

Legal Compliance Issues for Homeopathy

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Homeopathic medicine is a holistic system of treatment based on the thought that the substances that cause sickness can also cure people when given in the correct proportions. The general idea is that these remedies are believed to stimulate a person's healing properties. Homeopathic practitioners refer to the drugs that are used in conventional medicine as "allopathy."

While drugs may have a different meaning for homeopaths, everyone who works with homeopathic products needs to understand that FDA approval of drugs is required for any product designed to diagnose, treat, mitigate, or cure a disease. Homeopathic practitioners also need to understand when their practice may violate state corporate practice of medicine laws. When providers and practitioners work with conventional doctors, everyone needs to understand when referrals of patients and products may be illegal. There are many other compliance issues that an experienced healthcare care lawyer can explain.

What is homeopathy?

According to the [US National Institute of Health](#), homeopathy was developed in Germany in the early 19th century. Homeopathy is "based on two unconventional theories:

- "Like cures like"—the notion that a disease can be cured by a substance that produces similar symptoms in healthy people.
- "Law of minimum dose"—the notion that the lower the dose of the medication, the greater its effectiveness. Many homeopathic products are so diluted that no molecules of the original substance remain.

Homeopathic products come from many different sources such as:

- Plants – Red onion, arnica [mountain herb], poison ivy, belladonna [deadly nightshade], and stinging nettle).
- Minerals such as white arsenic.
- Animals such as crushed whole bees.

Homeopathic products are produced in many forms. The most common form is a sugar pellet placed under the tongue. Other forms include ointments, gels, drops, creams, and tablets.

The treatments are unique for each person. *"Homeopathy uses a different diagnostic system for assigning treatments to individuals and recognizes clinical patterns of signs and symptoms that are different from those of conventional medicine."*

Homeopathy in the United States – FTC and FDA compliance

The NIH states that based on a 2012 National Health Interview Survey, about 5 million adults and 1 million children used homeopathy in the prior year. A 2016 survey indicates that most adults who use homeopathic products *“self-prescribe them for colds and musculoskeletal pain”* instead of seeing a homeopathic practitioner.

There are several compliance issues regarding homeopathic products:

- The US Federal Trade Commission (FTC) stated in 2016 that it holds the sellers of over-the-counter homeopathic drugs to the same efficacy and safety standards as the sellers of other products making comparable claims. The agency said that the FTC will require that the companies making health claims about homeopathic products must have *“competent and reliable scientific evidence to support the claims – including claims that a product can treat specific conditions.”*
- The US Food and Drug Administration (FDA) in 2017 proposed more scrutiny of homeopathic products – especially the products with the greatest risks, including:
 - Homeopathic products with reported safety concerns.
 - Homeopathic products that are not taken by mouth or rubbed on the skin.
 - Homeopathic products for vulnerable populations.
 - Homeopathic products that do not meet *“legal standards for quality, strength, or purity.”*
 - Homeopathic products intended to be used for preventing or treating serious and/or life-threatening diseases and conditions.

HOW FTC COMPLIANCE WORKS: LABELING YOUR DIETARY SUPPLEMENTS

In today's video, we talk about more common labeling mistakes that dietary supplement manufacturers and distributors make when creating marketing claims for their products.

The scientific analysis of the effectiveness of homeopathy

The NIH states that:

“A 2015 comprehensive assessment of evidence by the Australian government's National Health and Medical Research Council concluded that there is no reliable evidence that homeopathy is effective for any health condition. However, it is important to note that studies included in the assessment of evidence were required to meet a number of rigorous criteria (e.g., having a sample size of more than 150 participants, the highest rating of methodological quality, and other measures). In total, 57 systematic reviews that contained 176 individual studies were included in this assessment. A new review of evidence by the Australian government is currently underway.”

“Homeopathy is a controversial topic.” Homeopathic theory and basic scientific concepts are often at odds. *“For example, homeopathic preparations can be so dilute that a substance considered to be the “active ingredient” becomes unmeasurable, which creates major challenges to the rigorous investigation of such products.”*

The US Centers for Disease Control and Prevention (CDC) says there is no credible scientific evidence to support claims that certain homeopathic products (called “nosodes” or homeopathic immunizations) are substitutes for conventional immunizations. *“The National Center for Complementary and Integrative Health (NCCIH) supports the Centers for Disease Control and Prevention's recommendations for immunizations/vaccinations.”*

The NCCIH provides information on numerous topics. Just the “A”s include:

- [Acai](#)
- [Acupuncture](#)
- [Aloe Vera](#)
- [Alzheimer’s Disease](#)
- [Antioxidants](#)
- [Anxiety](#)
- [Are You Considering a Complementary Health Approach?](#)
- [Aromatherapy](#)
- [Asian Ginseng](#)
- [Asthma](#)
- [Astragalus](#)
- [Attention-Deficit Hyperactivity Disorder](#)
- [Autism](#)
- [Ayurvedic Medicine](#)

The NIH also states that:

- Even though many homeopathic products are highly diluted, some products (labeled or sold as homeopathic) may contain *“substantial amounts of active ingredients, which may cause side effects or drug interactions. Negative health effects from homeopathic products of this type have been reported.”*
- Some homeopathic products may cause adverse effects – some of which may be serious.
- *“Liquid homeopathic products may contain alcohol. The FDA allows higher levels of alcohol in these than in conventional drugs.”*
- Research on homeopathic aggravations is scarce. Homeopathic aggravations are worsening of a patient’s condition after taking a homeopathic prescription.

FDA has issued warnings to consumers about homeopathic products. In one case, in 2017, FDA informed consumers that some homeopathic teething tablets had excessive amounts of the toxic substance belladonna. In another case, in 2015, FDA “warned consumers not to rely on over-the-counter asthma products labeled as homeopathic, because they are not evaluated by the FDA for safety and effectiveness”.

SEPTEMBER 2020 FDA WARNING LETTERS

FDA and FTC warning letters continue to find violations of the FD&C Act when companies boast their products can cure or treat diseases such as COVID-19.

FDA and homeopathic products

According to FDA, homeopathic products have *“been identified through “provings,” in which substances are administered to healthy volunteers in concentrations that cause symptoms. “If a substance causes a particular symptom, individuals experiencing that symptom would be treated with a diluted solution made from that substance.”*

FDA has not approved any products that have a homeopathic label. This means that homeopathic products sold in the United States are not being marketed with FDA evaluation of the products' safety or effectiveness. Homeopathic products are generally *"marketed as natural, safe and effective alternatives to approved prescription and nonprescription products, and are sold online and in major retail stores."*

What is FDA's concern about homeopathic products?

FDA is generally concerned:

- That some homeopathic products contain measurable amounts of active ingredients – which could cause patients significant harm.
- Some homeopathic products, after FDA testing, *"were improperly manufactured, which can cause incorrect dilutions and increase the potential for contamination."*
- Some homeopathic products are marketed to treat serious health disorders and diseases.

A few examples of FDA oversight include:

- [FDA alerts consumers of Kadesh Incorporation's voluntary nationwide recall of Puriton Eye Relief Drops due to non-sterile production conditions](#)
- [FDA alerts consumers of Sprayology's voluntary nationwide recall of homeopathic water-based medicines due to microbial contamination](#)
- [FDA alerts consumers and pet owners of Silver Star Brand's voluntary recall of homeopathic drug products](#)
- [FDA alerts consumers of HelloLife's voluntary recall of Neuroveen, Respitrol, Thyroveev and Compulsin](#)

Homeopathy and the corporate practice of medicine

Homeopathic practitioners and product companies need to review their FTC and FDA compliance issues with an experienced healthcare provider. Practitioners and product companies also need to review with a skilled healthcare lawyer how the California laws on the corporate medicine apply to their business.

In California, corporations and related businesses cannot conduct the practice of medicine. California corporate practice of medicine laws were enacted to ensure doctors make health decisions based on the patient's best interest and not their financial interests. The corporate practice of medicine law is called the [Moscone-Knox Professional Corporation Act](#). Non-physicians cannot own a medical practice.

An experienced healthcare lawyer will review the Moscone-Knox Professional Corporation Act and related issues such as the unauthorized practice of medicine by homeopathic practitioners.

CORPORATE PRACTICE OF MEDICINE, PSYCHOLOGY, PHYSICAL THERAPY RISKS TO INVESTORS

In today's video, we discuss how investors can profit from businesses that deliver clinical services—and where they get themselves in trouble.

Common questions about homeopathy in California

A few common questions and answers about homeopathy in California, provided by the [Naturopathic Medicine Committee](#), are the following. Your lawyer can help you understand how these questions and answers apply to your practice or business.

“Do I need to be licensed to practice naturopathy or homeopathy in California?”

No. You do not need a license to practice naturopathy and homeopathy in California. However, you must disclose in your advertisements and on your client intake form that you are providing unlicensed healing arts services (Business and Professions Code sections [2053.5](#) and [2053.6](#)).

Can I advertise as a naturopath?

Yes. You may advertise as a naturopath, traditional naturopath, or homeopath but you must state in your advertisements that you are not licensed by the State of California per [Business and Professions Code section 2053.6](#)

Do I need to tell my clients that I’m not licensed?

Yes. Before you begin treatment, you must inform each client in writing that you are not licensed. All clients must confirm in writing that they were given information about your license status (Business and Professions Code section 2053.6).

Am I allowed to diagnose as a naturopath?

No, unlicensed individuals may not diagnose a physical or mental condition of any person. In addition, unlicensed individuals must comply with BPC [2053.5](#) and [2053.6](#).

I am board-certified and hold a degree in naturopathic medicine but cannot get a license because my school is not approved. Can I still use the title ND, naturopathic doctor, or naturopathic physician?

No. In California, you must be licensed by the Naturopathic Medicine Committee to use the titles ND or naturopathic doctor, or other titles, words, letters, or symbols with the intent to represent that you practice, are authorized to practice, or are able to practice naturopathic medicine as a naturopathic doctor. ([Business and Professions Code section 3660](#)).

If I use the title “ND” or “naturopathic doctor” without being licensed, what will happen?

If you use the titles illegally, the Committee may issue you a citation and fine ([California Code of Regulations, Division 40, Title 16, Section 4254](#)).

If you violate these California laws, the Naturopathic Medicine Committee can refer your case to the Division of Investigation, Department of Consumer Affairs, where they may issue you a misdemeanor citation, as well. If someone is harmed by an unlicensed naturopath, *“the Committee may forward an enforcement case to the District Attorney’s office for criminal prosecution.”*

Additional compliance issues

Homeopathic practitioners need to comply with the Health Insurance Portability and Accountability Act (HIPAA) which regulates how a patient’s personal health information (in electronic form) is disclosed.

Homeopathic providers and companies who work with conventional physicians need to review with a skilled healthcare law how Stark Law, the Anti-Kickback Statute, and other referral laws apply to their business relationship. Violations of these laws can result in substantial fines and, in AKS cases, may result in criminal charges.

Other homeopathic integrative medicine compliance issues include informed consent issues, additional California Labor Code issues, and other federal and state compliance issues.

Homeopathic medicine is an alternative medical practice that appeals to millions of people. Anyone involved with the practice

of homeopathy needs to understand FTC compliance issues, FDA oversight including the illegal marketing of homeopathic as drugs, licensing, referral laws, and many other compliance issues.

Homeopathic practitioners and product companies should contact Cohen Healthcare Law Group, PC to discuss all the federal and state compliance issues that may affect their business. Our experienced healthcare attorneys help integrative healthcare practices including homeopathy.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.