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Rachel Pauerstein
Southern Methodist University, Dedman School of Law, rpauerstein@smu.edu

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Consumer Protections in the Context of Holistic Healthcare

Rachel Pauerstein*

I. HOLISTIC HEALTHCARE AND THE AMERICAN CONSUMER

In the last several years, wellness trends have rippled through the global economy, fueling a rapidly growing multi-trillion dollar market with a strong presence in the United States. Sometimes, these fads arise as treatments that initially seem legitimate; one of the most popular involves intravenous (IV) doses of vitamins and minerals, which is touted as a multifunctional “cure” for a variety of problems. These IV therapies have been adopted and shared by prominent celebrities, further propelling the treatments to popularity. However, as such holistic medicine and alternative therapies have gained traction with the American public, so too have marketing schemes aimed at individuals susceptible to misinformation about new treatment methods—many of which are scientifically unfounded and simply do not work. In fact, the consumer perception that alternative therapies are safe because they are “natural” contributes directly to potential harm, since treatments can cause adverse interactions with other drugs. In the context of American governance, consumer protection is a significant concern for the federal government, particularly through two agencies: the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). This concern is especially apparent in the context of complementary and alternative medical therapies, where misinformation can cause significant harm to consumers.

* Rachel Pauerstein is a 2021 candidate for a Juris Doctor from SMU-Dedman School of Law. She received a Bachelor of Arts from Trinity University in 2015.


2. See Fiona Tapp, Do Vitamin IVs Actually Work? Here’s Everything You Need to Know., HuffPost (Jan. 11, 2019, 5:45 AM), https://www.huffpost.com/entry/vitamin-iv-treatment-hangover_n_5c36634be4b05cb31c3f11a3.

3. See id.


7. See generally Ventola, supra note 5, at 514.
Within the last two decades, the FDA has heightened its regulation of the “integrative health” field. In 2006, the agency released a draft guidance document—a compilation of non-binding recommendations—to address the regulation of nonconventional health care approaches. This document identifies two categories of nonconventional health care: complementary, which is used in conjunction with conventional medicine, and alternative, which is used in lieu of conventional medicine. These approaches, described as complementary and alternative medicine (CAM), are further categorized as “biologically-based practices; energy therapies; manipulative and body based methods; and mind-body medicine.” These classifications assist the agency in clarifying “when a CAM product is subject to the [Food, Drug, and Cosmetic] Act” amid “increased confusion” about the FDA’s power to regulate in these areas.

The FTC has joined in the efforts to regulate the integrative health field. In February 2019, the agency entered an order barring the operator of iV Bars, a line of intravenous therapy establishments, from making claims about the legitimacy and effectiveness of its treatments for conditions like cancer, congestive heart failure, diabetes, and more. Essentially, “intravenous therapy” in this context describes treatments that directly inject “cocktails” of vitamins, minerals, and amino acids. These establishments sell therapies in the form of vitamin infusions allegedly tailored to treat specific conditions. The concept originated in the mid-twentieth century with the research of Dr. Linus Pauling, who explored the function of “vitamins and other essential micronutrients . . . in enhancing health and preventing dis-

9. See FDA Guidance on CAM Products, supra note 8, at 1.
10. See id. at 2.
11. See id. at 2–3.
12. See id. at 1–2.
16. See id. at *4–5; FTC Action Therapy Marketer, supra note 13.
ease.”17 This research continues today with organizations, like the Linus Pauling Institute, that continue to explore the connections between micronutrient therapies and disease treatment or prevention.18 Despite the relatively long history of using such therapies, this order represents the first time the FTC has pursued such a case.19

There are several areas for concern with protecting consumers who partake in IV therapies.20 Of course, consumers spend heavily on such treatments, paying between $100 and $250 for each “cocktail.”21 More concerning, though, is the fact that some consumers may forego conventional medical treatment like chemotherapy, believing that these alternative treatments are better for their overall health and will have similar results.22 Without regulatory action, consumers may be susceptible to misinformation—especially in the health care field, in which consumers likely lack sufficient expertise to make informed decisions.23 According to a 2012 study by the National Center for Complementary and Integrative Health (NCCIH), over thirty percent of the adult population reported using “complementary health approaches.”24 In fact, the press release announcing the FTC’s regulatory action against iV Bars specifically refers to the heightened popularity of alternative therapies as a driving concern.25 Furthermore, complementary therapies can have negative effects on existing conventional treatments in the form of “unintended drug interactions” and altered “response[s] to acute care.”26 The popularity of complementary and alternative treatment options, combined with potentially dangerous outcomes and lack of scientific or regu-

22. See id.
26. See Ventola, supra note 5, at 516.
latory scrutiny, presents a risk of consumer harm that practically demands agency regulation.27

The FTC and FDA function to protect consumers from misleading products like these treatments, but regulatory agencies should also balance the consumer’s right to choose their course of treatment. Their approach to this problem could influence future cases involving other types of alternative therapies, especially as holistic therapies gain traction with those searching for treatment.28 This note will focus on the foundation of federal agencies’ approaches to regulating alternative health care treatments and the interaction of those approaches with consumer and practitioner rights, specifically in the context of the recent order addressing intravenous therapy.

II. AUTHORITY OF CONSUMER PROTECTION AGENCIES

The FTC derives its authority from the Federal Trade Commission Act (FTCA), which empowers the FTC to, among other functions, identify particular “acts or practices that are unfair or deceptive” and establish rules and regulations to prevent those deceptive acts.29 In the FTC order against the intravenous therapy establishments, the agency targeted all misleading representations of IV therapies as treatments, mitigators, or cures for cancer, heart disease, multiple sclerosis, diabetes, fibromyalgia, neurodegenerative disorders, or “any disease.”30 Importantly, the order outlines a requirement for “competent and reliable scientific evidence,” for which it identifies the following criteria:

- tests, analyses, research, or studies, that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.31

27. See id. at 520.
31. See id. at *7–8.
Furthermore, the order included a prohibition on explicitly or implicitly mis-representing the results of scientific studies to further any claims that these therapies are effective treatments for diseases. This component is particularly important because some scientific studies do discuss the benefits of certain ingredients used in IV “cocktails”; for example, several studies have found that vitamin C may repair damaged cells or even have the potential to combat cancerous tumors. While such studies provide an empirical basis for promoting the benefits of vitamin C, the FTC order reflects a concern that providers of IV therapies may refer to these studies as hard evidence that a treatment can actually treat certain diseases even though they may only indicate a tangential benefit.

Similarly, the FDA derives its authority from the Federal Food, Drug, and Cosmetic Act (FDCA), which empowers the agency to regulate the food, medical, cosmetic, and pharmaceutical industries. The agency’s rulemaking on complementary and alternative medicine, however, is largely confined to the non-binding guidance document released in December 2006. This publication looks to statutory definitions of products used in complementary and alternative medicine to determine FDCA applicability. Interestingly, the FDCA’s definition of “product” does not seem to incorporate intravenous therapies like those used in the iV Bars case. Thus, while the guidance document addresses “new drugs” as those “not generally recognized [by qualified experts] . . . as safe and effective for use under the conditions prescribed, recommended, or suggested,” the existing definitions of drugs and products outlined in the FDA’s guiding statutes may not provide the breadth needed to address new and unique alternative therapies.

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32. See id. at *9.


36. See FDA GUIDANCE ON CAM PRODUCTS, supra note 8, at 1.

37. See id. at 2.


39. See FDA GUIDANCE ON CAM PRODUCTS, supra note 8, at 7–8.
III. CONSTITUTIONAL RIGHTS TO TREATMENT AND PRACTICE

The alternative approaches to health care presents several significant constitutional issues. First, patients’ rights to choose their methods of treatment presents a due process concern that demands a balance between protecting consumers from deceptive misrepresentations and ensuring that consumers retain their right to privacy.40 Second, the practitioners’ rights to conduct their businesses also presents a due process concern, especially considering the variation in licensing requirements between the states.41

A. Due Process and the Patient’s Right to Choose

While consumer protection is an essential government function, the agencies tasked with performing this function should balance regulation with individual liberties; in the healthcare context, patients still have a right to make their own decisions about care and treatment, with some exceptions.42 This concern is especially evident in the line of cases addressing the right to privacy and substantive due process concerns, which establish a test for evaluating whether an individual’s due process rights have been violated.43 First, courts evaluate what interest or right was affected or violated, then determine whether the right is “fundamental” based on the definition of liberty as established in the Fifth Amendment, incorporated from the Fourteenth Amendment as to the state governments.44 If there is a fundamental right, strict scrutiny applies and the government must show a compelling government interest underlying the regulation. Additionally, the government must show that the means used are sufficiently related to the ends with as little restriction as possible.45 If no fundamental right was violated, then the appropriate standard of review is the rational basis test, which evaluates whether there is a legitimate government interest plausibly served by the chosen means.46

The most relevant cases here include those addressing the right to privacy related to personal autonomy; the groundwork for this concept was established in Griswold v. Connecticut, in which the Supreme Court found that

41. See id. at 86–87, 89.
44. See Mathews, 424 U.S. at 335; see also Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).
45. See Skinner, 316 U.S. at 541–42; see also Lee Optical, 348 U.S. at 491.
46. See Lee Optical, 348 U.S. at 491.
the Bill of Rights implies a right to privacy.47 More importantly, in Roe v. Wade, the Court extended this right to medical care, finding that this implicit right included the right to choose to have an abortion.48 Proponents of patient rights could argue that this holding indicates a patient’s right to choose what kind of treatment path to take.49 In Cruzan v. Director, Missouri Department of Health, the Court considered for the first time whether individuals have a right to die.50 The Court ultimately found that the state had a compelling interest in establishing a standard of evidence for allowing guardians to remove life support from individuals in a vegetative state.51 The right to die existed only in the presence of clear and convincing evidence that the vegetative individual would have elected this treatment path—in this case, the removal of life support.52 The state’s interest in the preservation of life prevailed.53 That perspective was reinforced once again in Washington v. Glucksberg, when the Supreme Court held that the state’s interest in the preservation of life manifested in “preventing suicide,” and therefore upheld an state law that prohibited physician assisted suicide.54

According to the test for substantive due process rights violations, an injury must exist.55 In the case of holistic treatments, a potential plaintiff might argue that restricting access to a treatment that could improve quality of life is an injurious regulation.56 The next step in the substantive due process framework requires a determination of whether the injury resulted in the deprivation of a fundamental right.57 The Supreme Court’s due process jurisprudence suggests that the right to unique and unproven types of medical care is not a fundamental right; in Glucksberg, the Court noted that its jurisprudence contains no “sweeping conclusion that any and all important, intimate, and personal decisions” are protected by the Due Process Clause on “personal autonomy” grounds.58 Furthermore, the right described in Cruzan centered on the right to decline unwanted treatment, not on the right to

47. See Griswold, 381 U.S. at 484–85.
49. See id.
51. Id. at 284.
52. Id.
53. Id.
56. See Skinner, 316 U.S. at 541.
57. See id.
choose desired treatments.59 The Court has also approached the extension of due process protections hesitantly.60 Based on the Court’s aversion to creating a fundamental right to desired healthcare, the government’s interest in regulating alternative therapies need only be “rationally related to legitimate government interests.”61

Here, the federal government likely has a legitimate interest in protecting the public from misinformation and regulating questionable healthcare practices.62 Considering the substantive due process line of cases, it is important to identify what state interests are served by regulating complementary and alternative therapies.63 One criticism of state regulation of nonconventional health care is that it “reflect[s] a paternalistic stance” towards the consumer’s ability to understand and choose treatment.64 Additionally, the protection of conventional medicine might be viewed as practitioner-oriented rather than patient-oriented; essentially, it might benefit the conventional medicine industry more than the patients themselves.65 However, in situations like the iV Bars case, the state has a legitimate interest in preventing the spread of misinformation and ensuring that claims about health care are grounded in empirical evidence.66 The state also has a well-established legitimate interest in the preservation of life; if there is a risk that consumers will forego conventional, proven, life-saving treatments for holistic alternatives, then the state clearly may utilize rationally related regulatory means to preserve that interest.67

Another interesting facet of patients’ right to choose is the Right to Try Act (RTA), which allows patients who meet certain criteria to elect to use drugs or treatments that have not yet received FDA approval but have completed a clinical trial and are in the process of obtaining FDA approval.68 Passed in 2018, the RTA indicates an acceptance of alternative or complementary treatments in certain contexts, suggesting that future legislation may follow that trend towards favoring consumer choice.69 Despite that accept-

59. Id. at 725.
60. Id. at 720.
61. Id. at 728.
64. See Cohen, supra note 28, at 86.
65. Id.
66. See generally FTC Action Therapy Marketer, supra note 13.
69. See id.
ance, the RTA still requires a foundation in credible scientific evidence before it allows eligible patients to use an experimental treatment.\textsuperscript{70} In the future, though, this focus on patient autonomy might influence future legislation on other alternative or complementary treatments.\textsuperscript{71} While allowing certain patients to use certain experimental drugs is not precisely analogous to the use of complementary or alternative treatments, it indicates a shift towards openness to unconventional options.\textsuperscript{72} However, the RTA still requires an eligible experimental drug to be undergoing the approval process, so that openness relies on grounding unconventional choices in conventional methods of approval.\textsuperscript{73} Additionally, the very evolution of the NCCIH indicates an acknowledgment of the validity of complementary and alternative treatments in certain situations.\textsuperscript{74} One core objective of the Center’s “strategic framework” is to “improve care for hard-to-manage symptoms,” suggesting that even federal regulatory bodies recognize that integrative therapies can provide new ways to improve healthcare.\textsuperscript{75} Such an acknowledgment indicates increasing awareness of the role individuals should be able to play in their own treatment.\textsuperscript{76}

\textbf{B. Due Process and Practitioners’ Rights to Engage in a Profession}

Another concern with regulation of complementary and alternative medicine is that it might prevent some professionals, like naturopaths, from practicing their profession, since they rely on nonconventional methods.\textsuperscript{77} Just as courts have considered a patient’s right to choose treatment, so too have they considered professionals’ rights to conduct business.\textsuperscript{78} In 1923, the Supreme Court identified an economic liberty protected by the Due Process Clause: the freedom to pursue an occupation.\textsuperscript{79} \textit{Meyer v. Nebraska} addressed a German teacher’s right to teach German, and the Court ultimately held that while the state had a legitimate end, its means were too broad and interfered

\textsuperscript{70.} See id.
\textsuperscript{71.} See id.
\textsuperscript{72.} See id.
\textsuperscript{73.} See id.
\textsuperscript{75.} See id.
\textsuperscript{76.} See Complementary Health Approach, supra note 23.
\textsuperscript{77.} See Cohen, supra note 28, at 86.
\textsuperscript{79.} See Meyer, 262 U.S. at 400, 403.
with the teacher’s livelihood.80 Later, in *Williamson v. Lee Optical*, the Court considered an Oklahoma statute that prevented those other than licensed optometrists and ophthalmologists from fitting customers with glasses or putting lenses into a frame without obtaining a prescription from one such licensed individual.81 The statute was challenged by opticians who could no longer perform some essential functions.82 Ultimately, the Court found that the legislature’s enactment of the law was a rational exercise of its power to preserve the health and safety of its citizens.83 Thus, while individuals have a protected interest in the economic liberty to practice their profession, the government may regulate professions in the interest of public health and safety.84

Since licensing requirements vary by state, the above analysis also depends significantly on whether an individual’s profession is actually recognized and licensed by the state.85 For instance, the Texas Occupational Code does not provide for the licensing of naturopaths; under Texas law, such a person would be practicing medicine without a license.86 However, in a state like California, which recognizes naturopathy as a licensed profession, the extensive regulation of complementary and alternative medicine might deprive licensed naturopaths of their profession.87 Under *Meyer*, such individuals could have a substantive due process cause of action against the government for the deprivation of economic liberty.88 Conversely, in states that do not license such practitioners, agencies—both state and federal—might have even stronger grounds on which to regulate complementary and alternative medicine, since licensing would essentially indicate the state’s recognition of holistic practitioners as professionals with the associated rights.89 By declining to create that option, states that do not license holistic practitioners would clearly have a legitimate interest in preserving public health and safety by regulating the unlicensed practice of medicine.90

80. *Id.*
82. See *id.*
83. *Id.* at 491.
84. See *id.; Meyer*, 262 U.S. at 400, 403.
86. See generally *TEX. OCC. CODE ANN.* § 164.052 (West 2019).
87. See generally *CAL. BUS. & PROF. CODE* §§ 3630–37 (Deering 2019).
88. See *Meyer*, 262 U.S. at 400, 403.
89. See *id.*
IV. FUTURE INTERSECTIONS BETWEEN CONSTITUTIONAL RIGHTS AND HOLISTIC TREATMENTS

As complementary and alternative therapies gain in popularity among consumers, actions like the FTC’s targeting of iV Bars will likely become increasingly important. Restrictions on a treatment like intravenous therapy is a relatively minor and uncontroversial situation, especially considering the blatantly deceptive claims in this case. Additionally, the existence of some scientific studies that indicate a slight evidentiary basis for using these therapies provides greater legitimacy, as long as practitioners do not represent them as cures or proven treatments. However, other approaches to alternative therapy might completely lack any evidentiary basis and are sources of significant controversy—consider, for instance, the anti-vaccination movement and its rejection of conventional medicine in favor of holistic treatments. The way regulatory agencies approach relatively minor cases may eventually govern their approach to larger and more controversial cases involving patient and practitioner rights in the future. In doing so, these agencies must maintain a balance between the state’s interest, patients’ substantive due process right to privacy, and professionals’ substantive due process right to their practice. As indicated in the Supreme Court’s substantive due process jurisprudence, government regulations in this area likely only need to have a rational relation to their purpose. While it is important to preserve these rights, a proactive approach by consumer protection agencies will serve the state’s interests in preserving public health, safety, and life itself, and will likely remain within the boundaries of the Constitution so long as the means are rationally related to the ends.

91. See FTC Action Therapy Marketer, supra note 13.
92. See id.; see also In re A & O Enters., No. C-4670, 2019 F.T.C. LEXIS 13, at *3 (Feb. 13, 2019).
93. See Chambial et al., supra note 33, at 314; Blaszcak et al., supra note 33, at 454.
95. Lee Optical, 348 U.S. at 491.
96. Id.