

SNAKE OIL OR CURE: THE CASE FOR EVIDENCE-BASED REGULATION OF ALTERNATIVE MEDICINE

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INTRODUCTION

The practice of alternative medicine is increasingly broadening at a pace that surpasses regulatory oversight,¹ leaving patient safety precariously vulnerable. Americans spend a staggering \$30 billion a year out-of-pocket on complementary health approaches,² and over 35% of the U.S. population uses alternative medicine.³ Studies show that people use alternative medicine in increasing numbers due to its lower costs, ready accessibility, personalized interactions, and mistrust of modern medicine.⁴ But at what cost do these perceived benefits come?

At the heart of this issue are two key players—the patient and the healthcare practitioner. Patients, often unaware of the potential dangers of unresearched medicine, ask their providers to prescribe it, choose to self-medicate, or even fight for their right to do so.⁵ Healthcare practitioners—some informed, some not, and some either callous or conniving—prescribe it, recommend it, and practice it.⁶ Consider two extreme cases in which both of these players played an instrumental role.

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¹ See Michael S. Goldstein, *The Emerging Socioeconomic and Political Support for Alternative Medicine in the United States*, 583 ANNALS AM. ACAD. POL. & SOC. SCI. 44, 44–63 (2002), <http://www.jstor.org/stable/1049688> [<https://perma.cc/EQ62-K8VU>].

² *Americans Spend \$30 Billion a Year Out-of-Pocket on Complementary Health Approaches*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH (June 22, 2016), <https://www.nccih.nih.gov/research/research-results/americans-spend-30-billion-a-year-outofpocket-on-complementary-health-approaches> [<https://perma.cc/Z78V-Y2UU>].

³ *NIH Analysis Reveals a Significant Rise in Use of Complementary Health Approaches, Especially for Pain Management*, NAT'L INST. OF HEALTH (Jan. 31, 2024), <https://www.nih.gov/news-events/news-releases/nih-analysis-reveals-significant-rise-use-complementary-health-approaches-especially-pain-management> [<https://perma.cc/NLJ3-3UQK>]; see Goldstein, *supra* note 1, at 44–60.

⁴ See generally INST. OF MED. OF THE NAT'L ACADS., COMPLEMENTARY AND ALTERNATIVE MEDICINE IN THE UNITED STATES 50–54 (2005) [hereinafter IOM] (providing further information about the increasing popularity of alternative medicine).

⁵ *Id.* at 60; see *infra* text accompanying notes 8–14.

⁶ See discussion *infra* Part II.A.

In the unfortunate case of Joey Hofbauer, the seven-year-old was diagnosed with Hodgkin's disease, a form of cancer that has a 95% chance of complete recovery with proper treatment.⁷ However, Hofbauer's parents disavowed conventional chemotherapy and radiation; they instead chose to treat him with large doses of vitamins and laetrile, an untested remedy made from apricot pits.⁸ His cancer progressed unchecked, while the alternative medicine accelerated his liver damage.⁹ Tragically, Hofbauer died at ten years of age.¹⁰ While the case gained notoriety over the question of parental rights,¹¹ it was ultimately the parents' lack of awareness regarding the dangers of laetrile, along with its accessibility as a medication, that contributed to the child's untimely demise.

Abraham Cherrix's story begins similarly but unfolds differently. Diagnosed with Hodgkin's disease at sixteen years of age, Cherrix initially received chemotherapy.¹² Later, his family refused additional rounds of treatment and chose to treat him with alternative methods instead.¹³ After years of disease regressions and courtroom struggles over parental rights, Cherrix ultimately returned to conventional medicine, adopting stem-cell transplants and chemotherapy.¹⁴ Today, he is alive and well.¹⁵

The stark difference between the two cases underscores the truth: "There is only medicine that works and medicine that doesn't."¹⁶ This is because what is known as alternative medicine does not undergo the rigorous

⁷ PAUL A. OFFIT, DO YOU BELIEVE IN MAGIC?: THE SENSE AND NONSENSE OF ALTERNATIVE MEDICINE 7–8 (2013).

⁸ See *id.* at 9–12 (describing how Hofbauer's father also administered raw milk, raw liver juice, coffee enemas, among other treatments).

⁹ *Id.* at 13.

¹⁰ *Id.* at 18.

¹¹ See generally *id.* at 8–18 (describing the legal struggles between Hofbauer's parents and the government).

¹² Arthur L. Caplan, Op-ed, *Challenging Teenagers' Right to Refuse Treatment*, 9 AMA J. ETHICS 56, 56 (Jan. 2007) <https://journalofethics.ama-assn.org/article/challenging-teenagers-right-refuse-treatment/2007-01> [<https://perma.cc/8ZJ2-R4AG>].

¹³ *Id.* at 56–57.

¹⁴ *Id.*; Elizabeth Simpson, *A Decade After Being in the Spotlight, Virginia Man Turned to Stem Cells to Treat Cancer. They Saved His Life*, VIRGINIA PILOT (Aug. 9, 2019, at 06:18 ET), <https://www.pilotonline.com/2017/07/27/a-decade-after-being-in-the-spotlight-virginia-man-turned-to-stem-cells-to-treat-cancer-they-saved-his-life/> [<https://perma.cc/P83U-3MJB>] (statement of Abraham Cherrix) ("Honestly, if I had not done this, I would have died. The other treatments didn't have any hard evidence behind them. There was no concrete evidence. I know what I am doing now is founded in reality, and I know it's the best choice for me, and it's scientifically based.").

¹⁵ Simpson, *supra* note 14.

¹⁶ OFFIT, *supra* note 7, at 6; see also Phil B. Fontanarosa & George D. Lundberg, *Alternative Medicine Meets Science*, 280 JAMA 1618, 1618 (Nov. 11, 1988), <https://jamanetwork.com/journals/jama/article-abstract/188137> [<https://perma.cc/MHW2-MUT5>] ("There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking.").

evidence-based testing required of conventional medicine;¹⁷ as a result, it is impossible to tell whether it works or if it is even harmful. Generally, in the practice of medicine, any delay in diagnosis or treatment can cause unfavorable consequences,¹⁸ whether from acute incidents like strokes and heart attacks or chronic conditions such as cancer.¹⁹ Unfortunately, some physicians add to this problem by propagating false information about untested alternative treatments.²⁰ Harm occurs not only when a physician actively injures a patient, but also when they delay essential care, allowing the patient to deteriorate to a point where even conventional treatment methods cannot help them, or when they delay the diagnosis of an ailment by treating its symptoms superficially.²¹ This delay also hinders proper diagnosis and treatment.²² In fact, delayed or missed diagnosis tops the list of malpractice claims.²³ So, while the appeal of alternative medicine is understandable, it is difficult for people to avoid treatments that are ineffective or harmful in the absence of regulated testing and dissemination of resulting data.²⁴

For example, in Joey Hofbauer's case, the family could not have known about the dangers of laetrile because they were simply unknown at the time. All the investigation and regulation that came about occurred too late for

¹⁷ Marcia Angell & Jerome P. Kassirer, Editorial, *Alternative Medicine – The Risks of Untested and Unregulated Remedies*, 339 N. ENGL. J. MED. 839, 839–41 (Sep. 17, 1998), <https://pubmed.ncbi.nlm.nih.gov/9738094/> [<https://perma.cc/B7Y4-ALBJ>].

¹⁸ *Harm from Omitted and Delayed Drugs*, NURSING TIMES, (July 5, 2010), <https://www.nursingtimes.net/archive/harm-from-omitted-and-delayed-drugs-05-07-2010/> [<https://perma.cc/A484-RWFU>]; Sachin Nagar & Nicola Davey, *Reducing Avoidable Time Delays in Immediate Medication Administration – Learning From a Failed Intervention*, 4 BRIT. MED. J. QUALITY IMPROVEMENT R. 1, 1 (Feb. 11, 2015), <https://pmc.ncbi.nlm.nih.gov/articles/PMC4645713/> [<https://perma.cc/J6JX-TBW2>].

¹⁹ Colleen Moriarty, *Natural Cancer ‘Cures’: What are the Risks?*, YALE MEDICINE (July 1, 2019), <https://www.yalemedicine.org/news/natural-cancer-therapy-risks> [<https://perma.cc/J87Y-L7AK>]; Skylar B. Johnson et al., Brief Communication, *Use of Alternative Medicine for Cancer and its Impact on Survival*, 110 J. NAT'L CANCER INST. 121, 121–24 (2018), <https://academic.oup.com/jnci/article/110/1/121/4064136> [<https://perma.cc/SBZ5-PM9F>]; see *Harm from Omitted and Delayed Drugs*, *supra* note 18; see Nagar & Davey, *supra* note 18, at 1–4.

²⁰ See discussion *infra* Part II.A.

²¹ Moriarty, *supra* note 19. Alternative medicine may also interfere with the effective functioning of the conventional medicine. See Regina Schaffer, *Alternative HF Therapies Could Worsen Symptoms, Interact with Prescribed Medications*, HEALIO (Dec. 8, 2022), <https://www.healio.com/news/cardiology/20221208/alternative-hf-therapies-could-worsen-symptoms-interact-with-prescribed-medications> [<https://perma.cc/8MH6-67TW>].

²² See E Wallace et al., *The Epidemiology of Malpractice Claims in Primary Care: A Systematic Review*, 3 BRIT. MED. J. OPEN 1, 1 (2013), <https://bmjopen.bmj.com/content/3/7/e002929> [<https://perma.cc/32XQ-MN48>].

²³ *Id.*

²⁴ Nader Heidari, *Magical Thinking*, C&EN (Sep. 2, 2013), <https://cen.acs.org/articles/91/i35/Magical-Thinking.html> [<https://perma.cc/B5V2-WYSE>]; see Ed Stannard, *Yale Study: Cancer Patients Who Use Alternative Treatments More Likely to Die*, NEW HAVEN REGISTER (July 20, 2018), <https://www.nhregister.com/news/article/Yale-study-Cancer-patients-who-use-alternative-13089659.php> [<https://perma.cc/Z3YG-67FP>].

him.²⁵ Only after laetrile gained widespread popularity did the U.S. Food and Drug Administration (FDA) investigate and determine it caused cyanide toxicity, leading to its ban.²⁶ Retroactive testing and bans are inherently less safe than prospective testing, as most alternative medicines are not tested in advance, and their potential side effects remain unknown.²⁷ This suggests that when using alternative medicine, we cannot prevent potential harm, like what happened to Joey Hofbauer, without a way to identify harmful effects in advance. This further shows there is an undeniable need for a rigorous, evidence-based approach to the testing of alternative medicine, its application, and public communication about it, so that the public has access to accurate information in making informed healthcare decisions.

This Note identifies three primary, interrelated causes of harm associated with alternative care: (1) A poorly informed public—a state of affairs caused both by active misinformation disseminated by medical professionals²⁸ and a lack of transparent information sharing by the federal agency in charge of researching alternative cures;²⁹ (2) Deficient disciplinary methods—state medical boards bear the responsibility of disciplining physicians who deviate from their standard of care or cause harm,³⁰ but they are ineffective in curbing misinformation.³¹ Medical malpractice lawsuits filed against physicians who practice alternative medicine fall victim to legal barriers such as assumption of risk and informed consent;³² (3) The ready availability of untested medicines—The FDA currently does not regulate over-the-counter (OTC) drugs or supplements as drugs, permitting their introduction into the market without undergoing rigorous safety or efficacy testing.³³

This Note advocates for evidence-based statutory and agency reform to address the largely unregulated practice of alternative medicine and protect inadequately informed patients from potential harm. Part I offers a detailed examination of the key components involved in the practice of alternative medicine. It defines alternative medicine, identifies its practitioners, and describes regulatory standards. Additionally, it details the federal

²⁵ OFFIT, *supra* note 7, at 18.

²⁶ *Id.* at 18–19.

²⁷ Martins Ekor, *The Growing Use of Herbal Medicines: Issues Relating to Adverse Reactions and Challenges in Monitoring Safety*, 4 FRONTIERS 1, 1 (Jan. 9, 2014), <https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2013.00177/full> [<https://perma.cc/9CZD-DAGX>].

²⁸ Y. Tony Yang & Sarah Schaffer DeRoo, *Disciplining Physicians Who Spread Medical Misinformation*, 28 J. PUB. HEALTH MGMT. & PRAC. 595, 595–98 (Nov./Dec. 2022), https://journals.lww.com/jphmp/citation/2022/11000/disciplining_physicians_who_spread_medical.2.aspx [<https://perma.cc/KM2H-4VHE>]; *see* discussion *infra* Part II.A.

²⁹ *See* discussion *infra* Part II.C.2.

³⁰ *See* discussion *infra* Part I.B.2.

³¹ *See* discussion *infra* Part II.A.

³² *See* discussion *infra* Part II.B.

³³ *See* discussion *infra* Part II.C.1.

government's role, including key agencies and legislative catalysts in the field.

Part II examines deficiencies in multiple areas, beginning with state medical boards, which are underequipped to discipline physicians who disseminate misinformation. It also addresses the legal barriers that prevent plaintiffs from recovering damages in medical malpractice cases and examines how the lack of federal regulation results in the presence of unregulated substances on the market. Finally, recognizing the complexity of the healthcare system, Part III proposes a bimodal resolution: a comprehensive model state statute that promotes evidence-based practices and federal agency reform that increases patient awareness about alternative medicine research.

I. BACKGROUND: REGULATORY SYSTEM AND THE GROWTH OF ALTERNATIVE MEDICINE

The subject of Complementary and Alternative Medicine (CAM) is so vast and heterogeneous that learning its definition and understanding its differences from conventional medicine is essential for recognizing its potential for harm. It is also important to identify who practices this form of medicine and how these practices are regulated. An overview of state medical act statutes and health freedom statutes will serve as a valuable resource in the process. Moreover, to initiate a discussion on federal regulation of the practice, it is necessary first to understand the nature of existing federal oversight in the realm of CAM and the powerful lobby that enabled its pathway to the mainstream.

Part I.A. provides a comprehensive overview of the various types of alternative medicine. Part I.B. describes the various components involved in the state regulation of the practice of medicine: state medical practice acts, state medical boards, and health freedom statutes. Part I.C. examines the federal agency responsible for the regulation of drugs and the federal agency tasked with overseeing research in CAM. Part I.D. traces the growth of the CAM lobby and its role in insurance reform, which became a catalyst for the meteoric rise of CAM.

A. What is Alternative Medicine?

Conventional medicine is common knowledge—it is the system of testing and treatment one receives during visits to primary care physicians or specialists, which involves the use of pharmaceutical drugs or surgical

procedures, as applicable.³⁴ This form of medicine is practiced in hospitals and clinics by a variety of healthcare professionals, including nurses, physician assistants, and pharmacists.³⁵ Commonly referred to as allopathy or orthodox medicine, it is provided by physicians holding either a Doctor of Medicine (M.D.) or a Doctor of Osteopathy (D.O.) degree.³⁶

In contrast, alternative medicine involves the use of specific substances or methods instead of standard conventional treatments to treat various health conditions.³⁷ This means the alternative approach is relied upon instead of conventional medicine.³⁸ Complementary medicine, in comparison, is when alternative medicine is used along with conventional medicine as an additional method of treatment.³⁹ For example, a cancer patient undergoing chemotherapy might receive acupuncture to handle the side effects better.⁴⁰ Lastly, integrative medicine refers to the approach that combines conventional medical practices with CAM, creating a more comprehensive treatment strategy.⁴¹ These approaches involve varying degrees of reliance on non-conventional methods, from full replacement (alternative) to support (complementary) to a blended, holistic model (integrative).⁴²

Alternative medicine further encompasses several distinct forms of medicine.⁴³ Traditional forms, such as Ayurveda, Naturopathy, and Chinese Medicine, have been practiced for centuries around the world,⁴⁴ while newer methods like Homeopathy have emerged more recently.⁴⁵ Some methods, such as chiropractic medicine, Tai Chi, and yoga, are based on the belief that physical manipulation of the human body can heal illnesses or injuries.⁴⁶ Some other approaches incorporate dietary supplements and herbs.⁴⁷ Additionally, there are energy-based practices, like Reiki and

³⁴ *Complementary and Alternative Medicine*, NAT'L CANCER INST. (Oct. 31, 2024), <https://www.cancer.gov/about-cancer/treatment/cam> [https://perma.cc/EB3X-4WMU].

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*; *Complementary, Alternative, or Integrative Health: What's In a Name?*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH (Apr. 2021), <https://www.nccih.nih.gov/health/complementary-alternative-or-integrative-health-whats-in-a-name#definingcam> [https://perma.cc/NK2F-4MPD].

³⁸ *Complementary, Alternative, or Integrative Health: What's In a Name?*, *supra* note 37.

³⁹ *Id.*

⁴⁰ *Complementary and Alternative Medicine*, *supra* note 34.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Types of Complementary and Alternative Medicine*, JOHN HOPKINS MED. <https://www.hopkinsmedicine.org/health/wellness-and-prevention/types-of-complementary-and-alternative-medicine> [https://perma.cc/6SSJ-3EX4] (last visited Aug. 26, 2025).

⁴⁴ *Id.*

⁴⁵ *Homeopathy: What You Need to Know*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH (Apr. 2021), <https://www.nccih.nih.gov/health/homeopathy> [https://perma.cc/5V3E-MJH8].

⁴⁶ *Types of Complementary and Alternative Medicine*, *supra* note 43.

⁴⁷ *Id.*

electromagnetic therapy, as well as methods that involve engaging the mind and senses.⁴⁸

Among these alternative methods, homeopathy receives the most criticism and is readily dismissed.⁴⁹ Developed just two centuries ago, homeopathy is based on the controversial idea that substances diluted to the point where molecules are virtually nonexistent can still have therapeutic effects—a notion that contradicts modern understandings of chemistry.⁵⁰ As a result, several European countries, including Germany, where homeopathy originated, have started implementing regulations against its use.⁵¹

Additionally, there are several alternative methods that do not involve the ingestion of substances. For example, acupuncture involves placing needles at specific points on the body.⁵² According to traditional Chinese medicine, acupuncture is a way to balance the flow of energy, or chi, through pathways in the body.⁵³ But some Western practitioners believe acupuncture stimulates nerves, muscles, and connective tissue, which may help boost the body's natural painkillers.⁵⁴ According to them, this offers a scientific explanation for what is traditionally understood as the effect of "chi."⁵⁵ It may be so, but critics point out that the effects of acupuncture could be attributed to the placebo effect, as it has been shown to work even if needles are inserted in the wrong places or not inserted at all.⁵⁶ Furthermore, acupuncture presents its own set of risks.⁵⁷ Other treatment methods include music therapy and movement therapy, which, as their names suggest, use music and physical

⁴⁸ *Id.* (stating that mind techniques include meditation, hypnosis, and biofeedback, while techniques that influence senses include music and guided imagery).

⁴⁹ Joe Schwarcz, *Homeopathy is Scientifically Implausible*, MCGILL (Jan. 12, 2024), <https://www.mcgill.ca/oss/article/medical-pseudoscience/homeopathy-scientifically-implausible> [<https://perma.cc/3HUJ-F365>]; Natalie Grams, *Homeopathy-Where is the Science?*, 20 EMBO REP. 1, 1 (Feb. 14, 2019), <https://www.embopress.org/doi/full/10.15252/embr.201947761> [<https://perma.cc/VS2J-P97R>].

⁵⁰ Grams, *supra* note 49, at 1–2.

⁵¹ James Gallagher, *Homeopathy 'Could Be Blacklisted'*, BBC NEWS (Nov. 13, 2015), <https://www.bbc.com/news/health-34744858> [<https://perma.cc/7HWL-BU2G>]; see *Germany Set to End Homeopathy Refunds*, DEUTSCHE WELLE (July 11, 2019), <https://www.dw.com/en/german-health-insurers-urged-to-end-homeopathy-refunds/a-49546319> [<https://perma.cc/6GUA-3CS4>].

⁵² *Acupuncture*, MAYO CLINIC (Apr. 20, 2024), <https://www.mayoclinic.org/tests-procedures/acupuncture/about/pac-20392763> [<https://perma.cc/2M2P-R7HV>].

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ OFFIT, *supra* note 7, at 224.

⁵⁷ *Id.* at 5 (listing dangers such as serious viral infections and instances of needles ending up in the heart, lung, or liver).

movements, respectively.⁵⁸ These therapies are commonly used to reduce stress and improve physical fitness.⁵⁹

As for who practices alternative medicine, it varies widely. Some practitioners, such as naturopaths and chiropractors, practice it exclusively and are not medical doctors.⁶⁰ Some states require them to be licensed, while other states do not impose any such restrictions.⁶¹ However, they are generally not permitted to practice medicine as defined by their state's medical practice act.⁶²

On the other hand, conventional physicians who incorporate alternative medicine into their practice have considerably more freedom, as there are no explicit prohibitions against recommending or administering untested methods.⁶³ In fact, some states allow alternative treatments to be administered only by licensed physicians.⁶⁴ Consequently, licensed physicians may prescribe alternative medicine exclusively or in addition to conventional medicine.⁶⁵ The next step is to examine state laws regulating physicians that make this situation possible.

B. State Regulation of the Practice of Medicine

⁵⁸ *Music Therapy*, CLEVELAND CLINIC (July 18, 2023), <https://my.clevelandclinic.org/health/treatments/8817-music-therapy> [<https://perma.cc/8Q76-36UH>]; Melissa E Phuphanich et al., *Movement-Based Therapies in Rehabilitation*, 31 PHYSICAL MED. REHAB. CLIN. N. AM. 577, 577 (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC7476461/> [<https://perma.cc/9E95-LHA6>].

⁵⁹ *Music Therapy*, *supra* note 58; Phuphanich et al., *supra* note 58, at 577.

⁶⁰ See, e.g., Timothy M. Smith, *What's the Difference Between Physicians and Naturopaths?*, AMA (Feb. 26, 2024), <https://www.ama-assn.org/practice-management/scope-practice/whats-difference-between-physicians-and-naturopaths> [<https://perma.cc/DPP6-4UEX>].

⁶¹ *Id.*; *Chiropractic Professional Regulation FAQs*, FED'N CHIROPRACTIC LICENSING BDS., <https://fclb.org/chiropractic-professional-regulation-faqs.php#> [<https://perma.cc/J6VY-NYSL>] (last visited Aug. 26, 2025) (explaining that chiropractors are licensed in all 50 states but may only perform spinal manipulations, not diagnose or treat diseases or otherwise practice medicine); Michael H. Cohen & Harry Nelson, *Licensure of Complementary and Alternative Practitioners*, 13 AMA J. ETHICS 374, 374–77 (June 2011), <https://journalofethics.ama-assn.org/article/licensure-complementary-and-alternative-practitioners/2011-06> [<https://perma.cc/4VKK-DWB2>] (noting that in states that neither license nor prohibit naturopathy, anyone, including those without any formal medical training, may practice it without being subject to any regulation); Smith, *supra* note 60.

⁶² See, e.g., COLO. REV. STAT. § 6-1-724(2)(d) (2024).

⁶³ See discussion *infra* Part I.B.1. (describing medical practice acts that do not contain explicit prohibitions against alternative medicine practice).

⁶⁴ See *Homeopathic Physician Licensure Requirements – U.S. Trained Applicants*, CONN. ST. DEP'T. PUB. HEALTH, <https://portal.ct.gov/dph/practitioner-licensing--investigations/homeopathic-physician/homeopathic-physician-licensure-requirements--us-trained-applicants> [<https://perma.cc/JVX3-T2G3>] (last visited Aug. 26, 2025) (showing that homeopathy licensure, which is not allowed in most states, is available in Connecticut, but only to already licensed M.D. physicians); *About*, ARIZ. HOMEOPATHIC & INTEGRATED MED. EXAM'RS, <https://homeopath.az.gov/about> [<https://perma.cc/PK33-DPRQ>] (last visited Aug. 26, 2025) (showing that homeopathy licensure is also available in Arizona, but only to already licensed M.D. physicians).

⁶⁵ See discussion *infra* Parts II.A–B.

The practice of medicine is regulated at the state level. Each state formulates its own licensing requirements for physicians and surgeons.⁶⁶ This section describes the various state statutes that regulate the practice of medicine and allow the practice of alternative medicine by physicians.

1. State Medical Practice Acts: The Foundation

The Tenth Amendment empowers states with police powers to protect the health, safety, and welfare of their people,⁶⁷ through which states came to possess their licensing authority. In the landmark case *Dent v. West Virginia*, the Supreme Court held that states have the power to regulate the medical profession to protect the public from ignorance and deception.⁶⁸ Accordingly, states can require proof of healthcare providers' skill and knowledge through examinations or credentials from accredited institutions.⁶⁹ This decision granted states broad authority because it declared that the nature and extent of the required qualifications depend on the states' judgment of their importance.⁷⁰

States exercise this authority by enacting medical practice acts that empower state medical boards to establish licensing requirements and standards governing the scope of practice for physicians and surgeons.⁷¹ They do this through "practice of medicine" statutes that vary from state to state.⁷² A brief review of the statutes in three of the largest states highlights the differences in the standard practice of medicine statutes. For instance, the Texas statute defines practicing medicine as:

[T]he diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who

(A) publicly professes to be a physician or surgeon; or

⁶⁶ Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, 7 *AMA J. ETHICS* 311, 311–14 (Apr. 2005), <https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04> [<https://perma.cc/62PM-ZGKG>].

⁶⁷ U.S. CONST. amend. X; *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).

⁶⁸ *Dent*, 129 U.S. at 122.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Carlson & Thompson, *supra* note 66, at 314.

⁷² *Id.*

(B) directly or indirectly charges money or other compensation for those services.⁷³

In California, “the physician's and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.”⁷⁴ In contrast, the New York statute states, “the practice of the profession of medicine is defined as diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.”⁷⁵ Overall, statutes customarily define the practice of medicine as:

[T]he diagnosis, treatment, prevention, and cure; holding oneself out to the public as capable of diagnosing, treating, preventing, and curing disease; intending to receive compensation; attaching the title of M.D. or Dr. to one's name; maintaining an office for receiving, examining, and treating; performing surgery; using, administering or prescribing drugs.⁷⁶

Additionally, while most statutes, similar to the ones above, define the practice of medicine in conventional terms, some states also include alternative methods. For example, Illinois includes chiropractic physicians within its definition of physicians.⁷⁷ Hawaii allows hypnotism and the medicinal use of water and electricity.⁷⁸ Under Massachusetts law, acupuncture falls within the practice of medicine.⁷⁹

Under the practice of medicine statutes, a physician may be held liable only if their conduct falls below the required standard of care.⁸⁰ Generally,

⁷³ TEX. OCC. CODE ANN. § 151.002(a)(13) (West 2025).

⁷⁴ CAL. BUS. & PROF. CODE § 2051 (West 2025).

⁷⁵ N.Y. EDUC. LAW § 6521 (McKinney 2025).

⁷⁶ Peter J. Van Hemel, *A Way Out of the Maze: Federal Agency Preemption of State Licensing and Regulation of Complementary and Alternative Medicine Practitioners*, 27 AM. J.L. & MED. 329, 336–37 (2001) (citing MICHAEL H. COHEN, COMPLEMENTARY & ALTERNATIVE MEDICINE: LEGAL BOUNDARIES AND REGULATORY PERSPECTIVES 26–29 (1998)).

⁷⁷ 225 ILL. COMP. STAT. ANN. 60/2 (2025) (“‘Physician’ means a person licensed under the Medical Practice Act to practice medicine in all of its branches or a chiropractic physician.”).

⁷⁸ HAW. REV. STAT. § 453-1 (2025).

⁷⁹ 243 MASS. CODE REGS. 2.07(1) (2025).

⁸⁰ *About Physician Discipline*, FED’N ST. MED. BDS., [hereinafter *FSMB: Physician Discipline*], <https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-discipline/> [https://perma.cc/VZU9-X89F] (last visited Aug. 26, 2025); see discussion *infra* Part I.B.2.

prescribing alternative medicine is not considered substandard care.⁸¹ However, in *In re Guess*, an early case involving CAM, the North Carolina Medical Board suspended the license of a physician who treated patients routinely with homeopathic medicines.⁸² The Board based its decision on the grounds that Dr. Guess's divergence from accepted medical practice amounted to unprofessional conduct.⁸³ The Supreme Court of North Carolina upheld this decision as a lawful exercise of police power and dismissed the need for the Board to show specific injury or risk to the public.⁸⁴ This ruling caused the North Carolina legislature to amend the statute, requiring the Board to prove that an alternative treatment presents a higher safety risk than conventional treatment, or that it is generally ineffective, before disciplining a licensed practitioner.⁸⁵

In addition to the practice of medicine statutes, the medical practice acts also contain provisions that prohibit certain conduct.⁸⁶ Engaging in such conduct can lead to disciplinary actions by state medical boards. For example, Illinois lists several grounds for disciplinary action, including: "Engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public";⁸⁷ "Obtaining any fee by fraud, deceit, or misrepresentation";⁸⁸ and "Making a false or misleading statement regarding their skill or the efficacy or value of the medicine, treatment, or remedy prescribed by them at their direction in the treatment of any disease or other condition of the body or mind."⁸⁹ Similarly, New York prohibits "[e]xercising undue influence on the patient, including the promotion of the sale of services, goods, appliances, or drugs in such manner as to exploit the patient for the financial gain of the licensee or of a third party,"⁹⁰ as well as "[r]evealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law," among other violations.⁹¹

These examples illustrate that states prohibit various types of unprofessional conduct. While specific provisions may vary slightly across jurisdictions, the central theme regulating physician behavior is largely

⁸¹ *About Physician Discipline*, *supra* note 80; see discussion *infra* Parts I.B.2. & I.B.3.

⁸² *In re Guess*, 393 S.E.2d 833 (N.C. 1990).

⁸³ *Id.* at 835.

⁸⁴ *Id.* at 836–40.

⁸⁵ N.C. GEN. STAT. ANN. § 90-14(a)(6) (West 2025) (amended 2025).

⁸⁶ See, e.g., *id.*

⁸⁷ 225 ILL. COMP. STAT. ANN. 60/22(A)(5) (West 2025) (repealed effective Jan. 1, 2027).

⁸⁸ *Id.* at (A)(6).

⁸⁹ *Id.* at (A)(10).

⁹⁰ N.Y. EDUC. LAW § 6530(17) (McKinney 2025).

⁹¹ *Id.* at (21).

uniform. These different provisions of medical practice acts together form the legal basis for both the licensure and disciplinary oversight of physicians.

2. State Medical Boards in Disciplining Physicians: The Apparatus

As a logical supplement to overseeing licensure, state medical boards bear the responsibility of disciplining licensed physicians for unprofessional conduct that violates the state medical practice act.⁹² While harmed patients and beneficiaries can file malpractice suits against medical practitioners,⁹³ medical boards address physician misconduct through their regulatory authority.⁹⁴ This disciplinary process is mostly uniform across states.⁹⁵ Disciplinable unprofessional conduct includes:

[A]lcohol and substance abuse, sexual misconduct, neglect of a patient, failing to meet the accepted standard of care in a state, prescribing drugs in excess or without legitimate reason, dishonesty during the license application process, conviction of a felony, fraud, inadequate record keeping, and failing to meet continuing medical education requirements.⁹⁶

State medical boards across the country have different structures and authorities.⁹⁷ Some are independent bodies with complete control over licensing and disciplinary actions.⁹⁸ Others are part of their state health departments, where their roles may be limited or purely advisory.⁹⁹ These boards consist of volunteer physicians and public representatives, usually appointed by the governor.¹⁰⁰ In recent years, non-physician public members have become more common, resulting in greater transparency.¹⁰¹ State

⁹² *FSMB: Physician Discipline*, *supra* note 80.

⁹³ Yvette Brazier, *What Is Medical Malpractice?*, *MED. NEWS TODAY* (Apr. 5, 2017), <https://www.medicalnewstoday.com/articles/248175> [<https://perma.cc/Y8UL-PX6B>].

⁹⁴ *FSMB: Physician Discipline*, *supra* note 80.

⁹⁵ LUCINDA E. JESSON & STACEY A. TOVINO, *COMPLEMENTARY AND ALTERNATIVE MEDICINE AND THE LAW* 51 (2010).

⁹⁶ *FSMB: Physician Discipline*, *supra* note 80.

⁹⁷ *Introduction*, *FED’N ST. MED. BDS.*, [hereinafter *FSMB: Medical Regulation*], <https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/introduction/> [<https://perma.cc/E7AY-2JBC>] (last visited Jan. 18, 2025).

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*; *Guidelines for the Structure and Function of a State Medical and Osteopathic Board*, *FED’N ST. MED. BDS.*, 14 (Apr. 2024), <https://www.fsmb.org/siteassets/advocacy/policies/guidelines-for->

legislatures fund the boards through fees collected from physician licensing and registration.¹⁰² Irrespective of structural differences, state medical boards play a pivotal role in maintaining professional standards of conventional medical practitioners.

3. Health Freedom Acts: The Expansion

In addition to the practice of medicine statutes, several states have enacted Health Freedom statutes to enable citizens to make informed choices among all healthcare options available to them.¹⁰³ This approach indicates the growing emphasis on patient autonomy,¹⁰⁴ the cost benefits associated with nonconventional methods,¹⁰⁵ and the influence of the CAM lobby.¹⁰⁶ In some of these states, scientific standards have taken a backseat, placing the burden on the state medical board. For instance, Washington and Alaska have revised their medical practice statutes to require demonstrable physical harm to a patient before a physician can be disciplined.¹⁰⁷ Washington's statute reads, "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."¹⁰⁸ Alaska's statute, in part, states, "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."¹⁰⁹ North Carolina requires its medical board to establish that "the treatment has a safety risk greater than the prevailing treatment or that the treatment is generally not effective," before it can take *any manner* of disciplinary action on a practitioner who departs from prevailing medical practices.¹¹⁰

Some states have stricter regulations for alternative medicine. Colorado, for example, has two key provisions: (1) it requires that the reasonable

structure-function-of-state-medical-and-osteopathic-board-2024.pdf [https://perma.cc/6F6M-VCXF] (stating that at least 25% of the Board should be public members).

¹⁰² *FSMB: Medical Regulation*, *supra* note 97.

¹⁰³ *See, e.g.*, FLA. STAT. ANN. § 456.41(1) (West 2025).

¹⁰⁴ IOM, *supra* note 4, at 186 (discussing how patient autonomy often conflicts with medical paternalism).

¹⁰⁵ IOM, *supra* note 4, at 40.

¹⁰⁶ *See, e.g.*, *Health Freedom General Information*, NAT'L HEALTH FREEDOM COAL., <https://nationalhealthfreedom.org/health-freedom-information> [http://perma.cc/X9BA-JYUP] (last visited Jan. 18, 2025); *see also* Matt Hongoltz-Hetling, *The Anti-Vax Movement and the Medical Freedom Hustle*, THE NATION (Mar. 24, 2023), <https://www.thenation.com/article/society/the-anti-vax-movement-hustle/> [https://perma.cc/ST4K-KBBC] (showing how health freedom lobbyists are also related to the anti-vaccination movement).

¹⁰⁷ WASH. REV. CODE ANN. § 18.130.180 (4) (West 2025); ALASKA STAT. ANN. § 08.64.326 (a)(8)(A) (West 2025).

¹⁰⁸ WASH. REV. CODE ANN. § 18.130.180 (4) (West 2025).

¹⁰⁹ ALASKA STAT. ANN. § 08.64.326 (a)(8)(A) (West 2025).

¹¹⁰ N.C. GEN. STAT. ANN. § 90-14(a)(6) (West 2025) (amended 2025).

potential for therapeutic benefit of an alternative method not be outweighed by its risks, and (2) it mandates that licensed alternative medicine practitioners provide written information during the initial patient contact about their education, experience, and credentials.¹¹¹ Florida also has a similar information requirement, which need not be in writing, but goes a step further and requires that the alternative practitioner explain to the patient “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.”¹¹²

Of the states, California has one of the safest statutes for alternative medicine, as it covers various aspects of practice.¹¹³ The statute begins with a general exception that allows physicians and surgeons to prescribe alternative methods, but only if they comply with all of the statute’s other requirements.¹¹⁴ Practitioners must obtain informed consent and provide patients with detailed information—not just about the practitioner’s education, experience, and credentials, but also about conventional treatment.¹¹⁵ The statute also requires that alternative treatments “do not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.”¹¹⁶ This provision ensures that anyone recommending alternative treatments follows standards that put patient safety first. It mandates transparency about conventional treatment methods and protects against delays in diagnosis. By doing so, it ensures that while alternative therapies may be prescribed, they do not hinder timely and accurate diagnosis.

Furthermore, the statute entrusts the medical board with evaluating the necessity of 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.”¹¹⁷ This mandate could be interpreted as including the establishment of standards for assessing the safety and efficacy of alternative treatments.

C. Federal Agencies Related to Alternative Medicine

While state medical boards play a crucial role in regulating the practice of medicine, federal agencies, too, have their own responsibilities in overseeing drug regulation and alternative medicine research. To that end, this Note systematically describes the roles of three important entities: the FDA, which

¹¹¹ COLO. REV. STAT. ANN. § 12-240-121(5)(a) (West 2025).

¹¹² FLA. STAT. ANN. § 456.41(3) (West 2025).

¹¹³ CAL. BUS. & PROF. CODE § 2234.1 (West 2025).

¹¹⁴ CAL. BUS. & PROF. CODE § 2234.1(a) (West 2025).

¹¹⁵ CAL. BUS. & PROF. CODE § 2234.1(a)(1)–(2) (West 2025).

¹¹⁶ CAL. BUS. & PROF. CODE § 2234.1(a)(3) (West 2025).

¹¹⁷ CAL. BUS. & PROF. CODE § 2501(b) (West 2025).

regulates drugs; the National Center for Complementary and Integrative Health (NCCIH), which researches alternative medicine; and the Federation of State Medical Boards (FSMB), which issues periodic guidelines and special guidelines during crises.

1. The Food and Drug Administration

The FDA is the primary federal agency responsible for drug regulation.¹¹⁸ Under its current system of regulations, prescription drugs, OTC drugs, and dietary supplements are under different levels of scrutiny and oversight.¹¹⁹

Prescription drugs, which are conventional medicine, reach the market only after passing strict, multi-phase clinical trials.¹²⁰ This scientific method is commonly known as the evidence-based method, which came to be after decades of legislative reform.¹²¹ Among those, the first significant piece of legislation is the Federal Food, Drug, and Cosmetic Act (FDCA), which was passed in 1938.¹²² The Act distinguished between prescription and OTC drugs. It required pharmaceutical manufacturers to provide evidence of a drug's safety before marketing it.¹²³ This legislation was a result of the tragic sulfanilamide incident, which caused the death of 107 people, including many children.¹²⁴ The incident occurred because drug companies were allowed to release an unsafe sulfa drug without testing it properly.¹²⁵

A few decades after the FDCA, Congress passed the Kefauver-Harris Amendment in 1962.¹²⁶ It was a direct response to another tragedy, the thalidomide crisis in Europe, where a drug was linked to severe birth defects.¹²⁷ This amendment required proof of both efficacy and safety of drugs.¹²⁸ It also mandated that the FDA approve all clinical drug trials.¹²⁹ Many credit this measure with preventing a similar disaster in the U.S.¹³⁰

¹¹⁸ 21 U.S.C.A. § 393.

¹¹⁹ Helen W. Sullivan et al., *Consumer Understanding of the Scope of FDA's Prescription Drug Regulatory Oversight: A Nationally Representative Survey*, 29 PHARMACOEPIDEMIOL. & DRUG SAF. 134, 134–35 (2020).

¹²⁰ See 21 C.F.R. § 314.126 (2025).

¹²¹ Syed Amin Tabish, *Complementary and Alternative Healthcare: Is It Evidence-Based?*, 2 INT'L. J. HEALTH SCI. 1, 7 (2008), <https://pmc.ncbi.nlm.nih.gov/articles/PMC3068720/> [perma.cc/UYD4-G6JY].

¹²² IOM, *supra* note 4, at 77.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*; James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease*, 122 TOXICOL. SCI. 1, 1 (2011), <https://academic.oup.com/toxsci/article-abstract/122/1/1/1672454> [https://perma.cc/R2JJ-7EJD].

¹²⁸ IOM, *supra* note 4, at 77.

¹²⁹ *Id.*

¹³⁰ *Id.*

The described legislative reform culminated in the current system of regulations on prescription drugs. Accordingly, manufacturers must first submit clinical test results to the FDA before marketing the drugs.¹³¹ This data must show that the drug is proven safe and effective for a particular purpose and designated age range, or other such targets.¹³² The drug manufacturer must mention this information in the New Drug Application (NDA) form.¹³³ The FDA would then review the form, approve or deny the application, or ask for additional information.¹³⁴ In addition, the FDA determines the information that should appear on the drug label, including intended uses, warnings, and directions.¹³⁵

By contrast, OTC drugs, though regulated by the FDA, do not have to hold up to the same high standards as prescription medications. Granted, there are provisions in place to ensure the effectiveness and safety of these drugs. Effectiveness is defined as the reasonable expectation that, for the majority of the target population, the drug will provide the claimed relief when used as directed.¹³⁶ The safety and effectiveness of a drug are estimated by weighing its benefits against its risks.¹³⁷ However, a drug can be sold OTC unless it is highly toxic or poses other such risks that make it safe only when used under the recommendation of a licensed healthcare professional.¹³⁸

Lastly, dietary supplements have the most lenient regulations because they are classified as food substances, not as drugs.¹³⁹ This distinction is courtesy of the Dietary Supplement Health and Education Act (DSHEA) of 1994, which amended the FDCA to restrict the FDA's authority on these substances.¹⁴⁰ Accordingly, dietary supplement manufacturers need only label their products with a "Supplement Facts" panel.¹⁴¹ This panel should list serving sizes, ingredient amounts, and other essential nutritional information.¹⁴² The labels should also identify the products as "dietary supplements."¹⁴³ Still, the responsibility to meet these requirements and make

¹³¹ *Id.*

¹³² *Regulation of Over-the-Counter Drug Products Should Be Streamlined*, PEW (Mar. 28, 2017), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/03/regulation-of-over-the-counter-drug-products-should-be-streamlined> [<https://perma.cc/U59P-JMWW>].

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ 21 C.F.R. § 330.10 (a)(4)(ii) (2025).

¹³⁷ *Id.* at (a)(4)(iii).

¹³⁸ *See id.* at (a)(4)(vi).

¹³⁹ *See Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Oct. 1, 2024), <https://www.fda.gov/food/dietary-supplements> [<https://perma.cc/9CBN-4T5A>].

¹⁴⁰ *FDA 101: Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (June 2, 2022), <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements> [<https://perma.cc/V798-YA9F>].

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

no misleading claims is on the manufacturers.¹⁴⁴ Therefore, unlike prescription drugs, the FDA does not have the authority to pre-approve dietary supplements for safety or effectiveness before manufacturers market them.¹⁴⁵ In sum, the FDA has different levels of control over prescription drugs, OTC drugs, and dietary supplements.

2. The National Center for Complementary and Integrative Health

The other federal agency relevant to the discussion of alternative medicine is the NCCIH, which is responsible for scientific research on “complementary and integrative health approaches.”¹⁴⁶ It is located within the National Institutes of Health (NIH), which is part of the United States Department of Health and Human Services (HHS).¹⁴⁷ In the 2022 fiscal year alone, the NCCIH received a considerable budget of \$159.37 million.¹⁴⁸ Its mission is “to determine, through rigorous scientific investigation, the fundamental science, usefulness, and safety of complementary and integrative health approaches and their roles in improving health and health care.”¹⁴⁹ Similarly, its vision is to ensure that “scientific evidence informs decision making by the public, health care professionals, and health policymakers regarding the integrated use of complementary health approaches in a whole person health framework.”¹⁵⁰

The NCCIH originated in 1992, when it began as the Office of Alternative Medicine (OAM)¹⁵¹ following intense congressional lobbying.¹⁵² In 1993, the NIH Revitalization Act formally established OAM within the NIH Director’s Office and mandated the OAM to “facilitate the study and evaluation of complementary and alternative medical practices and to disseminate the resulting information to the public.”¹⁵³ Later, in 1998, the OAM became the National Center for Complementary and Alternative

¹⁴⁴ *Id.*

¹⁴⁵ Sara Berg, *What Doctors Wish Patients Knew about Vitamins and Supplements*, AMA (Oct. 1, 2021), <https://www.ama-assn.org/delivering-care/public-health/what-doctors-wish-patients-knew-about-vitamins-and-supplements> [https://perma.cc/5YUQ-L3QL].

¹⁴⁶ *About NCCIH*, NAT’L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH [hereinafter *About NCCIH*], <https://www.nccih.nih.gov/about> [https://perma.cc/GRR5-TH9R] (last visited Aug. 27, 2025).

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *NCCIH Timeline*, NAT’L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH [hereinafter *NCCIH Timeline*], <https://www.nccih.nih.gov/about/nccih-timeline> [https://perma.cc/H6C6-B49R] (last visited Aug. 27, 2025).

¹⁵² John E. Dodes, *Alternative Therapy: A Historical Perspective on Health Fraud*, 3 QUINNIPIAC HEALTH L. J. 37, 43 (1999-2000) (citing Eliot Marshall, *The Politics of Alternative Medicine*, 265 SCIENCE 2000, 2000 (1994) [perma.cc/PUW9-JTLD]).

¹⁵³ *NCCIH Timeline*, *supra* note 151 (emphasis added); see National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 209, 107 Stat. 122, 149 (1993).

Medicine, an independent center.¹⁵⁴ The Center was tasked with devising five-year strategic plans with the aim of investigating the scientific bases of alternative cures.¹⁵⁵

In response to the increasing interest in integrative medicine, the Center revamped once again and became the National Center for Complementary and Integrative Health.¹⁵⁶ It recommitted to research and public education activities in accordance with its congressional mandate.¹⁵⁷ Today, the Center conducts and supports research on alternative medicine as well as organizes events and issues press releases.¹⁵⁸

3. Federation of State Medical Boards

Unlike the other two agencies, the FSMB is not a federal agency but a national association of state medical boards. It supports its member boards in fulfilling their mandate to protect public health, safety, and welfare through proper medical regulation, licensing, and the discipline of healthcare professionals.¹⁵⁹ Its stated vision is “[a] medical regulatory system in which patients have access to high-quality health care, and the integrity of the practice of medicine is protected.”¹⁶⁰ Accordingly, it co-sponsors nationwide licensing exams for physicians and surgeons.¹⁶¹ Its mission is “[t]o serve as a national voice for state medical boards, supporting them with services and initiatives that promote patient safety, the integrity of the practice of medicine, access to high-quality health care and regulatory best practices.”¹⁶² To that end, it plays a crucial role in advocating for policies that promote patient health and safety.¹⁶³ It is important to note that these policies are only recommendations that states are not required to adopt.¹⁶⁴

For example, the FSMB provides resources on regular medical board matters, like board structure and function, telemedicine, and diversity, equity,

¹⁵⁴ *NCCIH Timeline*, *supra* note 151.

¹⁵⁵ *See id.*

¹⁵⁶ *NIH Complementary and Integrative Health Agency Gets New Name*, NAT’L INST. HEALTH (Dec. 17, 2014), [<https://perma.cc/C5UP-95XR>].

¹⁵⁷ *Id.*

¹⁵⁸ *About NCCIH*, *supra* note 146.

¹⁵⁹ *About FSMB*, FED’N ST. MED. BDS., <https://www.fsmb.org/about-fsmb/> [<https://perma.cc/Q5SP-3TBE>] (last visited Aug. 27, 2025).

¹⁶⁰ *Id.*

¹⁶¹ *Licensing*, NBME, <https://www.nbme.org/assessment-products/medical-licensing-exams> [<https://perma.cc/H2U9-PJWL>] (last visited Aug. 27, 2025).

¹⁶² *Id.*

¹⁶³ *Advocacy*, FED’N ST. MED. BDS., <https://www.fsmb.org/advocacy/> [<https://perma.cc/WQ5G-VQ26>] (last visited Aug. 27, 2025).

¹⁶⁴ *FSMB Policies and Regulatory Resources*, FED’N ST. MED. BDS., <https://www.fsmb.org/advocacy/policies-and-regulatory-resources/> [<https://perma.cc/4WZP-A89K>] (last visited Aug. 18, 2025).

and inclusion in patient care.¹⁶⁵ Beyond that, the FSMB takes proactive measures during times of crisis. During the COVID-19 pandemic, when anti-vaccine rhetoric and medical misinformation were widespread, the FSMB issued guidelines on professional expectations for physicians regarding the dissemination of medical misinformation and disinformation.¹⁶⁶ Similarly, in response to the escalating opioid crisis, the FSMB released multiple guidelines about prescribing opioids, preventing overdose, and best practices for pain management.¹⁶⁷ Even though these guidelines are timely and relevant, states are not required to follow them. The decision to adopt or disregard FSMB recommendations rests solely with each state, and many, if not all, choose not to adopt them.¹⁶⁸

D. Insurance Reform as a Proven Contributor to the Rise in CAM

Along with regulatory agencies, systemic factors like insurance reform also play a role in the increased acceptance and use of alternative medicine. A major factor that enabled this is the intense lobbying efforts of the CAM lobby. In the early days, the lobby was not as powerful and faced many defeats and challenges.¹⁶⁹ But the turning point came with *Wilk v. AMA*, in which a group of chiropractors prevailed against the American Medical Association (AMA) and their allied organizations.¹⁷⁰

In that case, the chiropractors claimed that the AMA conspired to eliminate the chiropractic profession by prohibiting physicians from associating with them.¹⁷¹ They contended the AMA used one of its Principles of Medical Ethics to label chiropractors as “unscientific practitioners” and instructed physicians that it was unethical to associate with them.¹⁷² The Seventh Circuit found that the AMA violated antitrust laws by conducting an illegal boycott of chiropractors and affirmed an injunction against it.¹⁷³

¹⁶⁵ *Id.*

¹⁶⁶ *FSMB Adopts Policies on Medical Disinformation, Telemedicine, DEI, Emergency Preparedness and Response*, FED’N ST. MED. BDS., [https://perma.cc/376V-C66Q] (last visited Aug. 27, 2025).

¹⁶⁷ *Opioids and Pain Management*, FED’N ST. MED. BDS., https://www.fsmb.org/opioids/ [https://perma.cc/6MC3-RXKG] (last visited Aug. 27, 2025).

¹⁶⁸ See, e.g., *Federation of State Medical Boards Adopts Model Policy Guidelines for Telemedicine*, MCGUIREWOODS (May 6, 2014), https://www.mcguirewoods.com/client-resources/alerts/2014/5/fsmb-model-policy-guidelines-for-telemedicine/ [https://perma.cc/63EM-693M]. During the COVID-19 pandemic, states did not adopt or codify the FSMB guidelines. See discussion *supra* Part II.A.

¹⁶⁹ See Steve Agocs, *Chiropractic’s Fight for Survival*, 13 *AMA J. ETHICS* 384, 384–88 (June 2011), https://journalofethics.ama-assn.org/article/chiropractics-fight-survival/2011-06 [perma.cc/STL3-XP25].

¹⁷⁰ Agocs, *supra* note 169, at 387; see generally Claire D. Johnson & Bart N. Green, *Looking Back at the Lawsuit that Transformed the Chiropractic Profession Part 6: Preparing for the Lawsuit*, 35 *J. CHIROP. EDUC.* 85, 85–96 (2021) (exploring the events surrounding *Wilk v. Am. Med. Ass’n*, 895 F.2d 352, 355 (7th Cir. 1990)).

¹⁷¹ *Wilk v. Am. Med. Ass’n*, 895 F.2d 352, 355 (7th Cir. 1990).

¹⁷² *Id.*

¹⁷³ *Id.* at 378.

Following the legal victory in *Wilk v. AMA*, the CAM lobbying movement became focused on campaigning for the inclusion of CAM in services covered by insurance.¹⁷⁴ Adding fuel to the growth of CAM were competitive pressures within the healthcare industry and a large number of state mandates passed during that time.¹⁷⁵ Moreover, more CAM providers began to obtain licenses, which lent a sense of legitimacy to the industry.¹⁷⁶ This naturally led some states to require insurers to cover CAM treatments.¹⁷⁷ It was also helpful that CAM grew from a small business to a wide variety of products and services produced and distributed by large corporations through the mainstream consumer economy.¹⁷⁸

The CAM lobby achieved one of its most significant victories with the passage of the “Harkin Law,” an anti-discrimination provision in the Affordable Care Act (ACA).¹⁷⁹ Accordingly, Section 2706(a) of the Public Health Service Act requires that insurers “shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider’s license or certification under applicable state law.”¹⁸⁰ This allows anyone who claims to provide healthcare, regardless of the plausibility of their claim, to sue for discrimination if an insurance company refuses to pay for their services.¹⁸¹

Initially, realizing that the provision gave a broad rein to even fringe practitioners, the HHS issued a joint FAQ along with the Department of Labor and the Treasury, and clarified that the provision does not require insurers to include all types of providers in their networks.¹⁸² However, persistent lobbying by CAM supporters led the HHS to change its interpretation.¹⁸³ Thereby, in a subsequent FAQ, the HHS announced its commitment to take enforcement action against insurers who fail to make “a good faith, reasonable interpretation” of Section 2706(a) of the Public Health Service Act.¹⁸⁴

¹⁷⁴ Steven Salzberg, *Alternative Medicine Providers Show Their Greedy Side*, FORBES: INNOVATION: HEALTHCARE (Aug. 26, 2013), at 08:01 ET), <https://www.forbes.com/sites/stevensalzberg/2013/08/26/alternative-medicine-providers-show-their-greedy-side/> [https://perma.cc/MKV7-RW8S].

¹⁷⁵ Goldstein, *supra* note 1, at 57.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 55.

¹⁷⁹ Salzberg, *supra* note 174.

¹⁸⁰ *Id.*; 42 U.S.C.S. § 300gg-5 (LexisNexis).

¹⁸¹ See Salzberg, *supra* note 174.

¹⁸² *Anti-Discrimination*, AM. COLL. NURSE-MIDWIVES (Aug. 26, 2013), [https://perma.cc/7Y7N-RH4S]; *Congress Strengthens Harkin Law, Boosts Nondiscrimination Protections*, CAL. OPTOMETRIC ASS’N (Feb. 2014), [https://perma.cc/4Z2Q-GKKM].

¹⁸³ *HHS Reverses Course on ‘Harkin Amendment’ Guidance*, CAL. OPTOMETRIC ASS’N (June 2015), [https://perma.cc/G63V-R265].

¹⁸⁴ *Id.*

Recognizing that such a broad interpretation would allow substandard care, some legislators tried to amend the provision. Representative Harris introduced H.R. 2817, the Protect Patient Access to Quality Health Professionals Act of 2013, to eliminate the anti-discrimination provision.¹⁸⁵ This bill proposed the amendment of the Public Health Service Act to remove the ACA's prohibition on health plans discriminating against providers who operate within the scope of their state-issued licenses or certifications.¹⁸⁶ But the bill ultimately failed to pass.¹⁸⁷

The Centers for Medicare & Medicaid Services (CMS) provides the current interpretation of how Section 2706(a) of the Public Health Service Act should be implemented.¹⁸⁸ According to the CMS, this section states that group health plans and health insurance issuers offering group or individual coverage cannot discriminate against any healthcare provider who is acting within the scope of their state license or certification.¹⁸⁹ However, it does not require health plans to contract with every provider who is willing to meet the terms of participation, nor does it prevent plans or insurers from setting different reimbursement rates based on quality or performance.¹⁹⁰

Having fully contextualized the issue by defining alternative medicine, identifying its practitioners, describing the medical licensing system, and outlining the federal agencies involved, this Note now moves to an analysis of the deficiencies within this complex system.

II. ANALYSIS: THE CONUNDRUM OF UNREGULATED ALTERNATIVE MEDICINE AMID EXTENSIVE HEALTHCARE REGULATIONS

With such an extensive system of healthcare regulations, one would expect it to nurture patient health and safety. However, each part of the system suffers from defects that make it improbable. State medical boards are tasked with bearing many responsibilities that they lack the power to control, such as the misinformation spread by physicians. Medical malpractice claims, the only mechanism for patients to seek justice, must overcome plaintiff barriers such as assumption of risk and informed consent. The FDA's lack of regulation of over-the-counter drugs and dietary supplements leaves a void in the safety checks that could be implemented.

¹⁸⁵ H.R. 2817, 113th Cong. (2013).

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*; *Anti-Discrimination*, *supra* note 182.

¹⁸⁸ *Affordable Care Act Implementation FAQs – Set 15*, CMS (Sep. 10, 2024), https://www.cms.gov/cciiio/resources/fact-sheets-and-faqs/aca_implementation_faqs15#ftn3 [<https://perma.cc/WN7Y-24S7>].

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

Untested and unproven medicines can infiltrate store shelves and stay there until their efficacy or safety becomes questionable and forces a recall.¹⁹¹

Part II.A. identifies the dissemination of misinformation by physicians as a widespread concern and proposes incorporating FSMB guidelines as a preventive measure. Part II.B. uses three older cases to illustrate how the assumption of risk defense is used against vulnerable patients and recommends strengthening informed consent requirements in state statutes where they are inadequate. Part II.C. discusses the myriad issues with federal agencies and reviews proposed solutions. It also examines an unlikely solution to the challenges posed by the ACA's non-discrimination provision.

A. Using FSMB Guidelines to Capacitate State Licensing Statutes that Do Not Address Misinformation Spread by Physicians

Misinformation spread by physicians compounds the effects of inadequate information dissemination by organizations like the NCCIH. This issue has been longstanding,¹⁹² but became particularly pronounced during the COVID-19 pandemic.¹⁹³ Misinformation is defined as “health-related information or claims that are false, inaccurate or misleading, according to the best available scientific evidence at the time.”¹⁹⁴ It differs from disinformation, which is the intentional spread of false or misleading information for malicious purposes, such as financial gain or political advantage.¹⁹⁵ Even in the past, patients have sought treatment from physicians who spread misinformation through platforms like radio advertisements and lectures.¹⁹⁶ This would be categorized as disinformation, as these physicians had clear pecuniary interests in promoting their treatments.

Take the example of Dr. Joseph Mercola. He has made a career out of leading the anti-vaccine movement while promoting dietary supplements and unproven alternative medicines as substitutes for vaccines.¹⁹⁷ Per an investigative report by *The Washington Post*, Dr. Mercola made millions of

¹⁹¹ Berg, *supra* note 145.

¹⁹² Richard S. Saver, *Physicians Spreading Medical Misinformation: The Uneasy Case for Regulation*, 108 MINN. L. REV. 911, 926–27 (2023); see FED’N ST. MED. BDS., PROFESSIONAL EXPECTATIONS REGARDING MEDICAL MISINFORMATION AND DISINFORMATION 1 (Apr. 2022) [hereinafter FSMB REPORT], <https://www.fsmb.org/siteassets/advocacy/policies/ethics-committee-report-misinformation-april-2022-final.pdf> [https://perma.cc/978S-9G55].

¹⁹³ Saver, *supra* note 192, at 914.

¹⁹⁴ FSMB REPORT, *supra* note 192, at 3.

¹⁹⁵ *Id.*

¹⁹⁶ See *infra* notes 258–59 and accompanying text.

¹⁹⁷ CTR. FOR COUNTERING DIGIT. HATE, THE DISINFORMATION DOZEN 12 (Mar. 24, 2021), <https://counterhate.com/wp-content/uploads/2022/05/210324-The-Disinformation-Dozen.pdf> [https://perma.cc/Y695-2NZL].

dollars selling his alternative cures.¹⁹⁸ His website is a giant source of misinformation and features sensational headlines such as “Learn How Homeopathy Cured a Boy of Autism,” “Your Flu Shot Contains a Dangerous Neurotoxin,” and “Vitamin D: The Silver Bullet for Cancer.”¹⁹⁹

During the COVID-19 pandemic, he spread many misleading claims, like COVID-19 was a scam, vaccination was part of a global economic reset plan, and that hydrogen peroxide could successfully treat the virus.²⁰⁰ His claims spread so far and wide that he topped the “Disinformation Dozen” list compiled by the Center for Countering Digital Hate.²⁰¹ The list identified people actively spreading misinformation and disinformation through their social media platforms.²⁰² What is particularly interesting about Dr. Mercola’s case is how quickly he removed misinformation articles from his website after an exposé by *The New York Times*.²⁰³ However, his marketplace website continues to sell supplements and alternative medicines,²⁰⁴ and his platform still promotes distrust in modern medicine.²⁰⁵

Amidst the wave of anti-vaccination rhetoric during the pandemic, other misleading claims were also being made. For example, a licensed physician posted a video claiming that inhaling hydrogen peroxide could prevent or cure COVID-19.²⁰⁶ Hydrogen peroxide is a chemical used in industrial bleaching and in rocket fuel, and inhaling its vapor can cause eye irritation and breathing difficulties.²⁰⁷ Similarly, some physicians announced that hydroxychloroquine and ivermectin could be used as treatments for COVID-

¹⁹⁸ Geoff Brumfiel, *For Some Anti-Vaccine Advocates, Misinformation Is Part of a Business*, NPR (May 12, 2021, at 05:08 ET), <https://npr.org/sections/health-shots/2021/05/12/993615185/for-some-anti-vaccine-advocates-misinformation-is-part-of-a-business> [<https://perma.cc/L4TH-4A4A>].

¹⁹⁹ Rachel Abrams & Jan Hoffman, *Dr. Joseph Mercola: The Misinformation “Superspreader”*, N.Y. TIMES (Oct. 7, 2022), <https://www.nytimes.com/2022/08/16/nyt-presents/joseph-mercola-coronavirus-misinformation.html#> [<https://perma.cc/9U27-PFWV>].

²⁰⁰ CTR. FOR COUNTERING DIGIT. HATE, *supra* note 197, at 12–13.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Local Doctor Removing Health Articles After Claims of Misinformation*, Fox 4 (Aug. 4, 2021, at 18:54 ET), <https://www.fox4now.com/news/coronavirus/local-doctor-removing-health-articles-after-claims-of-misinformation> [<https://perma.cc/WLT6-DD48>].

²⁰⁴ See MERCOLA MARKET, <https://www.mercolamarket.com/> [<https://perma.cc/6YUW-G7US>] (last visited Aug. 27, 2025) (showing, for instance, among the cures sold are “organic blood pressure support” and “premium line of immune support essentials.”).

²⁰⁵ See MERCOLA, <https://www.mercola.com/> [<https://perma.cc/7U2M-FKYN>] (last visited Aug. 27, 2025) (featuring a top story on the dangers of antidepressants by declaring it is a “crisis fueled by modern medicine,” and inviting readers in another story to “Discover the Powerful Potential of Hydrogen Peroxide Nebulization.”).

²⁰⁶ Victoria Knight, *Will ‘Dr. Disinformation’ Ever Face the Music?*, KFF HEALTH NEWS (Sep. 22, 2021), [<https://perma.cc/55WL-EYVZ>].

²⁰⁷ AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *Medical Management Guidelines for Hydrogen Peroxide*, CDC (Oct. 21, 2014), <https://wwwn.cdc.gov/TSP/MMG/MMGDetails.aspx?mmgid=304&toxid=55#:-:text=Depending%20on%20the%20concentration%2C%20breathing,contact%20with%20hydrogen%20peroxide%20solutions> [<https://perma.cc/NN6U-54HD>].

19.²⁰⁸ The problem is that these medications are typically used for autoimmune disorders and parasitic infections,²⁰⁹ but they are not approved for the treatment of COVID-19.²¹⁰ This misinformation spread mainly on social media, and now, even the minimal efforts by social media companies have been reduced due to complaints about perceived free speech violations.²¹¹

This problem of misinformation exists not just with individual physicians but also with several people nominated or appointed for high-level health-related positions. When President Trump announced his nominees for such roles, many in the medical community raised alarm.²¹² Their concern was due to the fact that these nominees all had a long history of spreading medical misinformation.²¹³ When individuals who wield high influential power in an official capacity endorse false claims, it increases the risk to public health and safety exponentially.²¹⁴

Another person appointed to a health-related leadership position is Dr. Mehmet Oz, a heart surgeon who champions ineffective treatments and fad diet pills.²¹⁵ Through his medical television talk show, he routinely makes medical recommendations that either lack evidence or contradict the best

²⁰⁸ Knight, *supra* note 206.

²⁰⁹ *Hydroxychloroquine Tablets*, CLEVELAND CLINIC, <https://my.clevelandclinic.org/health/drugs/19772-hydroxychloroquine-tablets> [<https://perma.cc/K4B8-FSYU>] (last visited Aug. 27, 2025); *Ivermectin and Covid-19*, U.S. FOOD & DRUG ADMIN. (May 4, 2024), <https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19> [<https://perma.cc/399E-WXD2>].

²¹⁰ *Id.*

²¹¹ Meghan Bobrowsky & Gareth Vipers, *Meta Ends Fact-Checking on Facebook, Instagram in Free-Speech Pitch*, WALL ST. J. (Jan. 7, 2025, at 15:03 ET), <https://www.wsj.com/tech/meta-ends-fact-checking-on-facebook-instagram-in-free-speech-pitch-8e46ad52> [<https://perma.cc/7QU6-ETGX>]. Twitter was sold due to its restrictions and has now been transformed into X, which gives free rein to those spreading misinformation. *Id.* Meta recently announced that it was ending its fact-checking efforts and restoring free expression. *Id.*

²¹² Bobby Cuza, *RFK Jr. Appointment Could Have Deadly Consequences, Experts Warn*, SPECTRUM NEWS (Nov. 18, 2024, at 20:01 ET), <https://ny1.com/nyc/all-boroughs/politics/2024/11/19/rfk-jr-appointment-could-have-deadly-consequences--experts-warn> [<https://perma.cc/JAY7-NR59>].

²¹³ Josh Nathan-Kazis, *Trump's Made His Health Picks. What they Mean for the Sector.*, WALL ST. J. (Nov. 25, 2024, at 14:38 ET), <https://www.barrons.com/articles/trump-picks-health-stocks-51da7edb> [perma.cc/3N4H-R7JB]; see *Fact-Checking RFK Jr's Views on Health Policy*, BBC NEWS (Nov. 15, 2024), <https://www.bbc.com/news/articles/c0mzk2y41zvo> [<https://perma.cc/YQW6-HUPV>]; see *Senate Confirms Marty Makary to Lead FDA, Jay Bhattacharya to Head NIH*, CBS NEWS (Mar. 25, 2025, at 23:44 ET) <https://www.cbsnews.com/news/senate-confirms-marty-makary-to-lead-fda-jay-bhattacharya-to-head-nih/> [<https://perma.cc/HX5Z-RD5P>] (discussing that Dr. Marty Makary now leads the FDA and serves under Robert F. Kennedy Jr., who leads the HHS).

²¹⁴ See Maria Godoy, *Amid a Growing Measles Outbreak, Doctors Worry RFK Jr. Is Sending the Wrong Message*, NPR (Mar. 7, 2025, at 05:00 ET), <https://www.npr.org/2025/03/07/nx-s1-5320352/measles-rfk-west-texas-outbreak> [<https://perma.cc/GCB4-VXYX>].

²¹⁵ Dani Blum, Emily Shmall & Nina Agrawal, *Dr. Oz, Tapped to Run Medicare, Has a Record of Promoting Health Misinformation*, N.Y. TIMES (Dec. 1, 2024), <https://www.nytimes.com/2024/11/20/well/dr-oz-health-medicare-record.html> [<https://perma.cc/UC85-FSBR>].

available evidence.²¹⁶ Dr. Oz actively pushes the most debunked form of alternative medicine, homeopathy,²¹⁷ and promotes bizarre fringe methods such as iridology.²¹⁸ He does this by featuring guests who promote these alternative methods and adding credibility to their claims through his own anecdotes and endorsements.²¹⁹ And one of his most famous guests is none other than Dr. Mercola, whom he called a “pioneer in holistic treatments.”²²⁰

During the COVID-19 pandemic, state medical boards, which are typically responsible for disciplining physicians, were ill-equipped to control the rapid spread of misinformation.²²¹ Their slow reaction time, along with a focus on offenses like felonies and molestations, led to minimal disciplinary action in this area.²²² Dr. Oz stands as a prime example of medical board incapacity. Despite being called to testify before the Senate regarding his misleading statements, he remains a licensed physician and retains his affiliation with Columbia University’s medical school.²²³

A study of medical board disciplinary proceedings in the five most populous states during the COVID-19 pandemic found that the most common reasons for disciplinary action against physicians were related to criminal conduct or patient harm, not misinformation.²²⁴ In fact, spreading medical misinformation to patients (MMP), disseminating it to the broader community (MMC), or engaging in problematic physician-patient interactions related to COVID-19 (C19) were among the least frequent causes for such proceedings.²²⁵ A graph from the study, shown in Figure 1 below, visually illustrates how insignificant these disciplinary proceedings

²¹⁶ Ashley N. Soriano, *Dr. Oz’s Disputed Health Claims Could Jeopardize Senate Confirmation*, NEWSNATION (Nov. 23, 2024, at 12:37 CT), <https://www.newsnationnow.com/politics/transition/dr-oz-health-claims-senate-confirmation/> [<https://perma.cc/Y8H6-GZ2B>]; Christina Korownyk et al., *Televised Medical Talk Shows-What They Recommend and the Evidence to Support Their Recommendations: A Prospective Observational Study*, 349 BRIT. MED. J. (Dec. 17, 2014), <https://www.bmj.com/content/349/bmj.g7346> [<https://perma.cc/AT5N-SRPP>].

²¹⁷ Steven J. Dell, Editorial, *What’s Wrong with Dr. Oz?*, 112 MO. MED. 332, 332–33 (Sep./Oct. 2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC6167233/pdf/ms112_p0332.pdf [<https://perma.cc/7DUM-JBMD>].

²¹⁸ *Id.* Iridology is a widely debunked belief that claims, “a person’s state of health can be diagnosed by examining particular regions of the iris.” *Id.*

²¹⁹ *Id.* For instance, he would casually add that his own family uses homeopathic medicine. *Id.*

²²⁰ David Corn, *How Dr. Oz Boosted an Osteopath Who Became a Top Spreader of Covid Misinformation*, MOTHER JONES (Oct. 12, 2022), <https://www.motherjones.com/politics/2022/10/how-dr-mehmet-oz-boosted-joseph-mercola-covid-misinformation/> [<https://perma.cc/TE8P-JBGD>].

²²¹ Knight, *supra* note 206.

²²² *Id.*; Richard S. Saver, *Medical Board Discipline of Physicians for Spreading Medical Misinformation*, JAMA NETWORK OPEN (Nov. 12, 2024), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2826059> [perma.cc/WFN6-Y4N8].

²²³ Timothy Caulfield, Opinion, *Dr. Oz Shouldn’t Be a Senator or a Doctor*, SCI. AM. (Dec. 15, 2021), <https://www.scientificamerican.com/article/dr-oz-shouldnt-be-a-senator-or-a-doctor/> [<https://perma.cc/L5C2-XQUS>].

²²⁴ Saver, *supra* note 222.

²²⁵ *Id.*

were in number compared to those for negligence (N) or problematic record-keeping (RK).

Figure 1. Reasons Underlying Medical Board Discipline in the 5 Most Populous US States, by Frequency of Offense vs Total Offenses

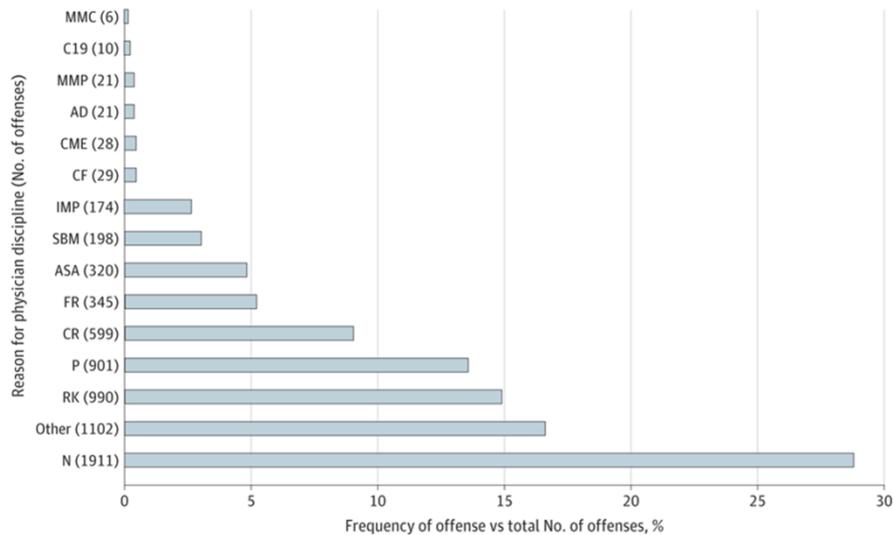


Figure 1.²²⁶

According to the study, among the 3,128 disciplinary proceedings, only six were for spreading misinformation to the public, compared to 1,911 for negligence or incompetence.²²⁷ Only one physician lost their license in the wake of such misleading claims, and many others saw their licenses renewed.²²⁸ This implies that misinformation persisted nationwide, largely unhindered by state laws.

This is where the FSMB's role in issuing guidelines during crises rose to the occasion. Where state boards had failed to rein in misinformation, the FSMB, despite lacking regulatory power, issued a report outlining the general expectations for physicians: "Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients."²²⁹ It identified

²²⁶ *Id.* (using data from January 1, 2020, through May 30, 2023, for California, Florida, New York, and Pennsylvania, and from January 1, 2020, through March 30, 2022, for Texas).

²²⁷ *See id.*

²²⁸ *Id.*

²²⁹ FSMB REPORT, *supra* note 192, at 8 (quoting *Position Statement on Sale of Goods by Physicians and Physician Advertising*, FED'N ST. MED. BDS. (April 2016),

additional grounds for disciplinary action that could relate to the dissemination of misinformation, but not directly related to fraud or deceit.²³⁰ It further recommended that physicians should base treatment recommendations on scientific evidence or sound medical opinions, ensuring transparency with patients about the risks and benefits, as well as reasonable alternatives to proposed treatments.²³¹ As has been the case, no state medical board formally adopted these recommendations.

In summary, while state medical boards faced criticism for their slow responses, they lacked clear authority to discipline transgressors and ended up renewing the licenses of several physicians in question.²³² Some argue that free speech protects public misinformation,²³³ but one might counter that physicians, because of their professional expertise and ethical obligations, have a special responsibility to avoid spreading false information.²³⁴ That naturally leads to: Do private physicians have a “societal role” when communicating to the general public?²³⁵

Tackling misinformation requires a targeted strategy. Some approaches have suggested addressing the spread of misinformation as fraud when it is committed for financial gain,²³⁶ however, in many cases, the reasons behind such physicians' actions are not clear.²³⁷ Therefore, while criminal actions may be appropriate in cases of intentional deceit, incorporating clear prohibitions into state licensing statutes or enacting an exclusive act could grant state medical boards the authority to act against any form of misinformation—whether intentional or reckless. These restrictions would also acknowledge that physicians, due to their professional responsibility, have a heightened duty to avoid advocating for false and unproven treatments.

An effective approach to handling this problem is to amend state licensing statutes to incorporate FSMB guidelines on medical misinformation and disciplinary actions. Doing so would allow the boards the authority to control misinformation in the medical profession and ensure patient safety. In

<https://www.fsmb.org/siteassets/advocacy/policies/position-statement-on-sale-of-goods-by-physicians-and-physician-advertising.pdf> [<https://perma.cc/Z7PH-SGDK>].

²³⁰ See *id.* at 8–9.

²³¹ *Id.* at 11.

²³² Saver, *supra* note 192, at 915.

²³³ See *id.* at 916–17.

²³⁴ Rachel Hajar, *The Physician's Oath: Historical Perspectives*, 18 HEART VIEWS 154, 156 (Oct.-Dec. 2017), <https://pmc.ncbi.nlm.nih.gov/articles/PMC5755201/> [<https://perma.cc/4F7K-ZH5T>]. For thousands of years, medical school graduates have taken the classic Hippocratic Oath, which proclaims, “[F]irst do no harm.” *Id.*

²³⁵ Saver, *supra* note 192, at 916.

²³⁶ See Chad G. Marzen & Michael Conklin, *Coronavirus “Cures” and the Courts*, 12 WM. & MARY BUS. L. REV. 1, 17 (2020); see generally Dodes, *supra* note 152 (discussing how the peddling of alternative treatments by quacks constitutes health fraud).

²³⁷ Saver, *supra* note 192, at 984.

addition to misinformation, another challenge to patient well-being arises in the area of medical malpractice.

B. Improving Informed Consent to Address Legal Barriers that Plague Medical Malpractice Lawsuits

The jurisprudence on harms resulting from the practice of alternative medicine has been largely equivocal in securing justice for patient-plaintiffs who have suffered harm. Malpractice suits are an avenue for wronged patients to seek redress against physicians for wrongful conduct.²³⁸ While they may be filed for various reasons,²³⁹ one study found that the most common cause is missed or delayed diagnoses.²⁴⁰ To win such a suit, the patient-plaintiff must prove the physician deviated from the standard of care, and this deviation caused an injury and recoverable damages.²⁴¹ In turn, physicians can raise one or many affirmative defenses. One such defense is the assumption of risk, which is based on the idea that the patient voluntarily and knowingly accepted the risks involved in the particular treatment.²⁴² Unsurprisingly, this defense is leveraged to its fullest extent in medical malpractice cases involving alternative medicine.²⁴³

In *Charell v. Gonzalez*, an alternative medicine practitioner convinced a cancer patient to reject chemotherapy and radiation and follow his unconventional treatment plan instead.²⁴⁴ This plan included a special diet in which the patient received six coffee enemas every day.²⁴⁵ The patient followed the plan, but her cancer returned, resulting in failing vision and severe back discomfort.²⁴⁶ The patient then filed a medical malpractice lawsuit against the practitioner.²⁴⁷

The patient testified that the practitioner never informed her that his treatment plan was experimental and not generally accepted in the medical

²³⁸ *What is Medical Malpractice?*, ABPLA, <https://www.abpla.org/what-is-malpractice> [<https://perma.cc/K63Q-54W9>] (last visited Aug. 27, 2025).

²³⁹ *See id.* (providing other reasons for malpractice suits, including improper medication or dosage, failure to order proper testing, and misreading or ignoring laboratory results).

²⁴⁰ Wallace et al., *supra* note 22, at 1.

²⁴¹ ABPLA, *supra* note 238.

²⁴² Lisa Burden, *Common Defenses in Medical Malpractice Cases*, LAW INFO (Jan. 2, 2025), <https://www.lawinfo.com/resources/medical-malpractice/common-defenses-in-medical-malpractice-cases.html> [<https://perma.cc/4DED-WNB4>]. There are many other defenses such as contributory and comparative negligence, no duty of care, and lack of causation, but they are beyond the scope of this Note. *Id.*

²⁴³ *See Charell v. Gonzalez*, 660 N.Y.S.2d 665 (Sup. Ct. N.Y. Co. 1997); *see Schneider v. Revici*, 817 F.2d 987 (2d Cir. 1987).

²⁴⁴ *Gonzalez*, 660 N.Y.S.2d at 666.

²⁴⁵ *Id.*

²⁴⁶ *Id.* at 666–67.

²⁴⁷ *Id.*

community.²⁴⁸ Accordingly, the jury found that the defendant failed to inform the patient about the risks involved in the treatment and other available alternatives.²⁴⁹ However, the jury also found that the plaintiff, who was a well-educated person, had conducted extensive independent research on the treatment with her husband and daughter.²⁵⁰ She had thus become “quite knowledgeable” on the subject.²⁵¹ So, the jury concluded that, since the plaintiff had gathered sufficient information about the treatment on her own, she assumed the risk of following the defendant practitioner’s method.²⁵²

But how can the average patient with no background in medicine gauge the differences between treatment options and understand their risks adequately? This almost esoteric task is even more challenging now that misinformation is widespread on the internet.²⁵³ Patients depend on their healthcare providers for accurate information about treatment methods and rely on their expertise.²⁵⁴ Therefore, the provider should bear the responsibility of ensuring that the patient receives such information. This information should take the form of an explanation of the risk, benefit, and efficacy of the alternative treatment, as well as a comparison to standard, evidence-based methods used for the same purpose.²⁵⁵

In *Schneider v. Revici*, a breast cancer patient who sought treatment from Dr. Revici later filed a medical malpractice and fraud action against him for using unconventional treatments, such as selenium, to treat her breast cancer.²⁵⁶ Revici’s treatment failed, and her cancer spread to her other breast and lymph nodes.²⁵⁷ The patient ended up needing extensive surgery, including the removal of both breasts and sixteen months of chemotherapy.²⁵⁸

The district court declined to permit an assumption of risk defense; however, the Second Circuit determined that there was enough evidence—both in the language of the consent form she signed and in testimony about her understanding of the risks associated with refusing conventional treatment in favor of the Revici method—to allow the jury to consider

²⁴⁸ *Id.* at 666.

²⁴⁹ *Id.* at 669.

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ See generally Knight, *supra* note 206 (highlighting the widespread sharing of online misinformation).

²⁵⁴ See *infra* notes 261–62 and accompanying text.

²⁵⁵ CAL. BUS. & PROF. CODE § 2234.1 (West 2025); FLA. STAT. ANN. § 456.41(3) (West 2025) (using language from the statutes).

²⁵⁶ *Schneider v. Revici*, 817 F.2d 987, 989–90 (2d Cir. 1987).

²⁵⁷ *Id.* at 990.

²⁵⁸ *Id.*

express assumption of risk as a valid defense that could completely bar recovery.²⁵⁹

In a similar case, *Boyle v. Revici*, which occurred five years later, the same doctor provided unconventional treatment to a cancer patient who later died.²⁶⁰ In that instance, the circuit court again ruled in favor of an instruction on assumption of risk, highlighting its role as a defense in cases involving unconventional medical treatments.²⁶¹

Moreover, in these cases, the patients sought alternative treatments after the practitioners themselves promoted misleading information. In *Gonzalez*, the patient first became aware of the defendant through attending one of his lectures and listening to his tapes.²⁶² Similarly, in *Schneider*, the patient sought treatment from Dr. Revici after hearing about his therapy on a radio program.²⁶³

Dr. Revici, in particular, was a repeat offender. After *Schneider*, he was found guilty of professional misconduct and given five years' probation.²⁶⁴ The Board of Regents specifically emphasized that he must demonstrate compliance with informed consent procedures.²⁶⁵ Despite this, in *Boyle*, Dr. Revici failed to obtain written informed consent, and the court dismissed the need for it, citing the absence of a statutory requirement for such documentation.²⁶⁶

These old cases help to highlight the gaps in the current statutory frameworks of states like Washington, Alaska, and North Carolina, where obligations on practitioners are inadequately addressed, and the courts are unable to offer a solution.²⁶⁷ In the absence of strict provisions that require written informed consent and clearly lay out the information required to obtain it, there is little to prevent the assumption of risk defense from being raised. By incorporating provisions from the California Health Freedom statute and the Florida Health Freedom statute, these statutes must compel practitioners to disclose relevant vital information.²⁶⁸ By requiring full disclosure of evidence-based information on risks and benefits, they can ensure that informed consent serves its intended purpose. These gaps in state

²⁵⁹ *Id.* at 996 & n.1. The consent form partly stated, "I fully understand that some of the treatment procedures and medications are still investigatory awaiting further research and submission for F.D.A. approval." *Id.* at n.1. Such language, *id.* at n.1, again shifts the onus onto the gullible patient and absolves the practitioner.

²⁶⁰ *Boyle v. Revici*, 961 F.2d 1060 (2d Cir. 1992).

²⁶¹ *Id.*

²⁶² *Charell v. Gonzalez*, 660 N.Y.S.2d 665, 666 (Sup. Ct. N.Y. Co. 1997).

²⁶³ *Schneider v. Revici*, 817 F.2d 987, 989 (2d Cir. 1987).

²⁶⁴ *Unproven Methods of Cancer Management: Revici Method*, 39 *CANCER J. FOR CLINICIANS* 119, 121 (Mar./Apr. 1989), <https://doi.org/10.3322/canjclin.39.2.119> [perma.cc/GNB5-5UE4].

²⁶⁵ *Id.*

²⁶⁶ *Boyle v. Revici*, 961 F.2d 1063 (2d Cir. 1992).

²⁶⁷ See discussion *supra* Part I.B.3.

²⁶⁸ *Id.*

statutes are further compounded by federal regulatory and legislative shortcomings.

C. Failures at the Federal Level

As part of the central system of regulation, federal bodies could protect the public from untested alternative medicines. However, the intense lobbying of the CAM industry and legislative inertia have created a dangerous situation instead—untested medicines are easily available on pharmacy shelves, and the public remains unaware of their risks. Meanwhile, insurance reforms quietly enable even fringe practitioners to operate with increasing freedom.

1. Gaps in FDA Regulation of OTC Drugs and Dietary Supplements

A major failure at the federal level is that the agency responsible for regulating drugs has long been unable to regulate dietary supplements and OTC drugs like homeopathic medicines.²⁶⁹ The current mechanism is insufficient to ensure safety because manufacturers can introduce products into the market based solely on their belief that the product is safe.²⁷⁰ The FDA does not evaluate them beforehand,²⁷¹ but only acts retroactively, identifying and removing harmful products after they have been on the market.²⁷² Essentially, the FDA's intervention occurs only after harm has been caused.

Adding to its inherently reactive role, the FDA often struggles to respond swiftly to new information, even when concerns about safety and efficacy arise.²⁷³ In many instances, the agency lacks an effective mechanism to gather the evidence necessary to take decisive action.²⁷⁴ When the FDA's role is not only reactive but also hindered by slow and inadequate response times, a critical question arises: How many disasters must occur before these regulations—or the lack thereof—are reformed?

For example, it took the death of Joey Hofbauer and others for the FDA to investigate and ban laetrile, a substance marketed as an alternative cancer

²⁶⁹ Elizabeth Richardson, Farzana Akkas & Amy Cadwallader, *What Should Dietary Supplement Oversight Look Like in the US?*, 24 *AMA J. ETHICS* 402, 402–03 (May 2022), <https://journalofethics.ama-assn.org/article/what-should-dietary-supplement-oversight-look-us/2022-05> [https://perma.cc/F666-Z64T].

²⁷⁰ *Regulation of Over-the-Counter Drug Products Should Be Streamlined*, *supra* note 132.

²⁷¹ *Id.*

²⁷² Berg, *supra* note 145.

²⁷³ *Regulation of Over-the-Counter Drug Products Should Be Streamlined*, *supra* note 132.

²⁷⁴ *Id.*

treatment.²⁷⁵ Yet, the other substance that contributed to Hofbauer's death is readily and abundantly available.²⁷⁶ Vitamin A continues to be used in excessive doses without any purchase limits despite its known potential to cause liver damage²⁷⁷—the same harm that contributed to Hofbauer's death. Certain vitamins are also linked to increased cancer risk and even cause death if taken excessively.²⁷⁸

Despite such risks, supplements remain unregulated due to a 1996 Act, which was brought about by intense lobbying from the supplement industry.²⁷⁹ The Act removed supplements from the control of the FDA,²⁸⁰ as a result of which, the current state of regulation is lacking. Manufacturers need not submit any evidence to support the claims they make about their products.²⁸¹ In fact, the FDA may not even be aware of basic information about the products, such as ingredients.²⁸² Similar to OTC drugs, there is no premarket review; only post-market surveillance exists.²⁸³ Moreover, quality issues in supplement manufacturing facilities are widespread.²⁸⁴ To top it all off, even if the FDA finds a product unsafe, it has no easy path to ban or recall it.²⁸⁵

This regulatory failure is further aggravated by false advertising. Under current regulations, supplement companies cannot advertise their supplements as cures or preventive treatments.²⁸⁶ But they circumvent this restriction by using vague language, like “immune booster” or “maintain a healthy immune system,” to indirectly convey benefits that have no evidence-based backing.²⁸⁷ Such claims are entirely legal and can signal to

²⁷⁵ Victor Herbert, *Nutrition Cultism*, 135 W. J. MED. 252, 254–55 (Sep. 1981), <https://pubmed.ncbi.nlm.nih.gov/6280398/> [<https://perma.cc/9G8L-BEHC>]; Barron H. Lerner, Essay, *McQueen's Legacy of Laetrile*, N.Y. TIMES (Nov. 15, 2005), <https://www.nytimes.com/2005/11/15/health/mcqueens-legacy-of-laetrile.html> [<https://perma.cc/H4PW-U3UH>].

²⁷⁶ See *Vitamin A Toxicity: How Much Vitamin A Is Too Much?*, CLEVELAND CLINIC (Apr. 21, 2023), <https://health.clevelandclinic.org/vitamin-a-toxicity> [perma.cc/25NP-YZK6].

²⁷⁷ *Id.*

²⁷⁸ *Taking Vitamins to Prevent Cancer? Think Again*, NBC NEWS (June 22, 2006, at 16:37 ET) (citing ASSOCIATED PRESS), <https://www.nbcnews.com/id/wbna13486447> [perma.cc/KXS7-88MG]; Lindsey Leake, *The Dark Side of Daily Vitamin D Supplements: After a Man Died from an 'Overdose' in the U.K., Experts Explain How Much Is Healthy*, FORTUNE WELL (Mar. 16, 2024, at 05:00 ET), <https://fortune.com/well/article/vitamin-d-toxicity/> [perma.cc/DAN3-BRSN].

²⁷⁹ Goldstein, *supra* note 1, at 58.

²⁸⁰ *Id.*

²⁸¹ Richardson, Akkas & Cadwallader, *supra* note 269, at 403–05.

²⁸² *Id.*

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *Id.* (discussing how although the FDA can recall supplements tainted with other potentially harmful ingredients, it cannot as easily recall those tainted with active pharmaceutical ingredients); see *United States v. Undetermined Quantities of All Articles of Finished & In-Process Foods*, 936 F.3d 1341, 1341–51 (11th Cir. 2019).

²⁸⁶ Berg, *supra* note 145.

²⁸⁷ *Id.*

consumers that the supplement can protect them from diseases like COVID-19, even if it is not the case.²⁸⁸ In the alternative drug world, homeopathic products often make claims that cannot be substantiated, and yet they are free to make those claims.²⁸⁹

Consider the case of CVS’s eyedrops. A plaintiff claimed that the product’s labeling misled consumers into believing it was a drug under the FDCA.²⁹⁰ The FDA had issued a warning letter recognizing the eyedrops as an “unapproved new drug” and raised safety concerns about their preservative, silver sulfate.²⁹¹ The letter also stated that products labeled as drugs, including homeopathic medicines, must comply with specific regulations so they are not misbranded or sold without proper approval.²⁹² And while the plaintiff here claimed paying a higher price for this product as an injury, this case also helps highlight additional weakness in the FDCA: “it is the federal government rather than private litigants who are authorized to file suit for noncompliance.”²⁹³

Since enforcement authority rests with the federal government, any meaningful strengthening of these regulations must also occur at the federal level. Developing a system that requires alternative medicine manufacturers to test their products for safety and efficacy is not insurmountable. It has been done once before.²⁹⁴ The pharmaceutical industry has already demonstrated that such a system can be implemented swiftly and comprehensively when supported by clear laws.²⁹⁵ Granted, there are arguments that alternative medicine is not well-suited for scientific testing: its effects are too subtle to be quantified, its effects are subjective, and its holistic nature cannot be evaluated with reductionist science.²⁹⁶ However, when proponents want to prove that CAM works, they accept favorable studies and tout them.²⁹⁷ These studies, of course, are cherry-picked and, at best, of poor quality.²⁹⁸

To address the current regulatory gaps, several solutions have been proposed. One of these is mandatory product listing, which would require supplement manufacturers to submit basic information about their product,

²⁸⁸ *Id.*

²⁸⁹ See *Jordan v. CVS Pharm., Inc.*, No. 23-CV-00979-JLS-HKS, WL 3258317, at *1 (W.D.N.Y. May 8, 2024).

²⁹⁰ *Id.* at *3.

²⁹¹ *Id.* at *1.

²⁹² *Id.*

²⁹³ *Id.* at *3.

²⁹⁴ See IOM, *supra* note 4, at 77–78.

²⁹⁵ *Id.*

²⁹⁶ See Edzard Ernst, *How the Public Is Being Misled About Complementary/Alternative Medicine*, 101 J. ROYALTY SOC’Y MED. 528, 528–29 (2008), <https://pmc.ncbi.nlm.nih.gov/articles/PMC2586853/> [<https://perma.cc/C494-2XPT>].

²⁹⁷ *Id.*; see Alastair MacLennan, *Alternative Therapies: Without Evidence They Do More Harm Than Good*, THE CONVERSATION (May 30, 2011, at 19:05 ET), <https://theconversation.com/alternative-therapies-without-evidence-they-do-more-harm-than-good-1547> [<https://perma.cc/AU7Z-ZM8F>].

²⁹⁸ MacLennan, *supra* note 297.

such as ingredient lists and product labels, to the FDA.²⁹⁹ This measure of transparency would provide the FDA with a more comprehensive view of products on the market. Another solution is the premarket review of labels and claims to ensure that labels meet regulatory standards and to prevent manufacturers from making illegal claims.³⁰⁰ Some experts call for the need to increase manufacturers' awareness of current manufacturing regulations and quality standards.³⁰¹ Another proposal is to clarify the FDA's mandatory recall authority so that the agency can recall even supplements tainted with active pharmaceutical ingredients.³⁰²

Despite these proposed solutions, which could be implemented, such improvements may not be possible in the near future due to the FDA's longstanding resistance to change. A great example is the requirement for cigarette warning labels. The Surgeon General issued a warning about the dangers of smoking in 1957,³⁰³ but the FDA did not mandate strong warning labels on cigarette packs until decades later, thanks to prolonged resistance from the tobacco industry and legislative inertia.³⁰⁴ Similarly, the supplements lobby is very powerful³⁰⁵ and will pose a massive challenge to implementing evidence-based regulatory standards at the FDA.

The FDA's own rulemaking process is another hindrance. Existing in the form of notice and comment procedures under the Administrative Procedure Act,³⁰⁶ it makes transparency from the agency and participation from stakeholders possible.³⁰⁷ However, it also makes changes time-consuming

²⁹⁹ *Id.*; Josh Long, *FDA, Consumer Groups in Favor of Mandatory Listing of Dietary Supplement Products*, SUPPLYSIDE SUPP. J. (Oct. 12, 2020), <https://www.supplysidesj.com/supplement-regulations/fda-consumer-groups-in-favor-of-mandatory-listing-of-dietary-supplement-products> [<https://perma.cc/97H2-2YLW>].

³⁰⁰ Richardson, Akkas & Cadwallader, *supra* note 269, at 405.

³⁰¹ *Id.*

³⁰² *Id.*

³⁰³ See Heikki Hiilamo, Eric Crosbie & Stanton A Glantz, *The Evolution of Health Warning Labels on Cigarette Packs: The Role of Precedents, and Tobacco Industry Strategies to Block Diffusion*, 23 BRIT. MED. J. 1, 2 (2012), <https://tobaccocontrol.bmj.com/content/23/1/e2> [<https://perma.cc/6V83-J8A7>].

³⁰⁴ *Id.* at 3–8 (noting that the U.S. initially implemented a weak warning, stating “Cigarette smoking may be hazardous to health” in 1965, and did not mandate high-level warning labels until 1985 after most other countries had already done so); see *Cigarette Labeling and Health Warning Requirements*, U.S. FOOD & DRUG ADMIN, <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements> [<https://perma.cc/6PC9-KESZ>] (last visited Aug. 27, 2025) (explaining that the implementation of a recent Final Rule on required warnings has been postponed until the resolution of ongoing litigation).

³⁰⁵ Dan Mitchell, *Why the Supplements Industry Is So Powerful*, TIME (Mar. 11, 2015, at 14:58 ET), <https://time.com/3741142/gnc-vitamin-shoppe-supplements/> [<https://perma.cc/NLV3-EGB9>].

³⁰⁶ See *FDA Rules and Regulations*, U.S. FOOD & DRUG ADMIN., (Apr. 9, 2024), <https://www.fda.gov/regulatory-information/fda-rules-and-regulations> [<https://perma.cc/A7XQ-B8P8>].

³⁰⁷ U.S. FOOD & DRUG ADMIN., *FDA LAWS, REGULATIONS, AND GUIDANCE DOCUMENTS 11*, <https://www.fda.gov/media/133830/download> [<https://perma.cc/S5QP-HEUP>] (last visited Aug. 27, 2025).

and vulnerable to legal challenges.³⁰⁸ The FDA is already entangled in numerous lawsuits alleging that its rulemaking is arbitrary and capricious and that the agency failed to follow appropriate procedural steps.³⁰⁹ Moreover, with the overturning of *Chevron* deference, the FDA would no longer receive judicial deference in rulemaking, making it less than ideal for the FDA to assume responsibility for rulemaking.³¹⁰

Congress has the authority to enact legislation that mandates evidence-based regulation of alternative medicine. As seen in the case of the FDCA and the Kefauver-Harris Amendment, congressional action that expressly delegates regulatory authority to the FDA provides a legally viable pathway for reform.³¹¹ Although the current Congress is unlikely to enact transformative legislation to regulate alternative medicine,³¹² some members of Congress support these reforms,³¹³ and legislative reform may be possible in the coming years.

2. Promoting Transparency and Proposing Regulatory Authority of the NCCIH

With the FDA's regulatory role facing uncertainty, another avenue worth considering is the NCCIH. The federal government has invested millions of dollars in research conducted by the Center, yet it has little to show in terms of promising results.³¹⁴ Despite a series of five-year strategic plans and millions of dollars spent on research, the Center's efforts mostly failed to generate positive, scientifically valid outcomes.³¹⁵ A 2002 study found that St. John's wort, an ancient herbal medicine, was not any more effective than a placebo for major depression.³¹⁶ The Glucosamine/Chondroitin Arthritis Intervention Trial in 2006 showed that glucosamine and chondroitin supplements did not provide significant relief from knee osteoarthritis

³⁰⁸ See Scott S. Liebman et al., *LDT Final Rule Series: Part 3 – Legal Challenges*, NAT'L L REV. (Dec. 16, 2024), <https://natlawreview.com/article/ldt-final-rule-series-part-3-legal-challenges> [<https://perma.cc/UG32-RB5U>].

³⁰⁹ See *id.*

³¹⁰ Tierney Sneed et al., *How the Supreme Court's Blockbuster 'Chevron' Ruling Puts Countless Regulations in Jeopardy*, CNN POLITICS (June 30, 2024, at 13:29 ET), <https://www.cnn.com/2024/06/30/politics/chevron-ruling-explained-supreme-court-meaning/index.html> [<https://perma.cc/P2RZ-XSH8>].

³¹¹ See discussion *supra* Part I.C.1.

³¹² See Nathan-Kazis, *supra* note 213.

³¹³ Richardson, Akkas & Cadwallader, *supra* note 269, at 405.

³¹⁴ Goldstein, *supra* note 1, at 58 (“[OAM’s] budget increased more than 600 percent at a time when the funding for its parent, the National Institutes of Health, remained flat.”); see discussion *supra* Part I.C.2. (explaining the OAM, which is the first version of the NCCIH).

³¹⁵ See *About NCCIH*, *supra* note 146.

³¹⁶ *Id.*

pain.³¹⁷ Several studies funded in 2010 showed that using echinacea for the common cold did not produce positive results.³¹⁸ The Center's most notable "success" was a study suggesting acupuncture could help knee arthritis, but this was later disputed by a larger, more rigorous study.³¹⁹ By 2009, the Center had spent a staggering \$2.5 billion, without much to show for it.³²⁰

The Center's research role is paramount now more than ever, as people seek "natural" cures in unprecedented numbers, under the assumption that they are inherently safe.³²¹ However, the truth is that "natural" does not mean "safe."³²² Who bears the responsibility of informing the public about this misconception? Many natural remedies, despite their popularity, have been found to cause liver damage and other adverse effects.³²³ Moreover, individuals who choose unproven alternative or natural treatments often forgo conventional medical care, leading to a decline in health and, in some cases, fatal consequences.³²⁴ Who is better positioned to correct this misinformation and misplaced reliance than the agency tasked with researching and disseminating information about such alternatives?

However, despite its renewed commitment as NCCIH, the Center has fallen short in communicating its research failures and the limitations of alternative medicines to the public.³²⁵ The public predominantly remains unaware that certain alternative treatments are ineffective and that some may even be harmful.³²⁶ More troubling, there have been allegations of questionable grant allocation practices, with funds being funneled into improbable studies without careful consideration³²⁷ and to board members, raising concerns about conflicts of interest.³²⁸ Despite the Center's commendable mission statement and vision, they have not truly translated into meaningful progress.

Given its congressional mandate to inform the public about ineffective alternative medicines, the NCCIH has yet to fully meet this obligation

³¹⁷ *Id.* (discussing how these substances are naturally present in joint cartilage and have been marketed as dietary supplements for degenerative joint disease (osteoarthritis)).

³¹⁸ *Id.*

³¹⁹ *\$2.5 Billion Spent, No Alternative Cures Found*, NBC NEWS (June 10, 2009, at 12:15 ET) (citing ASSOCIATED PRESS), <https://www.nbcnews.com/id/wbna31190909> [<https://perma.cc/3UY5-QE37>].

³²⁰ *Id.*

³²¹ *Id.*

³²² Corrie Pelc, *6 Popular Herbal Supplements Linked to Potential Liver Risks*, MED. NEWS TODAY (July 11, 2025), <https://www.medicalnewstoday.com/articles/6-popular-herbal-supplements-green-tea-curcumin-linked-potential-liver-risks> [<https://perma.cc/CJ87-S22K>].

³²³ *Id.*

³²⁴ Moriarty, *supra* note 19; *see* Stannard, *supra* note 24.

³²⁵ *\$2.5 Billion Spent, No Alternative Cures Found*, *supra* note 319.

³²⁶ *Id.*

³²⁷ *Id.* ("The acupressure weight-loss technique won a \$2 million grant even though a small trial of it on 60 people found no statistically significant benefit.").

³²⁸ *Id.*

beyond issuing occasional press releases.³²⁹ To address this shortcoming, the NCCIH could undergo two potential reforms.

The first, and arguably the more straightforward approach, is to optimize the process of reporting research results. As it stands, the NCCIH already possesses the authority to make improvements through its congressional mandate.³³⁰ The second, and significantly more transformative change the NCCIH could pursue, is assuming a formal regulatory role that enforces evidence-based practices in research involving CAM and informed consent requirements in the practice of CAM. While granting the NCCIH regulatory authority has been proposed in the past,³³¹ its potential impact becomes even more significant when done with the goal of promoting an evidence-based approach to CAM. An adaptable model for this transition can be found in the successful evolution of the Office for Human Research Protections (OHRP).

The OHRP is the organization that protects the rights, welfare, and well-being of subjects involved in research conducted or supported by the HHS.³³² The OHRP was once known as the Office for Protection from Research Risks (OPRR) and, like the NCCIH today, operated within the NIH.³³³ However, following significant concerns about research oversight, the OPRR was restructured in 2000 and moved under the HHS, a shift that expanded its role to include not only guidance and clarification but also regulatory enforcement.³³⁴

This major change was brought about by a top-level advisory group's recommendation to relocate the OPRR to the HHS and provide it with more resources and broader responsibility.³³⁵ This move came after the tragic death of Jesse Gelsinger in 1999.³³⁶ Gelsinger was a volunteer in a clinical gene therapy trial who later died due to complications that arose after he received the experimental treatment.³³⁷ Authorities later learned that these complications were a result of alarming lapses in the informed consent

³²⁹ *About NCCIH*, *supra* note 146.

³³⁰ *NCCIH Timeline*, *supra* note 151; *see* National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 209, 107 Stat. 122 (1993).

³³¹ *See* Van Hemel, *supra* note 76, at 340 (proposing that Congress delegate a regulatory role to the NCCAM via the HHS, modeling it after the Cigarette Labeling Act).

³³² *About OHRP*, U.S. DEP'T HEALTH & HUM. SERVS. (Mar. 19, 2025), <https://www.hhs.gov/ohrp/about-ohrp/index.html> [<https://perma.cc/7G6P-Q775>].

³³³ *OHRP History*, U.S. DEP'T HEALTH & HUM. SERVS (Aug. 1, 2024), <https://www.hhs.gov/ohrp/about-ohrp/history/index.html> [<https://perma.cc/SXV7-7AJM>].

³³⁴ *Id.*; Sue Coons, *OHRP Looks Back at Its First 20 Years*, RELIAS MEDIA (Jan. 1, 2021), <https://www.reliasmedia.com/articles/147389-ohrp-looks-back-at-its-first-20-years> [perma.cc/Y3DP-8PKZ].

³³⁵ Jeffrey L. Fox, *Human Research Protections Office Created*, 18 NATURE BIOTECH. 709, 709 (2000), https://www.nature.com/articles/nbt0700_709b [<https://perma.cc/R6JB-YW38>].

³³⁶ Coons, *supra* note 334; Meir Rinde, *The Death of Jesse Gelsinger, 20 Years Later*, SCI. HIST. INST. (June 4, 2019), <https://www.sciencehistory.org/stories/magazine/the-death-of-jesse-gelsinger-20-years-later/> [<https://perma.cc/9UST-UWUJ>].

³³⁷ Coons, *supra* note 334; Rinde, *supra* note 336.

process and the conduct of the study itself.³³⁸ The death of this apparently healthy volunteer called for stronger protections for research participants and more ethical research practices.³³⁹ As a result, the informed consent process in federally funded, regulated research is extensive today.³⁴⁰

Adopting a similar organizational change in the NCCIH would be a significant step that ensures patient well-being and practitioner accountability. This is because equipping the NCCIH with regulatory authority, similar to the OHRP, would directly protect the public from untested or unproven alternative treatments. However, while this organizational shift and regulatory emboldening could ossify the NCCIH's role in promoting evidence-based research, this implementation is unlikely under the current federal administration.³⁴¹ Granting the NCCIH regulatory authority would require a fundamental shift in how alternative medicine is governed, including removing it from the NIH and placing it under the direct authority of HHS.³⁴² In the absence of this reform, the NCCIH should improve its research reporting methods.

3. The ACA's Non-Discrimination Provision as a Deterrent: An Unlikely Solution

The possibility of adopting an evidence-based approach to alternative medicine also exists in the non-discrimination provision of the ACA.³⁴³ This provision, which was originally enacted to expand insurance coverage for CAM by preventing insurance companies from discriminating against healthcare providers who practice alternative medicine, is appropriate for this purpose.³⁴⁴ Namely, it could be amended to include informed consent requirements, such as providing information about the risks and benefits of the alternative treatment, and the practitioner's educational background.³⁴⁵ The advantage here for CAM practitioners is that this change would not impact the availability of CAM therapies but merely require transparency, allowing patients to make informed decisions. After all, if these treatments are safe and effective, why resist transparency?

³³⁸ Coons, *supra* note 334; Rinde, *supra* note 336.

³³⁹ Rinde, *supra* note 336.

³⁴⁰ See *Informed Consent FAQs*, OFF. FOR HUM. RSCH. PROTS., <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html> [<https://perma.cc/GAU7-F2N9>] (last visited Sep. 13, 2025).

³⁴¹ See Nathan-Kazis, *supra* note 213.

³⁴² See Coons, *supra* note 334 (describing how the OHRP went through a similar evolution).

³⁴³ 42 U.S.C.S. § 300gg-5 (LexisNexis).

³⁴⁴ See *supra* discussion Part I.D.

³⁴⁵ CAL. BUS. & PROF. CODE § 2234.1 (West 2025); FLA. STAT. ANN. § 456.41(3) (West 2025) (using language from the statutes).

The informed consent requirement could be tied to federal funding under the ACA. Hospitals and doctors rely on federal funding for reimbursement of their services.³⁴⁶ Such reimbursements constitute a significant portion of physicians' income, and losing them could be financially devastating in many cases.³⁴⁷ Congress could mandate that noncompliance, such as failure to procure proper informed consent, could result in the reduction or withdrawal of funding, creating a powerful incentive for healthcare providers to comply.

However, despite the practicality of this solution, effective reform through the ACA is unlikely, given its origins. Few laws in recent history have been as volatile and politically contentious as the ACA.³⁴⁸ Since its enactment, it has been the subject of ongoing debate and has faced constant legal challenges.³⁴⁹ This uncertainty makes the ACA an unreliable base for implementing new regulatory reforms related to CAM. In this context, while amending the ACA's non-discrimination provision presents a logical and effective strategy for improving patient safety, it remains an improbable solution for immediate reform.

Despite numerous deficiencies within federal legislative and regulatory bodies, and the availability of both theoretical and practical solutions, a significant federal overhaul is unlikely in the near future. However, state-level reforms and changes within the NCCIH are feasible and could pave the way for evidence-based regulation of alternative medicine.

III. RESOLUTION: A BIMODAL STRATEGY FOR REGULATING ALTERNATIVE MEDICINE THROUGH STATE AND FEDERAL REFORMS

In the absence of proper regulation, the increasing popularity of CAM continues to attract gullible patients.³⁵⁰ Public interest in non-traditional treatments and growing anti-establishment sentiments have fueled support for reforms that expand access to CAM.³⁵¹ While this allows people to use harmless treatments, it also creates a pathway for unproven or harmful practices to enter mainstream care.³⁵² When the public is misinformed or misled into seeking untested alternative treatments, oversight bodies have a

³⁴⁶ See Nathen Eddy, *Hospitals Confront Mounting Reimbursement Challenges and Diminishing Cash Reserves*, HEALTHCARE FIN. (Nov. 30, 2023, at 10:17 ET), <https://www.healthcarefinancenews.com/news/hospitals-confront-mounting-reimbursement-challenges-and-diminishing-cash-reserves> [<https://perma.cc/SD96-LZZV>].

³⁴⁷ See *id.*

³⁴⁸ See generally Jonathan Oberlander, *The Ten Years' War: Politics, Partisanship, and the ACA*, 39 HEALTH AFF. 471, 471–78 (2020) (describing how the ACA has continuously dealt with controversy).

³⁴⁹ See *id.*

³⁵⁰ See *supra* notes 1–5 and accompanying text.

³⁵¹ See discussion *supra* Part I.D.

³⁵² See discussion *supra* Part II.B. This Note does not advocate for banning adjuvant therapies like music or movement therapy if they are what the patient wishes. Subjective relief is difficult to quantify, and taking a paternalistic approach is neither practical nor desirable.

duty to intervene, as harm can result from the intake of unproven or untested medicines.³⁵³

With many spokes in the cogwheel of the healthcare system, addressing the deficiencies of only one would be insufficient. However, where federal agency overhaul faces obstacles, state-level reform offers a more viable path by targeting the critical point of interaction between patients and physicians. Accordingly, developing a comprehensive model state statute offers a practical solution. Such a statute would empower states to adopt clear, evidence-based regulations to combat misinformation and the use of untested medicine. This nonfederal approach allows proactive states to take preventive action without being constrained by central inertia.

Additionally, this Note proposes reporting reforms within the NCCIH to fulfill its congressional mandate and ensure patients are adequately informed before seeking alternative treatments. Even minimal reform in this area could significantly improve patient awareness and protection.

A. Model State Statute Overhauling the Medical Licensing System

In states like Washington, Alaska, and North Carolina, existing statutes fail to effectively prevent harm from alternative medical practices, as legal recourse is only available after a patient has been injured.³⁵⁴ While these laws may provide some benefit to patients using complementary treatments along with conventional care, they offer little protection against potentially harmful treatments.³⁵⁵ The risk is more pronounced when patients abandon conventional treatments in favor of ineffective or dangerous alternative methods.³⁵⁶

To address these gaps, a model state statute should be developed, integrating key provisions from California's Health Freedom Act, Florida's Health Freedom Act, and the FSMB recommendations on misinformation.³⁵⁷ These provisions must clearly define acceptable practices and explicitly prohibit misinformation. They should also include instructions on obtaining proper informed consent before administering alternative treatments, such as explaining "the benefits and risks associated with the (alternate) treatment"³⁵⁸ and about available conventional treatment.³⁵⁹

³⁵³ *Id.*

³⁵⁴ See *supra* text accompanying notes 107–10.

³⁵⁵ *Id.* Note: Complementary which is harmless like music or movement therapy; not complementary substances that are ingested that may interfere with conventional treatment.

³⁵⁶ See discussion *supra* Part II.B. and text accompanying notes 8–11.

³⁵⁷ See FLA. STAT. ANN. § 456.41(3) (West 2025); CAL. BUS. & PROF. CODE § 2234.1 (West 2025); FSMB REPORT, *supra* note 192, at 1–11.

³⁵⁸ FLA. STAT. ANN. § 456.41(3) (West 2025).

³⁵⁹ CAL. BUS. & PROF. CODE § 2234.1(a)(1)-(2) (West 2025).

Physicians who violate the statute by promoting or using unproven and dangerous treatments should face disciplinary measures, starting with the suspension or revocation of their medical license. When a physician's license is suspended, continuing to make misleading statements while using the titles "M.D." or "D.O." should be considered by states as unauthorized practice of medicine without a license. This provision is crucial because licensed physicians, such as Joseph Mercola and Mehmet Oz, utilize their medical credentials to gain public trust and mislead individuals into believing that their claims are medically valid.³⁶⁰ The public often associates "M.D." and "D.O." credentials with professional competence, and these physicians exploit that perception to their advantage.³⁶¹ If a physician persists in recommending or administering unsafe treatments after losing their license, they should not be allowed to use their credentials. Additionally, they should face appropriate civil penalties or criminal sanctions for practicing medicine without authorization, as monetary penalties and incarceration serve as strong deterrents.³⁶²

Additionally, the statute should empower patients to file malpractice lawsuits in their individual capacity if they suffer harm due to the practice of alternative medicine. The statute would do so by limiting the applicability of the assumption of risk defense in these cases and strengthening the informed consent process. This would, in turn, add another layer of accountability for physicians engaging in harmful practices. Both by legitimizing the authority of state medical boards in this respect and enabling private lawsuits, this approach attempts to remedy the issue.

Model Physician Discipline and Patient Protection Act

1. Definitions

(a) "Evidence-based" method is a systematic approach to medicine in which doctors and other health care professionals use the best available scientific evidence from clinical research.³⁶³

(b) "Medical misinformation" means any medical advice, treatment recommendation, or information

³⁶⁰ See discussion *supra* Part II.A.

³⁶¹ *Id.*

³⁶² Alexes Harris & Frank Edwards, *Fines and Monetary Sanctions*, OXFORD RSCH. ENCYC. CRIMINOLOGY & CRIM. JUST. (Apr. 26, 2017) [<https://doi.org/10.1093/acrefore/9780190264079.013.228>].

³⁶³ *Evidence-Based Medicine*, NAT'L CANCER INST., [<https://perma.cc/YT7X-UPEN>] (last visited Aug. 27, 2025).

provided by a physician that is not supported by the best available scientific evidence or prevailing scientific consensus.³⁶⁴

(c) "Off-label prescribing" refers to the prescription of medications for uses not approved by the U.S. Food and Drug Administration.³⁶⁵

2. Informed Consent Requirements

Physicians shall inform patients about the benefits and risks of the alternative treatment to be used, to the extent necessary to make an informed decision about such treatment.³⁶⁶ The physician shall also explain conventional treatment options to the patient and share information about their education, experience, and credentials.³⁶⁷ This disclosure must be recorded in a written consent form signed by the patient and saved as part of the patient's medical record. The assumption of risk defense may not be available to physicians who fail to comply with the requirement of procuring written informed consent.

3. Evidence-based Medical Practice

Physicians shall base all treatment recommendations on the best available scientific evidence or the prevailing scientific consensus.³⁶⁸ They shall base any off-label prescribing on information that is independently verified or peer-reviewed.³⁶⁹ Additionally, the use of alternative medicine shall not delay or discourage diagnosis of the patient's condition through conventional evidence-based methods.³⁷⁰

³⁶⁴ See FSMB REPORT, *supra* note 192, at 3.

³⁶⁵ See, e.g., Knight, *supra* note 206. Recommending ivermectin, which is approved for parasitic infections, for COVID-19, for which it is not approved, constitutes off-label prescribing. *Id.*

³⁶⁶ FLA. STAT. ANN. § 456.41(3) (West 2025) (using the statutory language to draft the model statute provision).

³⁶⁷ CAL. BUS. & PROF. CODE § 2234.1(a)(1)–(2) (West 2025) (using the statutory language to draft the model statute provision).

³⁶⁸ FSMB REPORT, *supra* note 192, at 10 (using recommendation 6 to draft the model statute provision).

³⁶⁹ FSMB REPORT, *supra* note 192, at 11 (using recommendation 10 to draft the model statute provision).

³⁷⁰ CAL. BUS. & PROF. CODE § 2234.1(a)(3) (West 2025) (using statutory language to draft the model statute provision).

4. Prohibited Conduct

Physicians shall refrain from disseminating misinformation about public health, medical diagnoses, or treatments. They shall not engage in unethical conduct that could harm the public, as well as unprofessional conduct that may bring the medical profession into disrepute.³⁷¹ They shall not propose alternative treatments that pose significant, foreseeable, or unjustified risks to patients,³⁷² nor base their recommendations on outdated, disproven, or false information.³⁷³

5. Professional Competence

Physicians shall stay current with evolving scientific evidence and practice standards to ensure they make current and accurate treatment recommendations.³⁷⁴ Additionally, physicians are encouraged to pursue continuing medical education in fields such as statistics, epidemiology, and public health.³⁷⁵

6. Disciplinary Measures

If the physician violates the Physician Discipline and Patient Protection Act by promoting or practicing unproven or harmful treatments, the state medical board shall classify this as "Unprofessional Conduct" under the relevant state statute.

(a) First Violation: Physicians found engaging in such conduct will face disciplinary action. For the first violation in an isolated case, state medical boards may impose remedial actions,

³⁷¹ FSMB REPORT, *supra* note 192, at 9 (using the grounds for disciplinary action section to draft the model statute provision).

³⁷² FSMB REPORT, *supra* note 192, at 11 (using recommendation 8 to draft the model statute provision).

³⁷³ FSMB REPORT, *supra* note 192, at 11 (using recommendation 12 to draft the model statute provision).

³⁷⁴ FSMB REPORT, *supra* note 192, at 11 (using recommendation 12 to draft the model statute provision).

³⁷⁵ FSMB REPORT, *supra* note 192, at 11 (using recommendation 15 to draft the model statute provision).

including educational programs on professional ethics and the mandate to disseminate accurate medical information. In cases where public safety is at risk, boards may impose more formal disciplinary actions such as license suspension or revocation.

(b) Subsequent Violations: Physicians who continue to engage in these practices after license suspension, such as using their medical credentials (M.D. or D.O.) while making false statements that a reasonable individual might interpret as medical recommendations, will face one or more of the following consequences for the unauthorized practice of medicine:

- (i) Civil penalties.³⁷⁶
- (ii) Criminal charges.³⁷⁷

7. State Medical Board Responsibilities and Rights

State medical boards must exert their statutory authority to protect public health by regulating the professional conduct of licensees.³⁷⁸ Accordingly, state medical boards shall adopt a clear policy clarifying expectations for licensees regarding the dissemination of misinformation and disinformation.³⁷⁹ In adjudicating cases involving misinformation or disinformation, state medical boards are encouraged to consider all authorized grounds for disciplinary action in their respective Medical Practice Acts.³⁸⁰ The boards shall not be discouraged from executing their duties to protect public health by concerns about potential legal challenges to their disciplinary decisions.³⁸¹

³⁷⁶ Sample penalties could include fines of up to \$10,000 per violation.

³⁷⁷ A sample charge could be a third-degree felony, which carries a sentence of two to ten years in prison.

³⁷⁸ FSMB REPORT, *supra* note 192, at 10 (using recommendation 2 to draft the model statute provision).

³⁷⁹ FSMB REPORT, *supra* note 192, at 10 (using recommendation 1 to draft the model statute provision).

³⁸⁰ FSMB REPORT, *supra* note 192, at 10 (using recommendation 3 to draft the model statute provision).

³⁸¹ FSMB REPORT, *supra* note 192, at 10 (using recommendation 5 to draft the model statute provision).

The adoption of the Model statute would enable evidence-based regulation of alternative medicine and the circulation of misinformation. By imposing stronger informed consent requirements, listing prohibited conduct in this area, and encouraging epidemiological competence, the statute clearly outlines the responsibilities of physicians. This explicit authority would allow state medical boards to discipline physicians who fail to follow these standards.

B. Federal Reform: Strengthening NCCIH Reporting Methods

Federal oversight is essential to the healthcare system and cannot be overlooked. Although the FDA cannot establish regulations without explicit congressional authority, and the concept of the NCCIH assuming a regulatory role would require significant legislative reform, there are still actions that can be taken at the federal level without the need for new legislation. One such action is improving the NCCIH's research reporting methods, which the agency already has the authority to do through its congressional mandate "to facilitate the study and evaluation of complementary and alternative medical practices and to disseminate the resulting information to the public."³⁸²

The term "disseminate" means to spread information.³⁸³ "The word creates the same picture as broadcast by radio."³⁸⁴ However, while the NCCIH holds events and issues newsletters to disseminate information,³⁸⁵ these efforts alone are insufficient. Establishing a system to accurately report alternative medicine research findings and ensuring they are widely accessible at the grassroots level would promote transparency, and allow patients who seek alternative cures to make informed decisions. The NCCIH also appears to be returning to the path of evidence-based research and,³⁸⁶ as such, can be expected to consider such proposed measures.

To maximize the exercise of its authority, the NCCIH should increase the accessibility and visibility of research results, ensuring that patients and the broader public are well-informed. For instance, by displaying notices of research findings in hospital waiting areas and pharmacies, the NCCIH could educate patients about ongoing research and its impact on their healthcare. To illustrate simply, an osteoarthritis patient contemplating the purchase of chondroitin supplements on a pharmacy shelf would likely not go ahead if

³⁸² *NCCIH Timeline*, *supra* note 151; National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 209, 107 Stat. 122, 149 (1993) (emphasis added).

³⁸³ *Disseminate*, BALLENTINE'S LAW DICTIONARY (3rd ed. 1969).

³⁸⁴ *Id.*

³⁸⁵ *See About NCCIH*, *supra* note 146.

³⁸⁶ *See Adapting Evidence-Based Mind and Body Interventions: Why, When, and How*, NCCIH, <https://www.nccih.nih.gov/news/events/adapting-evidence-based-mind-and-body-interventions-why-when-and-how> [<https://perma.cc/ME3D-E2P5>] (last visited Aug. 27, 2025).

they saw an official notice conspicuously stating that studies have shown it to be ineffective for this purpose.³⁸⁷

Additionally, integrating relevant research findings directly into the informed consent process can significantly improve transparency. By including research information about the particular treatment method in the informed consent form, patients are better able to understand the potential risks, benefits, and the broader context of alternative treatments. This method meets patients where they are—truly grassroots in nature. For example, if a breast cancer patient reads in the consent form that the alternative therapy that she is about to undergo has certain risks and has a five times greater chance of fatal consequences, she would likely choose not to undergo that particular alternative treatment.³⁸⁸ Other methods to directly reach patients through their care login portals or websites could also be helpful. By using different methods of communication, the NCCIH can reach the broader public and foster a culture of informed decision-making.

This Note proposes the foregoing minimal federal reform targeting greater public awareness. However, in more favorable times, one would hope that lawmakers will consider more substantial measures, such as FDA regulation of OTC drugs and supplements and the transformation of the NCCIH into a regulatory body.

IV. CONCLUSION

Even as people are watchful about their health, alternative medicines have been slowly but surely permeating the market and making themselves ubiquitous.³⁸⁹ This would not present a problem if they reach the market after adequate testing and approval. But untested medicines are present abundantly within easy reach, causing patients to unknowingly forgo effective conventional treatment in favor of those that are ineffective or even harmful.³⁹⁰

To rectify this precarious situation, we must take measures to educate the public about the risks of untested medicine. Patients should have access to accurate, evidence-based information to make informed decisions about their healthcare. Steps should also be taken to prevent the spread of misinformation by malicious or reckless actors and to strengthen state licensing laws to hold such physicians accountable. “Prevention is better than cure”—applying the old adage in this context means fastidiously

³⁸⁷ See *About NCCIH*, *supra* note 146.

³⁸⁸ See Johnson, *supra* note 19, 121–24; see Stannard, *supra* note 24.

³⁸⁹ See *supra* notes 2–3 and accompanying text.

³⁹⁰ *Id.*; see Johnson, *supra* note 19, 121–24; see Stannard, *supra* note 24.

investigating cures before they reach the patient rather than proving harm after the fact. An evidence-based approach is not just prudent; it is essential.