clinical Integration," also "Provider Networks and Community Integration," "Criminal and Civil Fraud Under Medicare Part B" Arlington, VA, Oct. 1998.
- "Legal and Regulatory Concerns of Providing Alternative Care," *Integrating Alternative & Complementary Medicine with Conventional Medicine,* AIG Conferences, Las Vegas, Sept., 1998.
- "Legal Issues in Health Care Freedom," *Comprehensive Cancer Care: Integrating Complementary and Alternative Therapies*, Center for Mind-Body Medicine, James Gordon. M.D., Chair, Washington, D.C., June, 1998.
- "Legal and Regulatory Concerns of Providing Alternative Care" and "Clinical Aspects of Alternative Medicine—Designing a Continuum of Care with Allopathic and Alternative Health Care Practitioners," *Integrating Botanicals into Allopathic and Alternative Care,* Institute for International Research, San Francisco, Oct. 1997.

- Conference Co-chair, *Third Annual Congress on Complementary & Alternative Medicine*; Plenary Chair, "The Politics of Alternative Medicine;" Panel Chair, "The Holy Grail: Integrating Alternative and Allopathic Medicine," Arlington, VA, Sept. 1997.
- "Integrating Disparate Practitioners of Care in a Team Practice: Legal and Clinical Considerations," *Integrating Alternative Medicine & Managed Care*, National Managed Health Care Coalition, Philadelphia, Jan. 1997.
- "Legal and Regulatory Concerns of Providing Alternative Care" and "Clinical Aspects of Alternative Medicine–Designing a Continuum of Care with Allopathic and CAM Practitioners," *Developing, Operating and Integrating Complementary Medicine*, AIC Conferences, Atlanta, Nov. 1996.
- "Malpractice and Reimbursement Issues for the Practitioner," *Second Annual Congress of Complementary & Alternative Medicine* Liebert Publishers, Washington, June 1996.
- "Malpractice Liability Imposed Upon Managed Care Organizations: Current Trends and Future Market-Driven Challenges," *Managing Risk: Conference for Managed Care Risk Managers*, AIC Conferences, Chicago, May 1996.

PROFESSIONAL LICENSES/MEMBERSHIPS

Practice of Law

Maryland, 1988; District of Columbia, 1990; United States District Court for the District of Columbia, 1991; United States Court of Federal Claims, 1991; United States Federal Circuit, 1992; United States Court of Appeals for the District of Columbia, 1992; United States Supreme Court, 1995.

Practice of Social Work

Licensed Graduate Social Worker, Maryland, 1989-1992; 1998 to 2000.

Practice in licensed settings, 1979-83, Michigan, 1984-85, Maryland.

PRACTICE/EMPLOYMENT HISTORY

Solo Private Practice

Washington, D.C., Rockville, Gaithersburg MD. August 1992 to present. Represent numerous integrative practices, physicians, acupuncturists, chiropractors, massage therapists, nutritionists and other complementary providers before licensing boards, FDA, CMS, HHS, insurance companies, and advise about practice issues; dietary supplement manufacturers, drug and device manufacturers on regulatory and research issues, national organizations on public policy issues.

LifeTree Consulting/ LifeTree Medical Center, Inc.

Founder and Executive Director. Washington, D.C. August 1993 to 2003.

Start-up health care service which evolved into consulting practice.

Adjunct Professor, American University, Dept. Justice, Law, Society.
Washington, D.C. January 1994 to December 1996. Part-time.

Swankin & Turner, Senior Associate Attorney.
Washington, D.C. October 1988 to August 1992.

Director/General Counsel, National Commission for the Certification of Acupuncturists and Oriental Medicine (during tenure at Swankin & Turner). Washington, D.C. October 1988 to December 1989.

Stein, Mitchell & Mezines; **Environmental Protection Agency,** Law Clerk. Washington, D.C. January 1987 to July 1988; May 1987 to August 1987.

Clinical/Planning Positions, Michigan, Maryland, District of Columbia.

Therapist–Private Clinical Practice; Karma Academy for Boys, Maryland; 1984-1985; Runaway Emergency Action Center and Hotline (REACH), Michigan; Probation Officer, Michigan; 1979-1983, 1984-1985.

Planning Technician—United Way, Michigan; Department of Community Development, Michigan; 1977-1979**.**

EDUCATION

Catholic University School of Law, Juris Doctorate, 1988, top 19 percent. Senior Staff Member, Journal of Contemporary Health Law and Policy; Professorial honors for trial practice; Bamberger Competition semi-finalist; Research Assist. Harold McDougall.

Catholic University School of Social Service, Master of Social Work, 1987. Chair, Alumnae/i Curriculum Committee; Post-grad coursework in experimental design.

University of Michigan, Bachelor of Arts, Clinical/Community Psychology, 1977; Debate competition honors.

Continuing Education

Law—"Clinical Research–Legal Developments, D.C. Bar; "Dealing with Incapacity: Advanced Directives and Living Wills, D.C. Bar; "The Unexamined Anatomy of the Kassebaum-Kennedy Act," ABA; "Making A Deal with Doctors," ABA; "Consumer Law," D.C. Bar; "Food and Drug Law, Health Claims on Foods," FDLI; "Employment Law," "Counseling Alternative Providers," ABA; "Vaccine Injury Law," U.S. Claims Court; "Medicare Reimbursement Issues," Medical Management Institute; "Appellate Advocacy," Public Defender's Office; "Intellectual Property," D.C. Bar, "Food and Drug Law," D.C. Bar, "Institutional Review Boards," D.C. Bar; "HIPAA Implementation", D.C. Bar; "Administrative Simplification Act Issues," D.C. Bar, "Introduction to Health Law," (six part series, D.C. Bar), numerous other CLE and other seminars.

Health Care—Extensive training and self-education in individual/family therapy, alternative care, medical ethics. Dozens of conferences in addition to those listed under presentations, including "Building Bridges: The Link Between Allopathic and Alternative Medicine in Clinical Practice and Research," Johns Hopkins University and the Traditional Acupuncture Institute; "Credentialing CAM Practitioners," Greeley Consulting; "Alternative Medicine Track" at National Managed Health Care Congress; coursework with the American College for the Advancement of Medicine; attend National Academy of Sciences' Institute of Medicine "Summit on Integrative Medicine and the Health of the Public," Feb. 25-27, 2009.

SAMPLE REFERENCES

"Thank you for your persistence and remarkable success [in accomplishing what] at least two other law firms had tried and failed. . . . Please feel free to use me as a reference for anyone wanting to know about your services."

C. Norman Shealy, M.D., Ph.D., Founding President
American Holistic Medical Association

"With today's litigious environment, and the FDA taking an antagonistic view of any treatment outside of the PDR, one cannot be too careful in the practice of medicine. To be safe in this arena, one needs great legal expertise and advice. I suggest to you Alan Dumoff. He came to us, in his own words, "as a member of the team." He has worn that hat wonderfully well for the past eight years. We do not put out even a promo piece without his input. This saves us from the rough waters and high waves of those who would suppress true health care. You can count on him. We do always!"

David Minkoff, M.D., Medical Director, LifeWorks Wellness Center

"The consideration of the issues under discussion by the Commission provided by . . Alan Dumoff, J.D., M.S.W. in private practice in Rockville, MD . . . are recognized and appreciated."

White House Commission on Complementary and Alternative Medicine Policy – Final Report, March 2002

"In recent years, Alan Dumoff has quietly emerged as one of the nation's leading attorneys specializing in complementary and alternative medicine (CAM)."

Daniel Redwood, D.C. Pathways Interview:
The Alternative Health Attorney, Pathways Magazine, Spring, 2003

SAMPLE ASSOCIATION CLIENTS

Academy for Integrative Health and Medicine

Acupuncture Society of the District of Columbia

American Board of Integrative Holistic Medicine

American College for Advancement in Medicine

American Massage Therapy Association–D.C. Chapter, Washington, DC

Alliance for Natural Health - USA, Washington, DC
(Formerly the American Association for Health Freedom)

Best Answer for Cancer Foundation, Austin, TX

Integrative Medical Consortium