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# Law and Natural Medicine

## Practice

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## Complementary and Alternative Medicine Legal Issues

### Phillipines - Traditional and Alternative Medicine Act of 1997
In Australia, the topic is termed as *complementary medicine* and the [Therapeutic Goods Administration](https://www.tga.gov.au) has issued various guidances and standards. Australian regulatory guidelines for complementary medicines (ARGCM) demands that the pesticides, fumigants, toxic metals, microbial toxins, radionuclides, and microbial contaminations present in *herbal substances* should be monitored, although the guidance does not request for the evidences of these traits. However, for the herbal substances in pharmacopoeial monographs, the detailed information should be supplied to relevant authorities.

The production of modern pharmaceuticals is strictly regulated to ensure that medicines contain a standardized quantity of active ingredients and are free from contamination. Alternative medicine products are not subject to the same governmental quality control standards, and consistency between doses can vary. This leads to uncertainty in the chemical content and biological activity of individual doses. This lack of oversight means that alternative health products are vulnerable to adulteration and contamination. This problem is magnified by international commerce, since different countries have different types and degrees of regulation. This can make it difficult for consumers to properly evaluate the risks and qualities of given products.
Legal Regulation of alternative medicine

Naturopathy

**Alternative medical systems**

- Acupuncture
- Anthroposophic medicine
- Chiropractic
- Homeopathy
- Naturopathy
- Osteopathy

**Traditional medicine**

- Ayurveda
- Faith healing
- Japanese
- Shamanism
- Siddha
- Chinese
- Korean
- Mongolian
- Tibetan
- Unani

**NCCIH domains**

- Mind–body interventions
- Biologically based therapies
- Manual therapy
- Energy therapies
Naturopathy or naturopathic medicine is a form of alternative medicine employing a wide array of "natural" modalities, including homeopathy, herbalism, and acupuncture, as well as diet (nutrition) and lifestyle counseling. Naturopaths favor a holistic approach with non-invasive treatment and generally avoid the use of surgery and drugs. Naturopathic medicine contains many pseudoscientific concepts and is considered ineffective and can be harmful, which raises ethical issues. Naturopaths have repeatedly been accused of being charlatans and practicing quackery.

Much of the ideology and methodological underpinnings of naturopathy are based on vitalism and self-healing, rather than evidence-based medicine. Naturopathic education contains little of the established clinical training and curriculum completed by primary care doctors, as naturopaths mostly train by studying unscientific notions and practicing unproven interventions and diagnoses. Naturopaths tend to oppose vaccines and teach their students anti- and alternative vaccine practices, resulting in lower vaccination rates. According to the American Cancer Society, "scientific evidence does not support claims that naturopathic medicine can cure cancer or any other disease."

The term "naturopathy" was created from "natura" (Latin root for birth) and "pathos" (the Greek root for suffering) to suggest "natural healing". Modern naturopathy grew out of the Natural Cure movement of Europe. According to the Merriam-Webster Dictionary, the first use in print that can be found is from 1901. John Scheel and popularized by Benedict Lust, the "father of U.S. naturopathy". Beginning in the 1970s, there was a revival of interest in the United States and Canada, in conjunction with the "holistic health" movement.
Naturopaths claim the ancient Greek "Father of Medicine", Hippocrates, as the first advocate of naturopathic medicine, before the term existed.[16][19] Naturopathy has its roots in the 19th century Nature Cure movement of Europe.[20][21] In Scotland, Thomas Allinson started advocating his "Hygienic Medicine" in the 1880s, promoting a natural diet and exercise with avoidance of tobacco and overwork.[22][23]

The term naturopathy was coined in 1895 by John Scheel,[24] and purchased by Benedict Lust, the "father of U.S. naturopathy".[18] Lust had been schooled in hydrotherapy and other natural health practices in Germany by Father Sebastian Kneipp; Kneipp sent Lust to the United States to spread his drugless methods.[19] Lust defined naturopathy as a broad discipline rather than a particular method, and included such techniques as hydrotherapy, herbal medicine, and homeopathy, as well as eliminating overeating, tea, coffee, and alcohol.[25] He described the body in spiritual and vitalistic terms with "absolute reliance upon the cosmic forces of man's nature".[26]

In 1901, Lust founded the American School of Naturopathy in New York. In 1902 the original North American Kneipp Societies were discontinued and renamed "Naturopathic Societies". In September 1919 the Naturopathic Society of America was dissolved and Benedict Lust founded the American Naturopathic Association to supplant it.[18][27] Naturopaths became
licensed under naturopathic or drugless practitioner laws in 25 states in the first three decades of the twentieth century. \[18\] Naturopathy was adopted by many chiropractors, and several schools offered both Doctor of Naturopathy (ND) and Doctor of Chiropractic (DC) degrees. \[18\] Estimates of the number of naturopathic schools active in the United States during this period vary from about one to two dozen. \[15\][18][24]

After a period of rapid growth, naturopathy went into decline for several decades after the 1930s. In 1910 the Carnegie Foundation for the Advancement of Teaching published the Flexner Report, which criticized many aspects of medical education, especially quality and lack of scientific rigour. The advent of penicillin and other "miracle drugs" and the consequent popularity of modern medicine also contributed to naturopathy's decline. In the 1940s and 1950s, a broadening in scope of practice laws led many chiropractic schools to drop their ND degrees, though many chiropractors continued to practice naturopathy. From 1940 to 1963, the American Medical Association campaigned against heterodox medical systems. By 1958 practice of naturopathy was licensed in only five states. \[18\] In 1968 the United States Department of Health, Education, and Welfare issued a report on naturopathy concluding that naturopathy was not grounded in medical science and that naturopathic education was inadequate to prepare graduates to make appropriate diagnosis and provide treatment; the report recommends against expanding Medicare coverage to include naturopathic treatments. \[15\][28] In 1977 an Australian committee of inquiry reached similar conclusions; it did not recommend licensure for naturopaths. \[29\] As of 2009, fifteen U.S. states, Puerto Rico, the US Virgin Islands and the District of Columbia licensed naturopathic doctors. \[30\] and the state of Washington requires insurance companies to offer reimbursement for services provided by naturopathic physicians. \[31\][32] South Carolina and Tennessee prohibit the practice of naturopathy. \[33\][34][35]

Beginning in the 1970s, interest waxed in the United States and Canada in conjunction with the holistic health movement. \[18\][25]

Practice

Naturopathic practice is based on a belief in the body's ability to heal itself through a special vital energy or force guiding bodily processes internally. \[1\] Diagnosis and treatment concern primarily alternative therapies and "natural" methods that naturopaths claim promote the body's natural ability to heal. \[25\][36] Naturopaths focus on a holistic approach, often completely avoiding the use of surgery and drugs. \[15\][37] Naturopaths aim to prevent illness through stress reduction and changes to diet and lifestyle, often rejecting the methods of evidence-based medicine. \[9\][38]

A consultation typically begins with a lengthy patient interview focusing on lifestyle, medical history, emotional tone, and physical features, as well as physical examination. \[25\] Many naturopaths present themselves as primary care providers, and some naturopathic physicians may prescribe drugs, perform minor surgery, and integrate other conventional medical approaches such as diet and lifestyle counselling with their naturopathic practice. \[29\][39] Traditional naturopaths deal exclusively with lifestyle changes, not diagnosing or treating disease. Naturopaths do not generally recommend vaccines and antibiotics, based in part on the early views that shaped the profession, and they may provide...
alternative remedies even in cases where evidence-based medicine has been shown effective. [3]

Methods

A 2004 survey determined the most commonly prescribed naturopathic therapeutics in Washington State and Connecticut were botanical medicines, vitamins, minerals, homeopathy, and allergy treatments. [40]

The particular modalities used by a naturopath vary with training and scope of practice. These may include herbalism, homeopathy, [40] acupuncture, nature cures, physical medicine, applied kinesiology, [41] colonic enemas, [41] chelation therapy, [41] color therapy, [41] cranial osteopathy, hair analysis, iridology [41] live blood analysis, ozone therapy, [15] psychotherapy, public health measures and hygiene, [38] reflexology, [41] rolfing, [27] massage therapy, and traditional Chinese medicine. Nature cures include a range of therapies based on exposure to natural elements such as sunshine, fresh air, or heat or cold, as well as nutrition advice such as following a vegetarian and whole food diet, fasting, or abstention from alcohol and sugar. [42] Physical medicine includes naturopathic, osseous, or soft tissue manipulative therapy, sports medicine, exercise, and hydrotherapy. Psychological counseling includes meditation, relaxation, and other methods of stress management. [42]

Practitioners

Naturopathic practitioners in Switzerland can be divided into three groups: those with federal diploma, those recognized by health insurances, and those with neither federal diploma nor recognition by health insurances. Naturopaths with federal diploma can be divided into four categories: European traditional medicine, Chinese traditional medicine, ayurvedic medicine and homeopathy. [43][44] The number of listed naturopaths (including traditional healers) in Switzerland rose from 223 in 1970 to 1835 in 2000. [45]

Naturopathic practitioners in the United States can be divided into three groups: naturopathic physicians, traditional naturopaths, and other health care providers who offer naturopathic services. [15][46][47][48][49]

Licensure

Naturopathic doctors are licensed in 17 US states and 5 Canadian provinces. [50] In jurisdictions where naturopathic doctor (ND or NMD) or a similar term is a protected designation, naturopathic doctors must pass the Naturopathic Physicians Licensing Examinations administered by the North American Board of Naturopathic Examiners (NABNE). [51] after graduating from a college accredited by the Council on Naturopathic Medical Education (CNME). [39]

Naturopathic doctors are not eligible for medical residencies, which are available exclusively for medical doctors and doctors of osteopathic medicine. There are limited post-graduate "residency" positions available to naturopathic doctors offered through naturopathic schools and naturopathic clinics approved by the Council on Naturopathic Medical Education. [52]
Most naturopathic doctors do not complete such a residency, and naturopathic doctors are not mandated to complete one for licensure, except in the state of Utah.

In 2005, the Massachusetts Medical Society opposed licensure based on concerns that NDs are not required to participate in residency and concerns that the "practices" of naturopaths included many "erroneous and potentially dangerous claims." The Massachusetts Special Commission on Complementary and Alternative Medical Practitioners rejected their concerns and recommended licensure.

Many naturopaths present themselves as primary care providers. Doctor of Naturopathy training includes basic medical diagnostic tests and procedures such as medical imaging and blood tests, as well as vitalism and pseudoscientific modalities such as homeopathy.

Continuing education in naturopathic modalities for health care professionals varies greatly.

Traditional naturopaths

Traditional naturopaths are represented in the United States by the American Naturopathic Association (ANA), representing about 1,800 practitioners and the American Naturopathic Medical Association (ANMA).

The level of naturopathic training varies among traditional naturopaths in the United States. Traditional naturopaths may complete non-degree certificate programs or undergraduate degree programs and generally refer to themselves as Naturopathic Consultants. These programs often offer online unaccredited degrees, but do not offer proper biomedical education or clinical training. Those completing a Doctor of Naturopathy (ND) degree from an ANMCB approved school can become a Board Certified Naturopathic Doctor.

Traditional naturopathic practitioners surveyed in Australia perceive evidence-based medicine to be an ideologic assault on their beliefs in vitalistic and holistic principles. They advocate the integrity of natural medicine practice. Some naturopaths have begun to adapt modern scientific principles into clinical practice.

Evidence basis

See also: Evidence-based medicine

Naturopathy lacks an adequate scientific basis, and it is rejected by the medical community. Some methods rely on immaterial "vital energy fields", the existence of which has not been proven, and there is concern that naturopathy as a field tends towards isolation from general scientific discourse. Naturopathy is criticized for its reliance on and its association with unproven, disproven, and other controversial alternative medical treatments, and for its vitalistic underpinnings. Natural substances known as nutraceuticals show little promise in treating diseases, especially cancer, as laboratory
experiments have shown limited therapeutic effect on biochemical pathways, while clinical trials demonstrate poor bioavailability.[61] According to the American Cancer Society, "scientific evidence does not support claims that naturopathic medicine can cure cancer or any other disease."[15]

In 2015 the Australian Government's Department of Health published the results of a review of alternative therapies that sought to determine if any were suitable for being covered by health insurance; Naturopathy was one of 17 therapies evaluated for which no clear evidence of effectiveness was found.[62]

Kimball C. Atwood IV writes, in the journal Medscape General Medicine,

Naturopathic physicians now claim to be primary care physicians proficient in the practice of both "conventional" and "natural" medicine. Their training, however, amounts to a small fraction of that of medical doctors who practice primary care. An examination of their literature, moreover, reveals that it is replete with pseudoscientific, ineffective, unethical, and potentially dangerous practices.[41]

In another article, Atwood writes that "Physicians who consider naturopaths to be their colleagues thus find themselves in opposition to one of the fundamental ethical precepts of modern medicine. If naturopaths are not to be judged "nonscientific practitioners", the term has no useful meaning".[4]

Treatments and practices

Naturopaths are often opposed to mainstream medicine and take an antivaccinationist stance.[3]

According to Arnold S. Relman, the Textbook of Natural Medicine is inadequate as a teaching tool, as it omits to mention or treat in detail many common ailments, improperly emphasizes treatments "not likely to be effective" over those that are, and promotes unproven herbal remedies at the expense of pharmaceuticals. He concludes that "the risks to many sick patients seeking care from the average naturopathic practitioner would far outweigh any possible benefits".[63]

The Massachusetts Medical Society states,

Naturopathic practices are unchanged by research and remain a large assortment of erroneous and potentially dangerous claims mixed with a sprinkling of non-controversial dietary and lifestyle advice.[64]

In terms of education, The Massachusetts Medical Society states:

Naturopathic medical school is not a medical school in anything but the appropriation of the word medical. Naturopathy is not a branch of medicine. It is a hodge podge of nutritional advice, home remedies and discredited treatments...Naturopathic colleges claim accreditation but follow a true “alternative” accreditation method that is virtually
meaningless. They are not accredited by the same bodies that accredit real medical schools and while some courses have similar titles to the curricula of legitimate medical schools the content is completely different. [64]

Certain naturopathic treatments offered by naturopaths, such as homeopathy, rolfing, and iridology, are widely considered pseudoscience or quackery. [65][66][67] Stephen Barrett of QuackWatch and the National Council Against Health Fraud has stated that naturopathy is "simplistic and that its practices are riddled with quackery". [5] "Non-scientific health care practitioners, including naturopaths, use unscientific methods and deception on a public who, lacking in-depth health care knowledge, must rely upon the assurance of providers. Quackery not only harms people, it undermines the ability to conduct scientific research and should be opposed by scientists", says William T. Jarvis. [68]

Safety of natural treatments

Naturopaths often recommend exposure to naturally occurring substances, such as sunshine, herbs and certain foods, as well as activities they describe as natural, such as exercise, meditation and relaxation. Naturopaths claim that these natural treatments help restore the body's innate ability to heal itself without the adverse effects of conventional medicine. However, "natural" methods and chemicals are not necessarily safer or more effective than "artificial" or "synthetic" ones, and any treatment capable of eliciting an effect may also have deleterious side effects. [6][15][69][70]

Vaccination

See also: Vaccine controversies

Naturopathy is based on beliefs opposed to vaccination and have practitioners who voice their opposition. The reasons for this opposition are based, in part, on the early views which shaped the foundation of this profession. [71] In general, evidence about associations between naturopathy and pediatric vaccination is sparse, but "published reports suggest that only a minority of naturopathic physicians actively support full vaccination". [72][73]

A naturopathy textbook recommends "a return to nature in regulating the diet, breathing, exercising, bathing and the employment of various forces" in lieu of the smallpox vaccine. [74] The British Columbia Naturopathic Association lists several major concerns regarding the pediatric vaccine schedule and vaccines in general. [75] The Oregon Association of Naturopathic Physicians reports that many naturopaths "customize" the pediatric vaccine schedule. [76]

Regulation

Naturopathy is practiced in many countries and is subject to different standards of regulation and levels of acceptance. The scope of practice varies widely between jurisdictions, and naturopaths in some unregulated jurisdictions may use the Naturopathic Doctor designation or other titles regardless of level of education. [47] The practice of naturopathy is illegal in two USA states. [33][34][35]
Australia

In 1977 a committee reviewed all colleges of naturopathy in Australia and found that, although the syllabuses of many colleges were reasonable in their coverage of basic biomedical sciences on paper, the actual instruction bore little relationship to the documented course. In no case was any practical work of consequence available. The lectures which were attended by the committee varied from the dictation of textbook material to a slow, but reasonably methodical, exposition of the terminology of medical sciences, at a level of dictionary definitions, without the benefit of depth or the understanding of mechanisms or the broader significance of the concepts. The committee did not see any significant teaching of the various therapeutic approaches favoured by naturopaths. People reported to be particularly interested in homoeopathy, Bach's floral remedies or mineral salts were interviewed, but no systematic courses in the choice and use of these therapies were seen in the various colleges. The committee were left with the impression that the choice of therapeutic regime was based on the general whim of the naturopath and, since the suggested applications in the various textbooks and dispensations overlapped to an enormous extent, no specific indications were or could be taught. [29]

The position of the Australian Medical Association is that "evidence-based aspects of complementary medicine can be part of patient care by a medical practitioner", but it has concerns that there is "limited efficacy evidence regarding most complementary medicine. Unproven complementary medicines and therapies can pose a risk to patient health either directly through misuse or indirectly if a patient defers seeking medical advice." The AMA's position on regulation is that "there should be appropriate regulation of complementary medicine practitioners and their activities." [77]

India

In India, naturopathy is overseen by the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); there is a 5½-year degree in "Bachelor of Naturopathy and Yogic Sciences" (BNYS) degree that was offered by twelve colleges in India as of August 2010. [78] The National Institute of Naturopathy in Pune that operates under AYUSH, which was established on December 22, 1986 and encourages facilities for standardization and propagation of the existing knowledge and its application through research in naturopathy throughout India. [79][80]

North America

In five Canadian provinces, seventeen U.S. states, and the District of Columbia, naturopathic doctors who are trained at an accredited school of naturopathic medicine in North America, are entitled to use the designation ND or NMD. Elsewhere, the designations "naturopath", "naturopathic doctor", and "doctor of natural medicine" are generally unprotected or prohibited. [35][47]

In North America, each jurisdiction that regulates naturopathy defines a local scope of practice for naturopathic doctors that can vary considerably. Some regions permit minor surgery, access to prescription drugs, spinal manipulations, midwifery (natural childbirth),
and gynecology; other regions exclude these from the naturopathic scope of practice or prohibit the practice of naturopathy entirely.\[81\]

**Canada**

Four Canadian provinces license naturopathic doctors: British Columbia, Alberta, Ontario, and Saskatchewan.\[82\] British Columbia has regulated naturopathic medicine since 1936 and together with Ontario (since 2009) are the only two Canadian provinces that allow certified NDs to prescribe pharmaceuticals and perform minor surgeries.\[83\]

The province of Quebec does not directly regulate naturopathy. The Quebec Ministry of Education has prohibited schools from offering doctoral programs in the subject, and there are no universities with a naturopath program. Therefore, studies must be done out of province. Furthermore, in Quebec, the Collège des médecins du Québec (CMQ) has exclusive rights to perform certain activities including but not limited to ordering diagnostic examinations, prescribing medication and other substances and clinically monitoring the condition of patients whose state of health presents risks. This severely restrains the scope of practice.\[84\]

**United States**

- U.S. jurisdictions that currently regulate or license naturopathy include Alaska, Arizona, California, Connecticut, Colorado, District of Columbia, Hawaii, Kansas, Maine, Minnesota, Montana, New Hampshire, North Dakota, Oregon, Puerto Rico, US Virgin Islands, Utah, Vermont, and Washington.\[80\] Additionally, Florida and Virginia license the practice of naturopathy under a grandfather clause.\[35\]
  - U.S. states which specifically prohibit the practice of naturopathy: South Carolina, and Tennessee.\[34\][35]

**United Kingdom**

Naturopathy is not regulated in the United Kingdom. In 2012, publicly funded universities in the United Kingdom dropped their alternative medicine programs, including naturopathy.\[86\]

**Switzerland**

The Swiss Federal Constitution seizes the Swiss Confederation and the Cantons of Switzerland within the scope of their powers to oversee complementary medicine.\[87\] In particular, the Federal authorities must set up diplomas for the practice of non-scientific medicine. The first of such diplomas has been validated in April 2015 for the practice of naturopathy.\[43\] There is a long tradition for naturopathy and traditional medicine in...
Switzerland. The Cantons of Switzerland make their own public health regulations. Although the law in certain cantons is typically monopolistic, the authorities are relatively tolerant with regard to alternative practitioners.[44]

See also

- Arnold Ehret
- Essential nutrient
- Friedrich Eduard Bilz
- Health freedom movement
- Heilpraktiker
- List of ineffective cancer treatments
- List of topics characterized as pseudoscience
- Megavitamin therapy
- Metamorphic Technique
- Orthomolecular medicine
- Osteopathy and osteopathic medicine
- Phytonutrient

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**Further reading**


**Alternative medicines can't escape the long arm of the law**

Practitioners of alternative medicine who do not abide by the rules of evidence-based practice may fall foul of the law

Practitioners who offer unscientific treatments are acting unprofessionally, regardless of whether they get patients' informed consent. Photograph: Getty
Alternative medicine has been in the firing line for a very long time. By and large, the critics are healthcare professionals who argue that the therapeutic claims made for alternative treatments are neither evidence-based nor plausible.

In recent years, their arguments have been increasingly adopted by the legal profession and the battles over alternative medicine are increasingly fought in the courts. In the UK, Simon Singh famously won the libel case brought against him by the British Chiropractic Association. Ever since Simon was sued, many of my articles for medical journals have had to be scrutinised by libel lawyers before being published.

In the US, a patient has accused Stanislaw R Burzynski, a proponent of alternative cancer cures, of swindling her out of nearly $100,000 (£63,000) by using "false and misleading tactics". The case is ongoing. Also in the US, a woman was awarded $7.4m (£4.7m) after suffering a stroke following the intake of a herbal supplement.

Most sensationally, perhaps, the world's largest homeopathic manufacturer Boiron recently settled for CAD$12m (£7.4m) after a class action that was brought against it in Canada for selling homeopathic remedies under false pretences.

Ian Freckelton, an Australian barrister and professor of law, has scrutinised alternative medicine in more general legal terms. This year he has written about homeopathy and the law, and in 2003 he addressed a wide range of unorthodox therapies by evaluating selected legal cases from across the world. The treatments examined included:
Law and Natural Medicine

- Laetrile ("vitamin B17")
- Spiritual healing
- Magnet healing
- Oxygen therapy
- Coffee enemas
- Colonic irrigation
- Topical application of sulphuric acid
- Ozone therapy
- High-dose vitamin C
- Live blood analysis
- Aqua Tilis
- Neck manipulation

These treatments have been used by clinicians for a wide range of serious, life-threatening conditions and the money spent on them has usually been considerable. Subsequently some of these clinicians have found themselves in the dock. In almost all cases, the practitioners were found guilty of professional misconduct or negligence.

Freckelton's conclusions are, I think, remarkable:

"It is the responsibility of the registered practitioner to abstain from engaging in unprofessional practice by obtaining genuinely informed consent from their patients and it is a criminal (and a disciplinary) offence under Australia's national regulatory scheme for registered health practitioners for them to engage in false, misleading and deceptive advertising, to use testimonials or purported testimonials about services or to create an unreasonable expectation of beneficial treatment. It is unprofessional conduct to provide treatment that is excessive, unnecessary or otherwise not reasonably required for the person's wellbeing."

Freckelton also urges clinicians to consider their professional obligations:

"By electing not to undertake treatment likely to be successful, or by refraining from orthodox clinical trials and instead proffering unscientific treatments, they are acting unprofessionally, regardless of whether they procure informed consent in that such conduct would be of a lesser standard than most of their colleagues and members of the public would reasonably expect of them. This issue is yet to be finally resolved by the courts and disciplinary tribunals. Generally, though, the theoretical distinction is not problematic. Contemporary health practice that involves the provision of assessments and treatments that are not justified by the relevant professional literature is usually accompanied by impoverished provision of information to patients and therefore by practice that has denied treatment options and thus been without informed consent."

In essence, this tells us that the practitioners, promoters or manufacturers of alternative medicines who do not abide by the rules of evidence-based practice are likely to be
operating outside the law. This makes a lot of sense. How much of alternative medicine would survive if the legal principles outlined by Freckelton were rigorously applied?

Complementary and Alternative Medicine
Legal and Regulatory Issues

by Michael H. Cohen, Esq.,

The Informed Consent Obligation in Complementary and Alternative Medicine

Informed consent presents one of the major unresolved areas in the integration of complementary and alternative therapies into the health care system. Legal requirements of informed consent aim to protect the patient against non-consensual interference with his or her body in medical matters. Informed consent requires the physician to disclose, and ensure that patients (or authorized surrogates) comprehend, all information material to the patient’s decision to undergo or reject a specific medical procedure. Inclusion of complementary and alternative medicine in any such requirement is likely to have a significant impact on clinical practice....

To satisfy informed consent in biomedicine, physicians must disclose the nature of the problem, the purpose of the proposed treatment and the probability of its benefits and risks, as well as the probability of benefits and risks of alternative treatments or doing nothing. Whether such disclosure must, or should, encompass complementary and alternative modalities has not yet been addressed in the literature.

The question of appropriate disclosure becomes especially complex where treatments are supported by results of studies published in medical literature, but are not generally accepted or adopted by physicians nationwide. For example, is a surgeon obligated to advise the patient that there are reports that chiropractic care may be more effective, and less invasive, than surgery for certain cases of low-back pain? Should neurologists afford patients the opportunity of taking ginkgo biloba for improving dementia due to circulation problems, and possibly Alzheimer’s? To what extent must primary care physicians disclose information about the possible benefits of nutritional therapies, such as treatment of benign prostatic hypertrophy with saw palmetto and other herbal preparations, and treatment of depression with hypericum (St. John’s Wort)?

Such questions will multiply as studies are conducted with increasing rigor by research centers, including those funded by the National Center for Complementary and Alternative Medicine. In terms of practical guidance for the clinician, a starting point is the test for informed consent in conventional medicine: would a reasonable patient, in a similar
situation, find the information regarding the complementary and alternative therapy to be material to the decision to use or forgo that therapy?

The issue of materiality may be difficult to answer, since some clinical choices may involve use of the therapy as an adjunct to conventional medicine, whereas others may involve a substitution. Nonetheless, asking this basic question forms a reasonable foundation for the physician in everyday clinical contexts to assess the legal boundaries of the informed consent disclosure obligation.

The above is adapted and reprinted with permission of Ann Arbor: University of Michigan Press from Chapter 3 of “Beyond Complementary Medicine: Legal and Ethical Perspectives on Health Care and Human Evolution” (University of Michigan Press, forthcoming 2000).

The Legal Framework Governing Complementary and Alternative Medicine

Physicians, hospitals and health care institutions, insurers, managed care organizations, dietary supplements manufacturers, and patients, face numerous legal and regulatory issues as they contemplate greater utilization of, and access to, complementary and alternative therapies such as chiropractic, acupuncture, naturopathy, and herbal medicine.

Some of the unexplored legal frontiers for practitioners and institutions include:

- malpractice liability for the integration of complementary and alternative medicine into clinical practice
- legal issues surrounding scope of practice
- liability for referrals to complementary and alternative medical providers
- relevant food and drug rules
- questions surrounding professional discipline
- federal and state fraud and abuse laws
- legal rules governing third-party reimbursement.

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Dietary Supplement Regulation: U.S. Food and Drug Administration Public Hearing


Thompson, Trevor DB (2004). Can the caged bird sing? Reflections on the application of qualitative research methods to case study design in homeopathic medicine. BMC Medical Research Methodology, 4(4)

FDA Medication Health Fraud

FDA, Alternative Medicine Fraud

FDA, Use Caution With Ayurvedic Products


Herbal and dietary supplements in Denmark www.vifab.dk/uk

Herbal Medicine Products in Denmark www.vifab.dk/uk

Strong vitamin and mineral preparations in Denmark www.vifab.dk/uk

Traditional botanical medicinal products in Denmark

Homeopathic medicinal products in Denmark www.vifab.dk/uk

Dietary supplements in Denmark www.vifab.dk/uk

Registration of Alternative Practitioners – RAB, Knowledge and Research Center for Alternative Medicines homepage

Art.118a Complementary medicine: The Confederation and the Cantons shall within the scope of their powers ensure that consideration is given to complementary medicine. [1] In official language, German [2], French [3], Italian [4]

MHRA: How we regulate medicines

MHRA: Licensing of medicines,[5]Legal status and reclassification],[6]

GMC: UK Health and Social Care Regulators
Health Law Boosts Status Of Alternative Medicine — At Least On Paper

By Ankita Rao  July 26, 2013

Jane Guiltinan said the husbands are usually the stubborn ones.

When her regular patients, often married women, bring their spouses to the Bastyr Center for Natural Health to try her approach to care, the men are often skeptical of the treatment plan — a mix of herbal remedies, lifestyle changes and sometimes, conventional medicine.

Chiropractor photo by Michael Dorausch via Flickr

After 31 years of practice, Guiltinan, a naturopathic physician, said it is not uncommon for health providers without the usual nurse or doctor background to confront patients’ doubts. “I think it’s a matter of education and cultural change,” she said.

As for the husbands — they often come around, Guiltinan said, but only after they see that her treatments solve their problems.

Complementary and alternative medicine — a term that encompasses meditation, acupuncture, chiropractic care and homeopathic treatment, among other things — has become increasingly popular. About four in 10 adults (and one in nine children) in the U.S. are using some form of alternative medicine, according to the National Institutes of Health.

And with the implementation of the Affordable Care Act, the field could make even more headway in the mainstream health care system. That is, unless the fine print — in state legislation and insurance plans — falls short because of unclear language and insufficient oversight.
One clause of the health law in particular — Section 2706 — is widely discussed in the alternative medicine community because it requires that insurance companies “shall not discriminate” against any health provider with a state-recognized license. That means a licensed chiropractor treating a patient for back pain, for instance, must be reimbursed the same as medical doctors. In addition, nods to alternative medicine are threaded through other parts of the law in sections on wellness, prevention and research.

“It’s time that our health care system takes an integrative approach ... whether conventional or alternative,” said Sen. Tom Harkin, D-Iowa, who authored the anti-discrimination provision, in an e-mail. “Patients want good outcomes with good value, and complementary and alternative therapies can provide both.”

The federal government has, in recent years, tapped providers like Guiltinan, who is also the dean at the Bastyr University College of Naturopathic Medicine, to help advise the federal government and implement legislation that could affect the way they are paid and their disciplines are incorporated into the health care continuum. In 2012, Guiltinan, based in Kenmore, Wash., was appointed to the advisory council of the National Center for Complementary and Alternative Medicine, part of the National Institutes of Health.

Proving that alternative medicine has real, measurable benefits has been key to increasing its role in the system, said John Weeks, editor of the Integrator Blog, an online publication for the alternative medicine community. The Patient-Centered Outcomes Research Institute, created by the health law, is funding studies on alternative medicine treatments to determine their effectiveness.

Weeks said both lawmakers and the general public will soon have access to that research, including the amount of money saved by integrating other forms of medicine into the current health system.

But the challenges of introducing alternative care don’t stop with science.
Because under the health care law each state defines its essential benefits plan — what is covered by insurance — somewhat differently, the language concerning alternative medicine has to be very specific in terms of who gets paid and for what kinds of treatment, said Deborah Senn, the former insurance commissioner in Washington and an advocate for alternative medicine coverage.

She pointed out that California excluded coverage for chiropractic care in its essential benefits plan, requiring patients to pay out of pocket for their treatment. Senn thinks the move was most likely an oversight and an unfavorable one for the profession. Four other states — Colorado, Hawaii, Oregon and Utah — ruled the same way in the past year.

“That’s just an outright violation of the law,” she said, referring to the ACA clause.

Colorado and Oregon are in the process of changing that ruling to allow chiropractic care to be covered, according to researchers at Academic Consortium for Complementary and Alternative Health Care.

Some states, like Washington, are ahead of the rest of the country in embracing alternative practitioners. The Bastyr University system, where Guiltinan works, treats 35,000 patients a year with naturopathic medicine. Sixty percent of the patients billed insurance companies for coverage.

Guiltinan said a change in the system is not only a boon for alternative medicine doctors, but helps families of all income levels access care normally limited to out-of-pocket payment. That’s why some alternative medicine aficionados like Rohit Kumar are hoping the law will increase the ability of his family — and the larger community — to obtain this kind of care.

Kumar, a 26-year-old business owner in Los Angeles, said his parents and brothers have always used herbs and certain foods when they get sick, and regularly see a local naturopath and herbalist. He’s only used antibiotics once, he says, when he caught dengue fever on a trip to India.

While the Kumar family pays for any treatments they need with cash — the only payment both alternative providers accept — they also pay for a high-deductible health plan every month to cover emergencies, like when his brother recently broke his arm falling off a bike.

Paying for a conventional health care plan and maintaining their philosophy of wellness is not cheap.

“We pay a ridiculous amount of money every month,” Kumar said of the high-deductible insurance. “And none of it goes toward any type of medicine we believe in.”

Even so, he said the family will continue to practice a lifestyle that values wellness achieved without a prescription — a philosophy that Guiltinan also adopted in her practice.

As a young medical technician in a San Francisco hospital she decided that the traditional medical system was geared more toward managing diseases and symptoms rather than
prevention. Naturopathic medicine, on the other hand, seemed to fit her idea of how a doctor could address the root cause of illness.

“The body has an innate ability for healing, but we get in its way,” Guiltinan said. “Health is more than the absence of disease.”
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