

# OFF-LABEL DRUG ADVERTISING AND THE FIRST AMENDMENT

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This Article explores the constitutionality of the Food and Drug Administration's ("FDA's") regulatory restrictions on so-called "off-label" pharmaceutical advertising and promotion—marketing efforts, typically by drug companies and their agents, that promote uses for drugs other than those approved by the FDA. This Article argues that the First Amendment has passed by the FDA's long-standing and near-absolute restriction on such off-label advertising, and that off-label promotion of drugs, when accompanied in certain cases by appropriate disclaimers, should be deemed protected by the First Amendment.

## I. THE FDA'S "NEAR-ABSOLUTE" RESTRICTIONS ON DISCOURSE REGARDING OFF-LABEL DRUG USES

### A. *FDA Regulation of Prescription Drug Labeling*

The federal government, through the FDA, regulates the entry of prescription drugs into the American marketplace. The Federal Food, Drug, and Cosmetic Act<sup>1</sup> ("FDCA"), first passed in 1938 and then significantly amended in 1962, creates a "preclearance" regulatory system, providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug."<sup>2</sup>

The federal government, through the FDA, also regulates the promotional and advertising expression of pharmaceutical companies in marketing those drugs. The FDA allows new drugs to enter the marketplace only for certain approved uses, and in turn requires that all of those uses be indicated on a drug's label.<sup>3</sup> Drug

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1. 21 U.S.C. §§ 301–399f (2012).

2. *Id.* § 355(a); see also Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938), amended by Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (current version at 21 U.S.C. §§ 301–399f).

3. The FDCA imposes this requirement through its definition of a so-called "new drug," which is defined as: "Any drug . . . not generally

manufacturers are only permitted to promote or advertise prescription drugs for uses approved by the FDA—for uses, in short, that are “on” the drug’s label.

This regulatory requirement is effectuated in a curiously indirect manner. No federal statute or regulation imposes, in so many words, a direct ban on off-label promotion of drugs. Instead, the FDCA and the FDA’s implementing regulations prohibit a drug from being “misbranded” and further provide that any promotion of a drug for off-label use amounts to “misbranding.”<sup>4</sup>

This matrix effectively operates as a “near-absolute ban” on promotion of off-label uses, exerting a powerful *in terrorem* chill on any off-label promotions. The phrase “near-absolute ban,” placed in quotes to demark it as a working term of art in this Article, merits some front-end unpacking. Make no mistake, those who market pharmaceuticals—those who are *regulated*—regard existing governmental policies and practices as “near absolute.”

For decades the federal government has prosecuted off-label promotion of drugs with single-minded zealotry. The overwhelming leverage that federal law provides to prosecutors tends to lead inexorably to guilty pleas in these prosecutions.<sup>5</sup> The risk of

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recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . .” *Id.* 21 U.S.C. § 321(p)(1).

4. The FDCA thus prohibits “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded.” *Id.* § 331(a). In turn, a drug is misbranded if the drug’s labeling fails to bear “adequate directions for use.” *Id.* § 352(f). The FDA’s regulations require directions under which a lay person “can use a drug safely and for the purposes for which it is intended.” 21 C.F.R. § 201.5 (2014). In determining the “purposes for which it is intended,” the FDA regards “the objective intent of the persons legally responsible for the labeling of drugs” as being demonstrated by “oral or written statements by such persons or their representatives” and “the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.” *Id.* § 201.128. The net effect of this regulatory matrix is to render *criminal* any advertising of off-label uses by a drug company or its representatives, because such off-label promotion is deemed to demonstrate the prohibited disconnection between the manner in which the drug is labeled (which may include only FDA-approved uses) and the actual “purposes for which it is intended,” namely the purposes indicated by the off-label advertising. *See* 21 U.S.C. § 333(a)(1) (2012) (“Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.”).

5. *See* *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012) (citing numerous cases in which “convictions” have been obtained through pleas and explaining that “[t]he government has repeatedly prosecuted—and obtained convictions against—pharmaceutical companies and their representatives for misbranding based on their off-label promotion”); *see also* Press Release, U.S. Dept’t of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), *available at* <http://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay>

contesting the criminal charges on the merits is simply too high to bear for most defendants, so they agree to pleas to cut losses.<sup>6</sup> The list of these “convictions” obtained through pleas is ostensibly an impressive string of government “victories.”<sup>7</sup>

But the list is highly misleading in that it fails to account for the overbearing leverage the government is able to bring to bear in these cases, which heavily skews the results toward plea agreements. This government leverage is enhanced by numerous practical factors. The legal fees and business costs and risks attendant to contesting government claims on the merits will often encourage companies to seek early settlement resolution of off-label advertising claims.<sup>8</sup> More importantly, companies and individuals face heavy pressure to cave to the government because of the power exerted through what are known as the “exclusion penalties.”<sup>9</sup>

Federal law contains two “exclusion” provisions relating to participation in health care programs: “mandatory exclusion” and “permissive exclusion.”<sup>10</sup> Exclusion is an enormously powerful enforcement tool, providing the federal government with prodigious prosecutorial leverage. The enforcement mechanism is exercised principally by the Inspector General of the Department of Health and Human Services (“HHS”);<sup>11</sup> it permits HHS to ban a company or individual from participation in any federal health care program, including, most importantly, Medicare and Medicaid.<sup>12</sup> Mandatory exclusion includes any felony conviction relating to health care fraud.<sup>13</sup> Permissive exclusion grants HHS the authority to extend

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-3-billion-resolve-fraud-allegations-and-failure-report. See generally Lindsey Devers, *Plea and Charge Bargaining: Research Summary*, BUREAU JUST. ASSISTANCE (Jan. 24, 2011), <https://www.bja.gov/Publications/PleaBargainingResearchSummary.pdf> (finding a plea-bargaining rate of 90–95% in all federal criminal cases).

6. Janice M. Symchych et al., *Settlement of Major Healthcare Fraud Enforcement Proceedings: A Probing and Frank Analysis of the Competing Variables*, HEALTH LAW., Feb. 2013, at 1, 3 (“If a business entity has been the recipient of a DOJ or other agency subpoena during the sealed period, it becomes acutely aware that an investigation is proceeding and may quickly realize it is expending large sums for legal fees during this important investigative period. Even in a booming economy, an entity may understandably seek to limit investigation-related expenditures. This business objective, sometimes fueled by some managers’ experience with various forms of private civil litigation, frequently leads to instructions from a client to their outside counsel to explore settlement.”).

7. See *Caronia*, 703 F.3d at 154 (citing numerous cases in which “convictions” have been obtained through pleas); see also Press Release, U.S. Dep’t of Justice, *supra* note 5.

8. Symchych et al., *supra* note 6.

9. 42 U.S.C. § 1320a-7(a)–(b) (2012).

10. *Id.*

11. 42 C.F.R. § 1001.1(b) (2013).

12. *Id.* § 1001.1(a).

13. 42 U.S.C. § 1320a-7(a)(3).

exclusion outside of criminal felony convictions, including misdemeanor convictions or circumstances in which a prosecutor has not sought or secured an indictment.<sup>14</sup> The impact of exclusion from federal reimbursement for programs such as Medicare and Medicaid is catastrophic for many entities—a health care reimbursement death penalty.<sup>15</sup> The invocation of these exclusion penalties is routinely in play in any governmental prosecution for off-label drug promotions by pharmaceutical companies. The threat hangs like the sword of Damocles, and companies will often do anything to avoid it.<sup>16</sup> Even when armed with First Amendment arguments that might well prevail if the prosecuted entity has the temerity and perseverance to contest the government's position as unconstitutional, prudent business judgment will often dictate settlement, given the potentially disastrous consequences of not taking the exclusion penalty off the table.<sup>17</sup>

For its part, the government is also incentivized to police discussion of off-label drug uses toward the end of stamping out such discussion without forcing a judicial showdown over the constitutionality of its efforts. The government will often prefer to opt for plea agreements rather than pursue legal theories that are suspect as a matter of constitutional law or statutory interpretation.<sup>18</sup> The government appears to employ a deliberate strategy to avoid making law in this arena, using its coercive power to force settlements or its interpretive power to deftly alter

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14. *Id.* § 1320a-7(b); *see also* 42 C.F.R. §§ 1001.201–1001.1701 (2013) (setting forth federal regulations governing all permissive exclusions).

15. *See* DAVID W. OGDEN & ELISEBETH COLLINS COOK, U.S. CHAMBER INST. FOR LEGAL REFORM, *THE EXCLUSION ILLUSION: FIXING A FLAWED HEALTH CARE FRAUD ENFORCEMENT SYSTEM* 5 (2012), *available at* <http://www.instituteforlegalreform.com/uploads/sites/1/ExclusionBooklet.pdf> (“[F]or companies, . . . exclusion means destruction.”).

16. *See id.* at 5–6 (explaining how unequal bargaining power between companies and the government diminishes companies' ability to contest liability).

17. *See id.* at 4 (“Put simply, because federal programs constitute an enormous and growing portion of the respective markets, essentially no pharmaceutical or medical device manufacturer can survive exclusion. For that reason, a concrete threat of exclusion—in the form of an indictment for an offense mandating exclusion—itself threatens to destroy a company in the way a mere indictment destroyed the accounting firm Arthur Andersen. Thus, a company will logically accept a settlement or plea agreement largely on the government's terms so long as exclusion is not among them.” (footnotes omitted)).

18. *See* Symchych et al., *supra* note 6 (“Arguably the DOJ would prefer to settle cases without putting its legal theories to the test in a binding, widely reported fashion. Prosecutors are typically not eager to run the risk of creating case law that could complicate their ability to pursue prosecution of major cases in the future.”).

regulatory positions so as to avoid a frontal First Amendment assault on its position.<sup>19</sup>

The stakes in this conflict are high by any measure, and the litigation battles are increasing in their intensity. To cite a very recent example, in *United States ex rel. Solis v. Millennium Pharmaceuticals, Inc.*,<sup>20</sup> a claim was brought under the False Claims Act,<sup>21</sup> predicated on claims of off-label marketing of Integrilin, a drug approved by the FDA for certain specified coronary conditions.<sup>22</sup> The plaintiffs, which include the United States and over half the states, allege that the pharmaceutical company defendants “funneled millions of dollars in unrestricted grant money to physicians in order to encourage them to speak and publish articles supporting the use of Integrilin in patients whose cardiovascular event symptoms did not meet the FDA criteria for Integrilin.”<sup>23</sup> The plaintiffs allege that the defendants targeted key physician opinion leaders, “influential doctors whom Defendants supported monetarily.”<sup>24</sup> Describing these promotional efforts as “kickbacks,” the plaintiffs allege that the drug company defendants provided the physicians with “speaking opportunities, unrestricted educational grants, lavish meals, and honoraria to promote and prescribe Integrilin off-label.”<sup>25</sup> As of late 2014, the litigation is still in the pleading stages.<sup>26</sup> The First Amendment issues discussed in this Article promise to be front and center in the litigation as it proceeds because the construction of the False Claims Act advanced by the plaintiffs, including the United States, seeks to impose liability for what the defendants and supporting amici argue is

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19. See Luke Dawson, Note, *A Spoonful of Free Speech Helps the Medicine Go Down: Off-Label Speech and the First Amendment*, 99 IOWA L. REV. 803, 805 (2014) (“However, until recently, the FDA forestalled drug manufacturers from obtaining a favorable circuit court decision by ‘defly maneuver[ing] around’ appeals, either by forcing settlements or modifying interpretations of regulations and guidance documents to make challenges ‘disappear[.]’” (alterations in original) (footnotes omitted) (quoting Wash. Legal Found. v. Henney, 202 F.3d 331, 335 (D.C. Cir. 2000))). The *Washington Legal Foundation* litigation, in which the government managed to make a critical appeal before the District of Columbia Circuit “disappear,” is discussed at length later in this Article. See *infra* text accompanying notes 114–36.

20. No. 2:09-cv-03010-MCE-EFB, 2014 WL 1270581 (E.D. Cal. Mar. 26, 2014).

21. 31 U.S.C. §§ 3729–3733 (2012).

22. *Solis*, 2014 WL 1270581, at \*1–2.

23. Second Amended Complaint for Damages at 6, *Solis*, 2014 WL 1270581 (Apr. 15, 2014) (No. 2:09-cv-03010-MCE-EFB).

24. *Id.*

25. *Id.*

26. See Minute Order, *Solis*, 2014 WL 1270581 (Nov. 24, 2014) (No. 2:09-cv-03010-MCE-EFB) (vacating and continuing Defendants’ Motions to Dismiss and Defendant’s Motion to Strike in November 2014).

truthful and non-misleading speech<sup>27</sup>—in this case, speech that largely originates from physicians and opinion makers within the medical profession.

### *B. The Regulation of Medicine and the Provenance and Value of Off-Label Uses*

The federal government generally does not regulate the practice of medicine in the American marketplace.<sup>28</sup> Doctors often prescribe drugs to patients to treat medical conditions other than the conditions that the FDA has recognized as among a drug's approved uses.<sup>29</sup> Because the FDA requires that all of a prescription drug's approved uses be listed on the drug's label, such prescribing for unapproved uses is popularly known as an "off-label" prescription.<sup>30</sup>

Off-label prescription is ubiquitous in modern medical practice.<sup>31</sup> Off-label prescription drug use accounts for approximately 20% of all medical prescriptions; for certain medications, such as cardiac and anticonvulsant prescriptions, the percentage may be as high as 50%.<sup>32</sup> Certain illnesses, such as

27. See, e.g., Pharmaceutical Research & Manufacturers of America's Amicus Brief at 2–4, *Solis*, 2014 WL 1270581 (Aug. 15, 2014) (No. 2:09-cv-3010-MCE-JFM).

28. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998) ("[The] FDA does not purport to regulate the practice of medicine, and the agency has long recognized that, in general, physicians may use an approved drug or device for an unapproved use." (citing 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994))), amended by 36 F. Supp. 2d 16 (D.D.C. 1999), and appeal dismissed, judgment vacated in part *sub nom.* *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. 26,720, 26,733 (June 9, 1983) (to be codified at 21 C.F.R. pt. 312) ("[T]he proposal: (1) Would clarify that the act does not regulate the 'practice of medicine' so that a licensed physician may prescribe an approved drug for an unapproved indication . . .").

29. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("Similarly, 'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." (citing James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 *FOOD & DRUG L.J.* 71, 76–77 (1998) (noting that courts, several states, and the "FDA itself recognize[] the value and propriety of off-label use"))).

30. *Id.*

31. *Wash. Legal Found.*, 13 F. Supp. 2d at 56 ("[O]ff-label use of FDA-approved drugs by physicians is an established aspect of the modern practice of medicine." (citing U.S. GEN. ACCOUNTING OFFICE, GAO/PEMD-91-14, *OFF-LABEL DRUGS: REIMBURSEMENT POLICIES CONSTRAIN PHYSICIANS IN THEIR CHOICE OF CANCER THERAPIES* 5 (1991) (noting that the use of off-label treatments is widespread))).

32. Muriel R. Gillick, *Controlling Off-Label Medication Use*, 150 *ANNALS INTERNAL MED.* 344, 345 (2009); David C. Radley et al., *Off-Label Prescribing*

cancer, are especially likely to be treated with off-label prescriptions. The General Accounting Office found that 25% of anticancer drugs were prescribed off-label and 56% of cancer patients were given at least one drug off-label.<sup>33</sup>

Why do doctors so often prescribe medications for off-label uses? It cannot be that doctors do not know what they are doing, do not care for their patients, or have somehow been seduced or suckered by drug companies—after all, drug companies have operated under a curtain of imposed silence regarding off-label uses for decades. The most *plausible* intuitive answer—and the answer, it turns out, that also appears to be borne out by what the extant literature reveals—is that doctors prescribe medications for off-label uses because they have made the independent, professional medical judgment that the prescription, on balance, holds more promise of doing good for the patient than harm.<sup>34</sup> Doctors, in short, in good conscience prescribe off-label uses of drugs when they have conscientiously reached the judgment that the prescription is good medicine.<sup>35</sup>

If off-label prescription of drugs by doctors was demonstrably injurious to public health, doctors would presumably not engage in the practice, and governments would presumably exercise the political will to ban the practice. That doctors continue to prescribe and governments continue to acquiesce is evidence in and of itself

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*Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1021 (2006).

33. U.S. GEN. ACCOUNTING OFFICE, GAO/PEMD-91-14, OFF-LABEL DRUGS: REIMBURSEMENT POLICIES CONSTRAIN PHYSICIANS IN THEIR CHOICE OF CANCER THERAPIES 4 (1991).

34. See *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989) (“Thus, the fact that [the] FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate.”).

35. See Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion Prosecutions*, 64 FOOD & DRUG L.J. 441, 444 (2009) (“For example, in 1982, [the] FDA said: ‘[O]nce a [drug] product . . . has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in the approved labeling . . . “[U]napproved” or more precisely “unlabeled” uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature . . . [.] Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations . . . .” (quoting *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. (Food & Drug Admin., Rockville, Md.), Apr. 1982, at 4, 5)); John E. Osborn, *Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information*, 10 YALE J. HEALTH POL’Y L. & ETHICS 299, 303 (2010) (“Physicians may prescribe FDA-approved drugs . . . for any therapeutic use that is appropriate in their medical judgment.”).

that off-label prescription is often good medicine.<sup>36</sup> For its part, the FDA has been unwilling to take the fateful step of presuming to regulate how physicians use FDA-approved drugs, and for good reason.<sup>37</sup> Indeed, in an oft-quoted guidance statement, the FDA lauded the positive medical benefits of off-label prescription:

The [Food, Drug and Cosmetic] Act does not . . . limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such

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36. See Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008) (noting a 2003 study of 160 common drugs where off-label use accounted for approximately 21% of prescriptions).

37. The FDA has admitted that off-label prescriptions by doctors often constitute medical practice consistent with recognized standards of medical care. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES 2 (2009), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm> (“[The] FDA does recognize, however, the important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities. Once a drug or medical device has been approved or cleared by [the] FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product’s approved labeling (or, in the case of a medical device cleared under the 510(k) process, in the product’s statement of intended uses). These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals’ receipt of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical products that are truthful and not misleading.”). The FDA recently issued a new “Revised Draft Guidance” for comment. In this Revised Draft, the FDA’s position appears somewhat more tough-minded and, for the reasons discussed throughout this Article, concomitantly in yet greater tension with the First Amendment. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY DISTRIBUTING SCIENTIFIC AND MEDICAL PUBLICATIONS ON UNAPPROVED NEW USES—RECOMMENDED PRACTICES: REVISED DRAFT GUIDANCE 2 (2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf> (“The evolution of drug and medical device regulation in the United States has been shaped by experience with the real and substantial risks to the public from uses of drugs and medical devices not shown to be both safe and effective through adequate and well-controlled clinical studies. While physicians may exercise their professional judgment to make individual patient care decisions, the public health often is not well served when those judgments rest on anecdotal experience or even preliminary scientific study—too often, the promise of safety and effectiveness made by such sources has not been demonstrated when adequate and well-controlled clinical studies are completed.”).

“unapproved” or, more precisely, “unlabeled” uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term “unapproved uses” is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. . . . [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only.<sup>38</sup>

The division of labor regarding regulation of medical practice and regulation of drug marketing is grounded in causes both legal and political. The legal restraints on the FDA start with the FDCA itself, which codifies the principles of federalism that separate regulation of drug marketing from regulation of medical practice.<sup>39</sup> The political restraints emanate from multiple sources, perhaps most notably the American medical profession, which has reacted with intense hostility to any perceived encroachments by the FDA into regulation of what legally available drugs doctors choose to prescribe for what purposes.<sup>40</sup> Whether the federal government *could*, if it chose, preempt all state regulation of medicine and invoke the Commerce Clause to take over regulation of all medical practice in the United States is a nice *academic* question of constitutional law, of the sort that some impish law professor might put on a final exam—but the question is purely academic as a

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38. *Use of Approved Drugs for Unlabeled Indications*, *supra* note 35, quoted in *Weaver*, 886 F.2d at 198.

39. The FDCA codifies this division between the power of the FDA to regulate drug approval and marketing, on the one hand, and the clear statement by Congress, on the other, that the FDA is *not* empowered by the FDCA to regulate the practice of medicine itself, including the uses for which doctors prescribe drugs. Section 396 of the Act is entitled, significantly, “Practice of medicine” and states:

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

21 U.S.C. § 396 (2012).

40. See DOMINIQUE A. TOBBELL, PILLS, POWER, AND POLICY: THE STRUGGLE FOR DRUG REFORM IN COLD WAR AMERICA AND ITS CONSEQUENCES 151–52 (2011) (discussing the American medical profession’s prior criticisms of the FDA).

matter of American *realpolitik*, for the country today is far from willing to tolerate such a wholesale federal takeover of the practice of medicine.<sup>41</sup> The FDA historically has been reluctant to directly intervene in the regulation of the practice of American medicine.<sup>42</sup> Indeed, on the few occasions in history in which the FDA has venturesomely threatened to cross the fateful threshold into the actual regulation of medical practice, the political pushback, led by the medical profession, has been so intense that the FDA has beat a swift retreat.<sup>43</sup>

### C. *The Impending Constitutional Showdown*

All of this serves as a prelude to a constitutional and public policy conflict of imposing significance. The duality of the present system—in which the FDA regulates the approval and marketing of drugs but does not regulate the actual practice of medicine—has led to a First Amendment showdown.

The FDA regime banning off-label drug advertising has been in place, essentially unchanged, for decades. During those same decades, however, First Amendment doctrines protecting

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41. The deep divisions in American society over the policy propriety and constitutional legitimacy of the Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.), tell it all. Whether the ACA is or is not good public policy is one of the central political issues of our time, and that public policy debate is driven at least in part by conflicting American instincts regarding federalism and whether regulation of health care is better left to states or ought be nationalized through uniform federal policies. That intense political debate has an echo boom in constitutional law litigation, as courts sort through multiple challenges to the ACA. In *National Federation of Independent Business v. Sebelius*, the first of the major challenges regarding the ACA to reach the Supreme Court, the Court ruled that Congress lacked the power under the Commerce Clause to enact the so-called personal mandate requiring the purchase of insurance, but possessed the power under the Taxing and Spending Clause to exact a tax penalty for the failure to comply with the mandate. 132 S. Ct. 2566, 2591–92, 2595 (2012).

42. See, e.g., *Weaver*, 886 F.2d at 198 (“FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.”).

43. See Coleen Klasmeier & Martin H. Redish, *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 AM. J.L. & MED. 315, 323 (2011) (“The FDA’s effort both to establish an off-label use policy in order to satisfy Congress and to avoid interfering in medical practice failed, largely because the 1972 proposed rule was fiercely opposed by physicians . . . . What followed, instead, was a series of statements from the FDA calculated to soothe the medical community by denying that the Agency’s proposal represented any genuine threat to prescribing decisions. The FDA went further, amending its regulations to make clear that the requirement for regulatory authorization for a new drug did ‘not apply to the use in the practice of medicine for an unlabeled indication of a new drug product approved’ by the FDA.” (footnotes omitted) (quoting 21 C.F.R. § 312.2(d) (2010))).

commercial speech have changed dramatically through a march of Supreme Court decisions rejecting paternalistic regulation and expanding constitutional protection for advertisers.<sup>44</sup>

This Article argues that First Amendment principles have passed by the FDA. For decades, the FDA has fought tenaciously to defend its draconian shutdown of all discussion of off-label uses of drugs by drug companies. The arguments advanced by the FDA to defend its ban on off-label drug promotion, however, are all deeply flawed when measured against modern First Amendment principles. Those principles no longer permit the FDA to exert its near-absolute ban on truthful, non-misleading promotional and marketing information by pharmaceutical companies and their agents regarding the off-label uses of drugs.

## II. THE FDA'S RESTRICTIONS ON OFF-LABEL MARKETING AND THE FIRST AMENDMENT

### A. *The Judicial Landscape*

#### 1. *The Supreme Court Decisions in Western States and Sorrell*

No Supreme Court decision has squarely ruled on the constitutionality of the FDA's off-label drug-marketing restrictions. Two highly important Supreme Court decisions, however, *Thompson v. Western States Medical Center*<sup>45</sup> and *Sorrell v. IMS Health Inc.*,<sup>46</sup> strike deeply debilitating blows against the FDA's draconian regime.

##### a. *Thompson v. Western States Medical Center*

In *Thompson v. Western States Medical Center*, the Supreme Court struck down the FDA's restrictions on the advertising of "compound drugs."<sup>47</sup> The decision in *Western States* goes a long distance, if not the entire distance, in establishing the unconstitutionality of the FDA's regime restricting the advertising

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44. See cases cited *infra* note 263 and accompanying text.

45. 535 U.S. 357 (2002).

46. 131 S. Ct. 2653 (2011).

47. 535 U.S. at 360–61 ("Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. It is a traditional component of the practice of pharmacy and is taught as part of the standard curriculum at most pharmacy schools. Many states specifically regulate compounding practices as part of their regulation of pharmacies. Some require all licensed pharmacies to offer compounding services. Pharmacists may provide compounded drugs to patients only upon receipt of a valid prescription from a doctor or other medical practitioner licensed to prescribe medication." (citations omitted)).

of off-label drug uses. In this case, the government sought to justify its ban on compound drug advertising by claiming that it was necessary to preserve the effectiveness and integrity of the FDCA's new drug-approval process<sup>48</sup>—the same argument the government routinely advances to justify its restrictions on the promotion of off-label drug use.<sup>49</sup> While positing that preserving the new drug-approval process was an important governmental interest, the Court rejected the view that the FDA's regime of allowing drug compounding to take place without "new drug" approval, but forbidding advertising of that drug compounding, was consistent with the commercial-speech protections emanating from *Central Hudson Gas & Electric Corp. v. Public Service Commission*.<sup>50</sup>

For decades, the commercial speech doctrine has been governed by the particular iteration of "intermediate scrutiny" emanating from *Central Hudson*. In *Central Hudson*, the Public Service Commission of New York ordered electric utilities to cease all advertising that promoted the use of electricity.<sup>51</sup> The Supreme Court held the restriction unconstitutional and, in the process of doing so, announced what is now a famous four-part test:

At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.<sup>52</sup>

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48. *Id.* at 368.

49. *See, e.g., id.*; *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012).

50. 447 U.S. 557 (1980). *Central Hudson* and its progeny form the doctrinal framework that has been in place regarding the regulation of "commercial speech" for over three decades. *See* Shannon M. Hinegardner, Note, *Abrogating the Supreme Court's De Facto Rational Basis Standard for Commercial Speech: A Survey and Proposed Revision of the Third Central Hudson Prong*, 43 *NEW ENG. L. REV.* 523, 532 (2009) ("The watershed decision of *Central Hudson* has been shaped and molded by subsequent Supreme Court cases about commercial speech."). It is not entirely clear, as discussed at length later in this Article, that information regarding off-label drug practices is properly classified as "commercial speech" at all. *See infra* text accompanying notes 216–30. Indeed, a strong argument may be made that the higher level of "heightened scrutiny" First Amendment protection applicable to noncommercial speech is the more appropriate constitutional standard to apply. The definition of commercial speech, the various elements of the *Central Hudson* standard, and how those principles apply to the FDA's ban on off-label drug uses are discussed at length later in this Article. *See infra* text accompanying notes 216–37.

51. *Central Hudson*, 447 U.S. at 558.

52. *Id.* at 566.

What the FDA attempted in *Western States* was analytically parallel to what it currently attempts with regard to off-label drugs: the preparation and prescription of the drugs themselves are legal, but promoting them is not.<sup>53</sup> As the Supreme Court explained in *Western States*, such “provisions use advertising as the trigger for requiring FDA approval—essentially, as long as pharmacists do not advertise particular compounded drugs, they may sell compounded drugs without first undergoing safety and efficacy testing and obtaining FDA approval.”<sup>54</sup> But “[i]f they advertise their compounded drugs, . . . FDA approval is required.”<sup>55</sup> In a powerful holding, the Court rebuffed the FDA’s regulatory approach of allowing the drug but not allowing the speech. The FDA’s regulation, the Court held, failed the *Central Hudson* test.<sup>56</sup> The ban, the Court held, was overkill. In a stern admonishment, the Court instructed “that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.”<sup>57</sup> Following a pattern familiar in commercial speech decisions striking down overly broad, paternalistic restrictions on advertising, the Court proceeded to suggest a plethora of paths not followed that alone or in combination would have accomplished the government’s interest without engaging in draconian restrictions on speech.<sup>58</sup>

The Court in *Western States* also squarely rejected an argument central to the FDA’s ongoing position defending its restrictions on off-label advertising—that the restrictions were justified by the fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway.<sup>59</sup> Because in the end doctors, exercising their professional judgment, must assess the costs and benefits of any particular prescription regimen, governmental efforts

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53. Mariestela Buhay, Comment, *Off-Label Drug Promotion Is Lost in Translation: A Prescription for a Public Health Approach to Regulating the Pharmaceutical Industry’s Right to Market and Sell Its Products*, 13 J. HEALTH CARE L. & POL’Y 459, 460–61 (2010).

54. *W. States Med. Ctr.*, 535 U.S. at 370.

55. *Id.*

56. *Id.* at 374.

57. *Id.* at 371.

58. *See id.* at 372–73. The Court observed that the government could ban the use of commercial scale manufacturing or testing equipment in compounding drug products, prohibit pharmacists from compounding more drugs in anticipation of receiving prescriptions than in response to prescriptions already received, or prohibit pharmacists from offering compounded drugs at wholesale to other state-licensed persons or commercial entities for resale. *Id.* at 372. However, in light of the failure of the government to explain why these alternatives, alone or in combination, would be insufficient to prevent compounding from occurring on such a scale so as to undermine the new drug approval process, the regulation failed under *Central Hudson*. *Id.* at 373.

59. *Id.* at 374.

to manipulate those decisions by restricting the free flow of information to doctors or patients could not be reconciled with the values of the First Amendment. The FDA's contrary argument, the Court reasoned, rested on the constitutionally infirm supposition that citizens will make what the government regards as bad decisions when supplied with truthful information—a paternalistic justification no longer permissible under modern commercial speech principles.<sup>60</sup>

b. *Sorrell v. IMS Health Inc.*

i. *The Court's Struggle to Identify the Proper Standard of Review*

In *Sorrell v. IMS Health Inc.*, the Supreme Court struck down restrictions on “data mining” and “detailing” practices within the pharmaceutical industry.<sup>61</sup> Pharmacies receive what is called “prescriber-identifying information” when processing prescriptions.<sup>62</sup> They in turn sell the information to “data miners.”<sup>63</sup> The data miners produce reports on prescriber behavior and lease their reports to pharmaceutical manufacturers.<sup>64</sup> “Detailers” employed by pharmaceutical manufacturers then use the reports to refine their marketing tactics and increase sales to doctors.<sup>65</sup>

The State of Vermont sought to limit this practice through passage of its Prescription Confidentiality Law, known as “Act 80.”<sup>66</sup> The Vermont statute provided that, absent the prescriber's consent, prescriber-identifying information could not be sold by pharmacies and similar entities, disclosed by those entities for marketing purposes, or used for marketing by pharmaceutical manufacturers.<sup>67</sup> There were certain limited exceptions. For example, the law allowed dissemination for “health care research.”<sup>68</sup>

The Supreme Court, in an opinion written by Justice Kennedy, struck down the law.<sup>69</sup> The Court's analysis began with a threshold inquiry into the appropriate standard of review.<sup>70</sup> Justice Kennedy's opinion for the Court in *Sorrell* began as if it were headed for the application of “strict scrutiny,” constitutional law's most rigorous form of judicial review. The strict-scrutiny test in modern First

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60. *Id.*

61. 131 S. Ct. 2653, 2659–61 (2011).

62. *Id.* at 2660.

63. *Id.*

64. *Id.*

65. *Id.*

66. Act of June 9, 2007, No. 80, 2007 Vt. Acts & Resolves (codified at VT. STAT. ANN. tit. 18, § 4631 (2012)).

67. VT. STAT. ANN. tit. 18, § 4631(d).

68. *Id.* § 4631(e)(1).

69. *Sorrell*, 131 S. Ct. at 2659.

70. *Id.* at 2663.

Amendment jurisprudence is a legal formulation borrowed from Equal Protection Clause analysis.<sup>71</sup> In the First Amendment context, the test is typically described as requiring that laws regulating speech on the basis of content be justified by “compelling” governmental interests, and that the laws be “narrowly tailored” to effectuate those interests.<sup>72</sup> The application of strict scrutiny almost always results in a content-based restriction on speech being struck down: “It is rare that a regulation restricting speech because of its content will ever be permissible.”<sup>73</sup> The standard is sometimes expressed through the shorthand that content-based restrictions on speech are “presumptively invalid.”<sup>74</sup>

Vermont argued that Act 80 was not a regulation of speech but a commercial restriction on trafficking in a “commodity”<sup>75</sup>—an argument that is a near cousin of the litigation claims typically advanced by the federal government in FDA cases involving off-label advertising, in which the FDA seeks to cast its regulation of off-label advertising as the regulation of mere conduct, invisible to the First Amendment.<sup>76</sup> In making this argument, Vermont relied on a decision from the United States Court of Appeals for the First Circuit upholding a similar law in its neighboring state of New Hampshire, a case in which the First Circuit had likened New Hampshire’s regulation to a regulation of the sale of “beef jerky.”<sup>77</sup>

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71. *Simon & Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 124 (1991) (Kennedy, J., concurring).

72. *See, e.g., Brown v. Entm’t Merchs. Ass’n*, 131 S. Ct. 2729, 2738 (2011) (“Because the Act imposes a restriction on the content of protected speech, it is invalid unless California can demonstrate that it passes strict scrutiny—that is, unless it is justified by a compelling government interest and is narrowly drawn to serve that interest.” (citing *R.A.V. v. City of St. Paul*, 505 U.S. 377, 395 (1992))); *see also Simon & Schuster, Inc.*, 502 U.S. at 118 (“The Son of Sam law establishes a financial disincentive to create or publish works with a particular content. In order to justify such differential treatment, ‘the State must show that its regulation is necessary to serve a compelling state interest and is narrowly drawn to achieve that end.’” (quoting *Ark. Writers’ Project, Inc. v. Ragland*, 481 U.S. 221, 231 (1987))).

73. *United States v. Playboy Entm’t Grp., Inc.*, 529 U.S. 803, 818 (2000).

74. *Ysursa v. Pocatello Educ. Ass’n*, 555 U.S. 353, 358 (2009) (“Restrictions on speech based on its content are ‘presumptively invalid’ and subject to strict scrutiny.” (citing *Davenport v. Wash. Educ. Ass’n*, 551 U.S. 177, 188 (2007); *R.A.V.*, 505 U.S. at 382)).

75. *Sorrell*, 131 S. Ct. at 2666.

76. *See, e.g., United States v. Caronia*, 703 F.3d 149, 160–61 (2d Cir. 2012); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 335 (D.C. Cir. 2000).

77. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 53 (1st Cir. 2008) (“In other words, this is a situation in which information itself has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.”).

The Supreme Court, however, like the Second Circuit,<sup>78</sup> saw Vermont's law not as regulation of beef jerky, but as regulation of the free flow of information falling squarely within the protection of the First Amendment. The Court in *Sorrell* observed that the creation of information is protected by the First Amendment, even when that information is devoid of advocacy and is simply a collection of "facts."<sup>79</sup> As the Court in *Sorrell* explained: "This Court has held that the creation and dissemination of information are speech within the meaning of the First Amendment."<sup>80</sup> Vermont, the Court held, could not avoid subjecting its law to First Amendment scrutiny through the convenient expedient of characterizing the information it was regulating as merely factual. "Facts, after all, are the beginning point for much of the speech that is most essential to advance human knowledge and to conduct human affairs."<sup>81</sup>

As the Court correctly recognized, the Vermont law prohibited the sale of information, subject to exceptions that were based in large part on the content of a purchaser's speech.<sup>82</sup> The law therefore prohibited the disclosure when pharmaceutical manufacturers used the information for marketing.<sup>83</sup> The law thus targeted speech used for "marketing" with specific content, which was a content-based restriction.<sup>84</sup> Finding that Vermont had

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78. The Second Circuit rejected Vermont's claim and rejected the reasoning of the First Circuit in *Ayotte*, noting that "the [S]tate seeks to limit the acquisition and use of information in the hands of pharmacies, data miners, and pharmaceutical companies. This is a case about the extent of the permissible governmental regulation of information in the hands of private actors." *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 273 (2d Cir. 2010).

79. *Sorrell*, 131 S. Ct. at 2666–67.

80. *Id.* at 2667 (citing *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) ("[I]f the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct."); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (holding that "information on beer labels" is speech); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 (1985) (plurality opinion) (holding that a credit report is "speech"))).

81. *Id.*

82. *Id.* at 2663.

83. *Id.* at 2660.

84. *Id.* at 2664 ("Act 80 is designed to impose a specific, content-based burden on protected expression. It follows that heightened judicial scrutiny is warranted." (citing *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 658 (1994) (explaining that strict scrutiny applies to regulations reflecting "aversion" to what "disfavored speakers" have to say); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 (1993) (applying heightened scrutiny to "a categorical prohibition on the use of newsracks to disseminate commercial messages"); *id.* at 429 ("[T]he very basis for the regulation is the difference in content between ordinary newspapers and commercial speech" in the form of "commercial handbills" . . . . Thus, by any commonsense understanding of the term, the ban in this case is 'content based.'"))).

attempted to regulate speech protected by the First Amendment, the Court proceeded to apply “heightened scrutiny” to the law.<sup>85</sup>

*ii. The Ambiguity of “Heightened Scrutiny”*

It was unclear in *Sorrell*, however, precisely what “heightened scrutiny” meant. The phrase “heightened scrutiny” is invoked in Supreme Court opinions with surprising frequency—and with even more surprising lack of precision.<sup>86</sup>

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85. *Id.* at 2667.

86. Justice Kennedy’s majority opinion in *Sorrell* is one of the most recent Supreme Court opinions to invoke the phrase “heightened scrutiny.” The term has a lineage dating back to at least 1976 in *Kelley v. Johnson*, 425 U.S. 238 (1975), in which Justice Thurgood Marshall stated that he found no need to apply heightened scrutiny to a police department’s regulation of hair length because the regulation failed rational basis scrutiny. *Id.* at 256 n.8 (Marshall, J., dissenting). It has been used in scores of opinions—majority, concurring, and dissenting—by virtually all members of the Supreme Court on a vast expanse of constitutional law issues. *See, e.g.*, *Nev. Comm’n on Ethics v. Carrigan*, 131 S. Ct. 2343, 2349 (2011) (“In the past we have applied heightened scrutiny to laws that are viewpoint discriminatory even as to speech *not* protected by the First Amendment.”); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514–16 (2009) (rejecting application of heightened scrutiny when reviewing an agency action under the Administrative Procedure Act in a context that did not reach First Amendment issues); *District of Columbia v. Heller*, 554 U.S. 570, 691 (2008) (Breyer, J., dissenting) (citing a prior heightened scrutiny gender case in a Second Amendment case); *Gonzalez v. Carhart*, 550 U.S. 124, 187 (2007) (Ginsburg, J., dissenting) (objecting to, in an abortion case, the majority’s application of rational basis review, stating that the majority had failed to employ “the heightened scrutiny we have previously applied” to abortion regulations); *San Remo Hotel, L.P. v. City & Cnty. of S.F.*, 545 U.S. 323, 332–33 (2005) (discussing the California Supreme Court’s use of heightened scrutiny to describe the constitutional test applicable to the imposition of conditions in certain Takings Clause zoning and land use cases); *Clingman v. Beaver*, 544 U.S. 581, 603 (2005) (O’Connor, J., concurring) (referring to the review of election laws, Justice O’Connor observed that “applying heightened scrutiny helps to ensure that such limitations are truly justified and that the State’s asserted interests are not merely a pretext for exclusionary or anticompetitive restrictions”); *McConnell v. FEC*, 540 U.S. 93, 231 (2003) (noting that, in a case involving First Amendment review of campaign contribution laws, “[w]hen the Government burdens the right to contribute, we apply heightened scrutiny”), *overruled in part by Citizens United v. FEC*, 558 U.S. 310, 365–66 (2010); *Nike, Inc. v. Kasky*, 539 U.S. 654, 676 (2003) (Breyer, J., dissenting) (determining the proper standard of review to be applied to the speech of Nike defending its labor practices in third-world countries, Justice Breyer argued against the application of commercial-speech principles and in favor of what he described as “public-speech” principles: “In my view, a proper resolution here favors application of the last mentioned public-speech principle, rather than the first mentioned commercial-speech principle. Consequently, I would apply a form of heightened scrutiny to the speech regulations in question, and I believe that those regulations cannot survive that scrutiny.”).

Unlike the well-defined standards attached to many other constitutional terms of art (such as “strict scrutiny”<sup>87</sup> or “intermediate scrutiny”<sup>88</sup>) or various stylized tests governing specific forms of speech regulation (such as the test for public-figure and public-official libel suits,<sup>89</sup> prior restraints,<sup>90</sup> incitement,<sup>91</sup> the standards governing time, place, or manner regulations,<sup>92</sup> or the four-part commercial speech test emanating from *Central Hudson*<sup>93</sup>), the phrase “heightened scrutiny” tends to be invoked by the Court as a grab-bag catchall to describe any form of “elevated” scrutiny above mere “rational basis” review. In short, when the Court announces it is appropriate to apply heightened scrutiny, it is not always clear at the outset what level of scrutiny one will get.

The Court in *Sorrell* emphasized that heightened scrutiny may be triggered by laws that *burden* speech based on its content, even

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87. The strict-scrutiny standard is the highest level of judicial review customarily applied in constitutional law to “suspect classifications,” such as classifications based on race, *see Fisher v. Univ. of Tex. at Austin*, 133 S. Ct. 2411, 2417–21 (2013) (elaborating at length on the rigor required in applying strict scrutiny to race-based university admissions policies), or regulations implicating restrictions on fundamental rights, such as freedom of speech. In speech cases, strict scrutiny is usually articulated as triggered by content-based or viewpoint-based regulation of speech, and while the exact verbal formulations used in cases varies slightly, it is generally understood to require a “compelling” governmental interest and be “narrowly tailored,” “precisely tailored,” or the “least restrictive means” to achieve that interest. *See supra* note 72 and accompanying text.

88. *See, e.g., United States v. Virginia*, 518 U.S. 515, 533 (1996) (applying “intermediate scrutiny,” which requires the classification to be “substantially related” to the achievement of an “important governmental objective[],” to a gender-discrimination, equal-protection case); *Turner Broad. Sys., Inc.*, 512 U.S. at 641–52 (applying intermediate scrutiny in a First Amendment case involving the FCC’s “must-carry” rules for cable and broadcast television regulation, deeming the rules to be content-neutral, not content-based, regulations of speech).

89. *See, e.g., Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350–52 (1974) (holding that private-figure libel suits may be predicated on a showing of mere negligence, as opposed to the “actual-malice” requirement for public-figure libel suits); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 279–80 (1964) (holding that the First Amendment allows a public official to recover for defamation only upon a showing of “actual malice,” defined as knowledge of falsity or reckless disregard for truth or falsity).

90. *N.Y. Times Co. v. United States*, 403 U.S. 713, 714 (1971).

91. *Brandenburg v. Ohio*, 395 U.S. 444, 447–49 (1969).

92. *See, e.g., Regan v. Time, Inc.*, 468 U.S. 641, 648 (1984) (“In order to be constitutional, a time, place, and manner regulation must meet three requirements. First, it may not be based upon either the content or subject matter of speech. Second, it must serve a significant governmental interest. And third, it must leave open ample alternative channels for communication of the information.” (citations omitted) (internal quotation marks omitted)).

93. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). The *Central Hudson* test is described and elaborated upon at length in Subpart II.D below.

though the law may not effect an outright *ban* on the speech. “Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content.”<sup>94</sup>

In *Sorrell*, the Court seemed sorely tempted to apply the full measure of strict scrutiny traditionally triggered by laws that engage in content-based and viewpoint-based discrimination. Applying strict scrutiny would have been plausible because the Vermont law plainly discriminated both on the basis of content and on the identity of the speaker—two forms of discrimination that normally trigger First Amendment strict scrutiny.<sup>95</sup> Moreover, it was not at all clear that the speech in *Sorrell* was commercial speech in the classic sense. Although those trading in the prescription proclivities of doctors clearly had a commercial motivation—the data being harvested for use by detailers in encouraging doctors to prescribe their drugs—the information *itself* was not commercial in any intrinsic sense, but was rather data germane to the medical practice itself. In this sense, it was like information that might be provided by pharmaceutical companies or their representatives regarding off-label uses of drugs. Indeed, data germane to off-label prescriptions was surely included within the data being mined in *Sorrell*—as Justice Breyer suggested in his dissent.<sup>96</sup>

### iii. *The Court’s Application of Central Hudson*

After seeming to struggle with whether or not to apply a First Amendment standard higher than the stylized version of intermediate scrutiny applicable to commercial speech under *Central Hudson*, the Supreme Court in *Sorrell* did what it has often done in cases in which elements of noncommercial speech and commercial speech appear intertwined—it ruled in the alternative that under *either* standard the law must be struck down and proceeded to apply the lower commercial-speech standard to accomplish the task.<sup>97</sup>

Applying the *Central Hudson* test, the Court struck down the Vermont law with quick dispatch. The Court first rejected Vermont’s assertion that the law was justified by the State’s interest

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94. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011) (citing *Simon & Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 115 (1991) (content-based financial burden); *Minneapolis Star & Tribune Co. v. Minn. Comm’r of Revenue*, 460 U.S. 575 (1983) (speaker-based financial burden)).

95. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 658 (1994) (speaker-based regulation); *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992) (content-based regulation).

96. *Sorrell*, 131 S. Ct. at 2678 (Breyer, J., dissenting).

97. *Id.* at 2667 (majority opinion) (“As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.”).

in safeguarding physician privacy, noting that the State made the prescriber information regarding physician prescriptions of drugs available to a vast audience.<sup>98</sup>

The second argument advanced by Vermont to defend its law, and the Supreme Court's emphatic rejection of it, is by far the most important element of *Sorrell* in evaluating its relevance to the constitutionality of the FDA's restrictions on promotion of off-label drug use. Vermont argued that the statute advanced the State's interest in promoting generic drugs over more expensive brand-name drugs, which would serve to lower health care costs.<sup>99</sup> Yet even assuming that this was a substantial governmental interest, the Supreme Court held that Vermont's law did "not advance [it] in a permissible way."<sup>100</sup> The Court's explanation as to why Vermont's approach was impermissible speaks volumes as to why the FDA's essentially identical approach to restricting off-label advertising is also impermissible. The Court in *Sorrell* perceptively observed that Vermont sought "to achieve its policy objectives through the indirect means of restraining certain speech by certain speakers—that is, by diminishing detailers' ability to influence prescription decisions."<sup>101</sup> This is a familiar motif, for just as regulators abhor a regulatory vacuum, regulators "who seek to censor or burden free expression often assert that disfavored speech has adverse effects."<sup>102</sup>

The Court in *Sorrell* admonished that the First Amendment exerts a powerful anti-paternalistic counter to this regulatory impulse. "[T]he 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech."<sup>103</sup> Drawing on the single most dominant theme of modern commercial speech jurisprudence—the ever-increasing hostility of the Court toward paternalistic regulations that seek to influence the behavior of citizens by limiting the information available to them—the Court roundly rejected the premise upon which Vermont's law was grounded. The First Amendment's antagonism to paternalistic regulation, the Court observed, applied with full force when the intended audience for the speech consisted of sophisticated and experienced consumers, such as prescribing physicians—the same audience that FDA regulations seek to shelter from receiving information on off-label drug uses.<sup>104</sup>

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98. *Id.* at 2668 ("Instead, Vermont made prescriber-identifying information available to an almost limitless audience.").

99. *Id.* at 2670.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* at 2670–71 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002)).

104. *Id.* at 2671 ("These precepts apply with full force when the audience, in this case prescribing physicians, consists of 'sophisticated and experienced' consumers." (quoting *Edenfield v. Fane*, 507 U.S. 761, 775 (1993))).

The whole purpose of Vermont's law was to diminish the force of pharmaceutical marketing on the prescribing practices of doctors.<sup>105</sup> Yet this purpose, the Supreme Court sternly lectured, is exactly what the First Amendment forbids:

This reasoning is incompatible with the First Amendment. In an attempt to reverse a disfavored trend in public opinion, a State could not ban campaigning with slogans, picketing with signs, or marching during the daytime. Likewise the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.<sup>106</sup>

The parallels to the FDA's restrictions on off-label marketing are obvious. The FDA, like the State of Vermont in *Sorrell*, seeks to keep doctors in the dark, even though many doctors find information about off-label uses instructive, precisely as the doctors in *Sorrell* found detailing instructive.<sup>107</sup> The FDA, like the State of Vermont in *Sorrell*, seeks through paternalistic regulation to undo a basic truth of medicine—that information is power.<sup>108</sup>

Divergent views exist regarding the efficaciousness of certain common off-label uses of drugs. Under the First Amendment, however, resolution of those divergent views is for the marketplace, not the government.<sup>109</sup> *Sorrell* stands as the capstone of a long jurisprudential march in which the central anti-paternalistic assumptions of First Amendment law are deemed every bit as

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105. *Id.* ("As Vermont's legislative findings acknowledge, the premise of § 4631(d) is that the force of speech can justify the government's attempts to stifle it. Indeed the State defends the law by insisting that 'pharmaceutical marketing has a strong influence on doctors' prescribing practices." (quoting Brief for Petitioners at 49–50, *Sorrell*, 131 S. Ct. 2653 (No. 10-779))).

106. *Id.*

107. *Id.* ("The defect in Vermont's law is made clear by the fact that many listeners find detailing instructive. Indeed the record demonstrates that some Vermont doctors view targeted detailing based on prescriber-identifying information as 'very helpful' because it allows detailers to shape their messages to each doctor's practice." (quoting Joint Appendix, Volume I at 274, *Sorrell*, 131 S. Ct. 2653 (No. 10-779))).

108. *Id.* ("As one Vermont physician put it: 'We have a saying in medicine, information is power. And the more you know, or anyone knows, the better decisions can be made.'" (quoting Joint Appendix, Volume I, *supra* note 107, at 279)).

109. *Id.* ("There are divergent views regarding detailing and the prescription of brand-name drugs. Under the Constitution, resolution of that debate must result from free and uninhibited speech.").

applicable to commercial speech as to speech in the realms of politics, culture, religion, or science.<sup>110</sup>

*iv. The Illuminating Role of Justice Breyer's Dissent*

Sometimes the meaning of a Supreme Court majority opinion may be illuminated by how it is characterized by a dissenting Justice. Justice Breyer's dissent in *Sorrell* discusses off-label drug advertising and plainly expresses the view that the rules established by the majority in *Sorrell* would tend to undermine the validity of the FDA's efforts to control off-label promotion by pharmaceutical companies.<sup>111</sup> Here is Justice Breyer's complaint:

Or the FDA might control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products. Such a firm, for example, could not suggest to a potential purchaser (say, a doctor) that he or she might put a pharmaceutical drug to an "off label" use, even if the manufacturer, in good faith and with considerable evidence, believes the drug will help. All the while, a third party (say, a researcher) is free to tell the doctor not to use the drug for that purpose.

If the Court means to create constitutional barriers to regulatory rules that might affect the *content* of a commercial message, it has embarked upon an unprecedented task—a task that threatens significant judicial interference with widely accepted regulatory activity.<sup>112</sup>

Justice Breyer was exactly right in his characterization of the import of the majority opinion in *Sorrell*. He was also exactly wrong in complaining about it. Justice Breyer was absolutely correct in his

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110. *Id.* ("There are similar sayings in law, including that 'information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.' The choice 'between the dangers of suppressing information, and the dangers of its misuse if it is freely available' is one that 'the First Amendment makes for us.' Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting brand-name drugs. The State can express that view through its own speech." (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)); *id.* at 2671–72 ("But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction. "The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented." (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993))).

111. *Id.* at 2678 (Breyer, J., dissenting).

112. *Id.* (citations omitted).

surmise that the principles articulated in *Sorrell* place great stress on the FDA's off-label advertising ban; to the extent that drug companies seek to share information about the prescribing habits of other doctors and extant medical literature regarding off-label uses, the companies, even if sharing this information for a commercial purpose, appear to be trafficking in scientific data regarding prescription habits analytically indistinguishable from the information held protected by the First Amendment in *Sorrell*. Justice Breyer was also correct in recognizing that *Sorrell* may thus portend "significant judicial interference with widely accepted regulatory activity."<sup>113</sup> He was simply wrong in his judgment that this "interference" is a bad thing. It is in fact an interference long overdue—one person's "judicial interference" is another's judicial intervention to protect constitutional rights.

## 2. *The Litigation Outcomes in Lower-Court Challenges to the FDA Restrictions*

### a. Overview: A Tale of FDA Defeat

The constitutionality of the FDA's restrictions on off-label drug manufacturing has yet to be tested in the Supreme Court. The story of litigation outcomes in cases in which the FDA's authority to restrict off-label drug marketing has been challenged under the First Amendment is generally a narrative of FDA defeat.

There have been cases in which federal prosecutions of off-label advertising have been "successful" from the government's perspective, but only because in the *particular* facts of the case the allegations of aggressively false or misleading advertising were sufficiently strong that the government would probably have prevailed against the advertiser, with no affront to the First Amendment, even in the absence of any near-absolute FDA ban on off-label drug promotion. Those victories, in short, were easy pickings and not really probative of where the constitutional line dividing between permissible and impermissible regulation of off-label promotion should be drawn.

In contrast, in the lower-court showdowns in which the FDA's power and the First Amendment principles constraining that power have squarely been in contest, the FDA has usually come out a loser. Although the FDA has prevailed occasionally on some points—most notably, on its one genuinely significant argument that there is an important societal interest in encouraging drug manufacturers to pursue the process of obtaining formal FDA approvals of drugs for "on-label" uses—on balance, courts have *rejected* virtually every litigation argument the FDA has advanced in defense of its regulatory regime.

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113. *Id.*

b. *Washington Legal Foundation v. Friedman*

In *Washington Legal Foundation v. Friedman*,<sup>114</sup> U.S. District Judge Royce Lamberth struck down FDA guidance documents that limited the distribution of scientific literature to doctors by drug manufacturers, including reprints from medical textbooks and peer-reviewed medical journal articles, discussing off-label drug uses.<sup>115</sup> The court classified the distribution of the literature as commercial, not academic, speech largely because of the promotional motivation of the manufacturers.<sup>116</sup> In a cascade of rulings, the court rejected the FDA's claim that the agency was regulating only conduct, not speech;<sup>117</sup> rejected the FDA's argument that little or no First Amendment protection was warranted because the pharmaceutical industry is heavily regulated;<sup>118</sup> rejected the FDA's argument that the speech at issue was "illegal" because any discussion of off-label uses rendered the drug "misbranded";<sup>119</sup> rejected the FDA's claim that the speech was inherently misleading because the FDA had not approved of the off-label uses;<sup>120</sup> rejected the more specific argument of the FDA that it had a substantial interest in keeping from physicians information that might encourage them to prescribe more off-label uses;<sup>121</sup> but agreed with the FDA in its general assertion that it had a substantial interest in protecting public health.<sup>122</sup> The court accepted the FDA's assertion that it had a substantial interest in encouraging manufacturers to engage in the process of seeking to move off-label uses through the FDA approval process to become on-label uses,<sup>123</sup> and in turn also accepted the FDA's assertion that its restriction on off-label promotion directly and materially advanced the FDA's interest in compelling manufacturers to get off-label uses on-label,<sup>124</sup> but ultimately struck down the FDA guidance as not narrowly tailored to achieve the government's interests,<sup>125</sup> citing the less-restrictive alternative of mandatory disclosure, which would have achieved the government's interests.<sup>126</sup>

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114. 13 F. Supp. 2d 51 (D.D.C. 1998), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *and appeal dismissed, judgment vacated in part sub nom.* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

115. *Id.* at 74.

116. *Id.* at 64–65.

117. *Id.* at 59.

118. *Id.* at 61.

119. *Id.* at 66.

120. *Id.* at 67.

121. *Id.* at 69–70.

122. *Id.* at 69.

123. *Id.* at 70–71.

124. *Id.* at 72.

125. *Id.* at 72–73.

126. *Id.* at 73.

On the whole, Judge Lamberth's opinion was a victory for drug manufacturers. While the court treated the literature as commercial and not academic speech<sup>127</sup> (a minor win for the FDA) and accepted that the FDA's regulations did directly and materially advance a substantial interest in compelling manufacturers to move drugs from off-label to on-label<sup>128</sup> (a more important win for the FDA), the court nonetheless rejected all of the FDA's truly load-bearing arguments, often in highly assertive tones, and ultimately ruled that the FDA's restrictions violated the First Amendment.<sup>129</sup>

On appeal, the case took a simpering turn, with the U.S. Court of Appeals for the D.C. Circuit not reaching the merits and vacating Judge Lamberth's order, rendering his opinion persuasive for its reasoning but without any apparent precedential force.<sup>130</sup> After the issuance of Judge Lamberth's injunction, Congress passed a law that superseded the FDA guidance at issue before the district court, essentially providing the Washington Legal Foundation (and by extension drug manufacturers) most of the relief they had sought in court with regard to the dissemination of academic literature regarding off-label uses.<sup>131</sup> The Food and Drug Administration Modernization Act of 1997<sup>132</sup> permits a manufacturer to disseminate "written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device"<sup>133</sup> as long as it submits an application to the FDA seeking approval of the drug for the off-label use, supplies the materials to the FDA prior to dissemination, distributes the materials unabridged, includes disclosures regarding unapproved use of the drug, and, if the FDA so requires, includes "additional objective and scientifically sound information . . . necessary to provide objectivity and balance."<sup>134</sup> Against this backdrop, the government conceded that it lacked statutory authority to prevent the disseminations it had sought to prevent, and the Washington Legal Foundation conceded that it no longer had any constitutional objection.<sup>135</sup> Stating that "the dispute between the parties has disappeared before our eyes," the D.C. Circuit dismissed the appeal and vacated the district court's decisions and injunction.<sup>136</sup>

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127. *Id.* at 65.

128. *Id.* at 71.

129. *Id.* at 73–74.

130. *Wash. Legal Found. v. Henney*, 202 F.3d 331, 336–37 (D.C. Cir. 2000).

131. *Id.* at 334.

132. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21 U.S.C.).

133. 21 U.S.C. § 360aaa(a) (2006) (repealed 2006).

134. *Id.* § 360aaa(b)(1)–(6) (repealed 2006); *id.* § 360aaa(c) (repealed 2006); 21 U.S.C. § 360aaa-1 (2006) (repealed 2006).

135. *Henney*, 202 F.3d at 336.

136. *Id.* at 335, 337.

c. *United States v. Caputo*

In *United States v. Caputo*,<sup>137</sup> the Seventh Circuit, in an intriguing opinion by Chief Judge Frank Easterbrook, affirmed a conviction for the sale of medical devices for uses not approved by the FDA, but on very narrow grounds, and only after an extended discussion suggesting that powerful First Amendment doctrines limited the FDA's authority to restrict off-label drug advertising.<sup>138</sup> The court thus noted that the Supreme Court's opinion in *Western States*<sup>139</sup> stood for the proposition that the FDA's limit on off-label drug advertising "is unconstitutional in at least some applications"<sup>140</sup> and that "[*Western States*] establishes that drugs are not a special case for first-amendment analysis."<sup>141</sup> Exploring the issue more deeply, the court in *Caputo* elaborated on what it called a "difficult [constitutional] question," musing on the strong hostility in modern First Amendment law toward paternalistic regulations that seek to keep consumers ignorant for their own benefit:

Whether *Virginia Citizens Consumer Council* and [*Western States*] apply to promotion by a product's manufacturer, which struck a bargain with the FDA in the approval process by promising to limit its promotion—a bargain that the private litigants in the earlier cases had not struck—is a difficult question. The doctrine of unconstitutional conditions places limits on the promises that an agency may extract from those who seek approval. And if a given use is lawful, and thus can be written about freely in newspapers or blogs, and discussed among hospitals that already have purchased a Plazlyte, doesn't it make a good deal of sense to allow speech by the device's manufacturer, which after all will have the best information? Why privilege speech by the uninformed? The manufacturer has an incentive to slant the speech in its favor and may withhold bad news, but many listeners (especially professionals such as physicians) understand this and can discount appropriately. That, at any rate, is the anti-paternalist view of *Virginia Citizens Consumer Council* and the cases that followed in its wake.<sup>142</sup>

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137. 517 F.3d 935 (7th Cir. 2008).

138. *Id.* at 937–44.

139. *See supra* text accompanying notes 47–60.

140. *Caputo*, 517 F.3d at 939.

141. *Id.*

142. *Id.* The court's internal references are to *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), which the *Caputo* court had earlier in the opinion characterized as "holding that the government cannot regulate by ensuring ignorance among consumers," *Caputo*, 517 F.3d at 938; and *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), which the *Caputo* court had characterized as establishing that certain restrictions on off-label use violated the First Amendment. *Caputo*, 517 F.3d at 939.

The court in *Caputo* ultimately avoided resolution of this “difficult [constitutional] question,” however, by finding that on the facts before it the medical device at issue was not lawfully on the market *at all*, and thus by definition no off-label promotion of the device was legal.<sup>143</sup> *Caputo* is thus a case in which the court’s reasoning casts powerful doubt on the constitutional validity of the FDA’s sweeping efforts to constrict off-label drug use, while its strict holding falls short of establishing any actual binding precedent because the First Amendment issue was mooted by the absence of any predicate medical device lawfully on the market.

d. *United States v. Harkonen*

In *United States v. Harkonen*,<sup>144</sup> the Northern District of California refused to dismiss a criminal indictment against Scott Harkonen, the CEO of a Bay Area pharmaceutical company, arising from the company’s marketing of the drug Actimmune for off-label uses.<sup>145</sup> The district court’s opinion drew on the reasoning of *Washington Legal Foundation*, observing that the First Amendment protects scientific discourse about drug products.<sup>146</sup> Even so, the court refused to dismiss the indictment against Harkonen,<sup>147</sup> and with understandable reason. Harkonen’s company had engaged in over-the-top promotion of Actimmune, aggressively touting the drug for its effectiveness in treating idiopathic pulmonary fibrosis (“IPF”) and making much of data published in the *New England Journal of Medicine* regarding the use of the drug to treat IPF.<sup>148</sup> The *New England Journal* was ambivalent in its findings regarding the value of the drug in treating IPF, but the company’s publicity campaign

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143. *Caputo*, 517 F.3d at 940 (“Fortunately, we need not decide today whether a seller of drugs or medical devices has a constitutional right to promote off-label uses. *Virginia Citizens Consumer Council* and its successors rest on the assumption that the law allows the activity that the speaker seeks to promote. Here that assumption holds only if AbTox lawfully could sell the large Plazlyte for the (approved) use with solid stainless-steel instruments. Unless the machine itself could be sold lawfully, there were no lawful off-label uses to promote. And the jury found, by its verdicts on both the fraud-on-the-United-States count and the misbranded-device counts, that the large Plazlyte could *not* lawfully be sold.”).

144. No. C 08-00164 MHP, 2009 WL 1578712 (N.D. Cal. June 4, 2009).

145. *Id.* at \*12.

146. *Id.* at \*5 (“The law provides a boundary for what drug product-related speech the government may prohibit. While the FDCA prohibits speech that promotes off-label uses for approved drug products (which thereby ‘misbrands’ the drug), the government cannot wholesale proscribe the open dissemination of scientific opinions and ideas concerning all beneficial uses for approved drug products. Such a prohibition has been deemed to violate the First Amendment rights of the speakers to communicate scientific information and engage in scientific discourse about such products.” (citing *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998))).

147. *Id.* at \*13.

148. *Id.* at \*2.

pushed the impression that the drug reduced mortality rates for certain patients by 70%, a claim not supported by the article or any other extant medical literature.<sup>149</sup> In this posture, Harkonen had gone well beyond simply discussing the drug's off-label uses—his company and its advertising vendor had affirmatively and aggressively marketed the drug with representations regarding its effectiveness that they presumably had to know were not scientifically supported, while creating the impression that they were. After discussing at length the strong First Amendment values protecting scientific discourse regarding off-label drug uses, the district court thus ruled that Harkonen's speech was still out-of-bounds:

What the indictment alleges, and what the law does not protect as a First Amendment carve-out to liability under the FDCA, is that the press release and associated speech incorporates, reformats and post hoc reinterprets scientific results in a false and misleading manner and is then disseminated at Harkonen's direction to physicians and patients.<sup>150</sup>

While the decision in *Harkonen* may count as an FDA victory in its prosecutorial campaign against off-label drug promotion, it is a weak victory in its precedential significance regarding the constitutionality of the FDA's sweeping prohibitions on off-label use because the assertions made by Harkonen's company regarding Actimmune could well have been found fraudulent and misleading under straightforward principles of fraud and false advertising, even if no FDA regulation against off-label branding of drugs existed.

e. *United States v. Caronia*

The decision of the Second Circuit in *United States v. Caronia*<sup>151</sup> is the first off-label drug marketing case to be decided since *Sorrell* and, for that reason alone, is highly significant.<sup>152</sup> The decision was a stunning defeat for the FDA.<sup>153</sup> The case arose from an FDA sting

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149. *Id.*

150. *Id.* at \*6.

151. 703 F.3d 149 (2d Cir. 2012).

152. Dawson, *supra* note 19, at 824.

153. There is a slight ambiguity as to whether the holding of the court in *Caronia* was an exercise in the use of the "avoidance doctrine," giving the FDCA a narrowing construction to avoid First Amendment tensions, or was instead a straightforward constitutional ruling that the FDA's approach to prosecuting the off-label promotion of drugs violates the First Amendment. The court, at an early stage of its legal analysis, invoked the language of the avoidance doctrine. *Caronia*, 703 F.3d at 162 ("To the extent there is any ambiguity as to whether off-label promotion is tantamount to illegal misbranding, we construe the FDCA narrowly to avoid a serious constitutional question." (citing *Skilling v. United States*, 561 U.S. 358, 406 (2010) (instructing courts to "avoid constitutional

operation that caught a pharmaceutical company and its marketing agents promoting off-label uses of the prescription drug Xyrem.<sup>154</sup> The defendants were plainly guilty of promoting off-label uses, though, unlike the defendants in *Harkonen*, the statements made by the defendants in *Caronia* were truthful.<sup>155</sup> In short, *Caronia* presented a pure test of the FDA's restrictions on off-label marketing because there was nothing false or misleading about the information the *Caronia* defendants were caught purveying—the offense was entirely the offense of “misbranding” as the FDA's severe regulatory regime defines it, effectively barring all promotion of off-label uses.<sup>156</sup>

The court in *Caronia* rejected the FDA's attempt to avoid First Amendment scrutiny by arguing that the defendants were not being prosecuted for promoting off-label uses.<sup>157</sup> The FDA asserted that the defendants' promotion of off-label uses was merely introduced as “evidence of intent” to misbrand the drug.<sup>158</sup> The court then carefully reviewed the Supreme Court's decision in *Sorrell*, holding that *Sorrell* required that heightened scrutiny be applied to

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difficulties by adopting a limiting interpretation if such a construction is fairly possible” (internal quotation marks and brackets omitted)); *Allstate Ins. Co. v. Serio*, 261 F.3d 143, 150 (2d Cir. 2001) (“Thus, the courts will take pains to give a statute a limiting construction in order to avoid a constitutional difficulty.”)). The court in *Caronia* elaborated by stating:

As we now explain, we decline the government's invitation to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction—and a conviction obtained under the government's application of the FDCA—would run afoul of the First Amendment.

*Id.* at 162. However, the bulk of its subsequent analysis was plainly cast in language indicating that the FDA's regime violated the First Amendment. *Id.* at 162–69; see *infra* notes 159–71 and accompanying text. As a practical matter, this is an insignificant nuance, for the law of the Second Circuit after *Caronia* is plainly that the FDA's approach to effectively banning off-label drug promotion is illegal (either as a matter of statutory construction to avoid First Amendment infirmity or as a matter of straight-up constitutional law). And as to the persuasive force of *Caronia* outside the Second Circuit, that force will depend on the extent to which other courts are persuaded by the Second Circuit's First Amendment analysis, an analysis whole-heartedly endorsed in this Article.

154. *Caronia*, 703 F.3d at 156.

155. *Id.* at 160.

156. *Id.* at 165 n.10 (“The government does not contend that off-label promotion is in and of itself false or misleading. Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection.”).

157. *Id.* at 160–62.

158. *Id.* at 160–61. The court in *Caronia* properly saw this “evidence-of-intent” argument as both circular and as fundamentally misunderstanding the “evidence-of-intent” principle. The evidence-of-intent argument, which the FDA periodically invokes in off-label cases, is discussed at length in Subpart II.B.1 below.

restrictions on off-label drug promotion.<sup>159</sup> The court reasoned that the FDA's restrictions here were content based and speaker based for precisely the same reasons that Vermont's restrictions in *Sorrell* were found to discriminate on the basis of content and speaker identity.<sup>160</sup> As in *Sorrell*, however, the Second Circuit in *Caronia* found it unnecessary to determine whether the FDA restrictions should be subjected to a level of First Amendment scrutiny higher than that of the standard *Central Hudson* commercial-speech test because the FDA restrictions were unconstitutional under a straightforward application of *Central Hudson*.<sup>161</sup>

The court in *Caronia* found that the speech was about lawful activity and not misleading under *Central Hudson*'s first prong, and that the FDA's interest in promoting drug safety and public health was assuredly "substantial" under *Central Hudson*'s second prong.<sup>162</sup> In a major defeat for the government, however, the court held that the FDA's regulatory regime regarding off-label drug manufacturing failed both the third "direct-and-material-advancement" prong and the fourth "narrow-tailoring" prong of *Central Hudson*.<sup>163</sup>

As to direct advancement, the court held:

As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs.<sup>164</sup>

Indeed, the FDA's entire approach, the court held, was fatally paternalistic.<sup>165</sup>

The court also held that FDA's approach failed *Central Hudson*'s fourth prong because there were many alternative regulatory mechanisms that the FDA might constitutionally invoke to advance its purposes short of restricting speech.<sup>166</sup> These

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159. *Caronia*, 703 F.3d at 163.

160. *Id.* at 164–65.

161. *Id.* at 164.

162. *Id.* at 165–66.

163. *Id.* at 166–67.

164. *Id.* at 166.

165. *Id.* ("[P]rohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use 'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions.").

166. *Id.* at 167–68 ("To advance the integrity of the FDA's drug approval process and increase the safety of off-label drug use, the government could pursue several alternatives without excessive First Amendment restrictions.").

included, the court suggested, providing guidance to doctors and patients “in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information”;<sup>167</sup> developing warning or disclaimer systems;<sup>168</sup> developing “safety tiers within the off-label market[] to distinguish between drugs”;<sup>169</sup> or requiring “pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug’s development.”<sup>170</sup>

In sum, echoing the potent First Amendment jurisprudence that a resort to restrictions on speech must be a last resort,<sup>171</sup> the court in *Caronia* delivered a major blow to the FDA’s restrictions on off-label marketing.

## B. A First Amendment Doctrinal and Policy Analysis

### 1. The Spurious “Evidence-of-Intent” Argument

Stepping back from a case-by-case narrative and analyzing the First Amendment picture from a larger doctrinal and policy perspective, a threshold question is whether the government’s enforcement efforts against off-label promotion of drugs implicate the First Amendment at all.

Government prosecutors have argued that its prosecutions do not target speech protected by the First Amendment, but rather target only *illegal conduct*.<sup>172</sup> While the speech of defendants promoting off-label drug uses may be the center point of the government’s case, prosecutors argue that this speech is introduced only for its *evidentiary force* in proving an element of the underlying criminal conduct.<sup>173</sup> This argument, while persistently invoked, is inherently flawed.<sup>174</sup> The so-called “conduct” being regulated is

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167. *Id.* at 168.

168. *Id.*

169. *Id.* (citing *Klasmeier & Redish*, *supra* note 43, at 334).

170. *Id.*

171. *Id.* (“If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.” (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002))).

172. *See, e.g.*, *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 59 (D.D.C. 1998), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *and appeal dismissed, judgment vacated in part sub nom.* *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

173. *See, e.g.*, *Caronia*, 703 F.3d at 160–61.

174. *Wash. Legal Found.*, 13 F. Supp. 2d at 66 (“Were the FDA’s characterization of what constitutes ‘lawful activity’ accurate, First Amendment protections for commercial speech could be all but eviscerated by the government: First Amendment challenges to speech restrictions would be defeated by noting that Congress had made the speech illegal, and therefore unlawful activity is at issue.”).

*expressive conduct*—conduct as protected by the First Amendment as moving one's lips to talk.<sup>175</sup>

Similarly, and perhaps slightly more ingeniously, government prosecutors repeatedly invoke the maxim emanating from *Wisconsin v. Mitchell*<sup>176</sup> that “[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.”<sup>177</sup> Government prosecutors in off-label drug promotion cases attempt to press *Mitchell* to their advantage, arguing that the federal crime being committed is the promotion of a misbranded drug.<sup>178</sup> Indeed, prosecutors argue, federal law does not even explicitly prohibit or criminalize promotion of off-label drug uses.<sup>179</sup> Rather, the law prohibits introduction of a misbranded drug

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175. *Id.* at 59 (“FDA’s first contention—that the Guidance Documents are a restraint upon conduct and not upon speech—may be addressed quickly. There is little question that the relevant ‘conduct’ is the off-label prescription of drugs by physicians. The distribution of enduring materials and sponsorship of CME seminars addressing and encouraging that conduct is speech. Mailing enduring materials and/or discussing off-label uses is not inherently ‘treacherous’; it is only treacherous (if at all) to the extent that physicians choose to pay attention to the message communicated and alter their prescription practices accordingly. As plaintiff’s counsel aptly noted at oral argument, the activities at issue in this case are only ‘conduct’ to the extent that moving one’s lips is ‘conduct,’ or to the extent that affixing a stamp and distributing information through the mails is ‘conduct.’”).

176. 508 U.S. 476 (1993).

177. *Id.* at 489. The *Mitchell* case was a prosecution against Todd Mitchell, a nineteen-year-old African American man, who was convicted for his part in the brutal beating of a fourteen-year-old white boy. *Id.* at 479–80. After discussing a racially charged scene in the motion picture *Mississippi Burning*, where a white man assaulted a young black boy who was praying, Mitchell asked the group of black men and boys, “Do you all feel hyped up to move on some white people?” *Id.* at 480. Then, when a white teen casually walked by the group, Mitchell said, “You all want to fuck somebody up? There goes a white boy; go get him.” *Id.* At that point, the group ran after the boy and beat him until he was unconscious. *Id.* He remained in a coma for four days. *Id.* After being convicted by a jury for aggravated battery, Mitchell’s two-year sentence was increased to four years under a Wisconsin hate-crime statute that increased the penalties for crimes committed with racial animus. *Id.* at 480–81. The Supreme Court, in a unanimous opinion, rejected Mitchell’s First Amendment challenge to his conviction. *Id.* at 479. Mitchell was not punished for his racist statements, the Court reasoned, but rather for engaging in a brutal beating with a racist intent. *Id.* at 487. Mitchell’s statements were used against him, to be sure, but he was not prosecuted for the content of his statements, but rather for the racist intent that motivated his act of violence. Mitchell’s statements were merely evidence of that intent. Speech is constantly used in criminal and civil trials to prove a person’s motivation or intent. Such evidentiary use of speech, the Court in *Mitchell* held, does not trigger the protections of the First Amendment because the defendant is not being punished for what the defendant said, but for the motive underlying the defendant’s conduct. *Id.* at 487, 489.

178. See *supra* notes 157–58 and accompanying text.

179. See *supra* notes 4–7 and accompanying text.

into interstate commerce.<sup>180</sup> A drug is misbranded, the government reasons, when it fails to include on its label all of its intended uses.<sup>181</sup> In proving what uses are “intended,” the government is entitled to use the words spoken by a drug’s promoters as evidence of their intent.<sup>182</sup> In this sense, prosecutors argue, the speech of a defendant touting a drug’s off-label uses is used only for the evidentiary purpose of establishing the intent to misbrand.<sup>183</sup>

This argument was rejected by the majority opinion written by Judge Denny Chin for the Second Circuit in *Caronia*,<sup>184</sup> but it did win the approval of Judge Debra Ann Livingston in dissent.<sup>185</sup> Who has the better of this battle?

The very invocation of this argument betrays a curious defensive timidity on the part of the government, as if it fears confronting the First Amendment head-on, afraid it will lose. To assert that prosecutions focusing on statements made by defendants promoting the off-label uses of a drug are not really prosecutions *for the statements made* seems to confess misgiving over the legitimacy of such prosecutions *were they in fact for the statements made*, as if the government doubts its own power or premises.<sup>186</sup>

There is also an almost surreal catch-22 quality to the government’s argument. In the classic Joseph Heller novel *Catch-22*,<sup>187</sup> a World War II pilot sought to be grounded from flying future missions, claiming to the army doctor that he (the pilot) was

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180. See *supra* notes 1–2 and accompanying text.

181. See, e.g., *United States v. Caronia*, 703 F.3d 149, 160–61 (2d Cir. 2012).

182. See *supra* note 158 and accompanying text.

183. See *supra* note 158 and accompanying text.

184. *Caronia*, 703 F.3d at 162 (“The FDCA defines misbranding in terms of whether a drug’s labeling is adequate for its intended use, and permits the government to prove intended use by reference to promotional statements made by drug manufacturers or their representatives. Assuming that this approach to the use of evidence of speech is permissible, it affords little support to the government on this appeal because *Caronia* was not prosecuted on this basis. Rather, the government’s theory of prosecution identified *Caronia*’s speech alone as the proscribed conduct.” (footnote omitted) (citation omitted)).

185. *Id.* at 171–72 (Livingston, J., dissenting) (“To demonstrate that *Xyrem* was intended for off-label uses (and thus that it was misbranded) the prosecution in this case relied, *inter alia*, upon *Caronia*’s statements that *Xyrem* could be used to treat ‘insomnia, [f]ibromyalgia[,] periodic leg movement, restless leg, . . . Parkinson’s[,] and . . . MS.’ Because *Caronia*’s speech was used simply as evidence of *Xyrem*’s intended uses, I agree with the government that *Caronia*’s conviction does not run afoul of the First Amendment.” (alterations in original) (footnote omitted)).

186. See *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting) (“If you have no doubt of your premises or your power and want a certain result with all your heart you naturally express your wishes in law and sweep away all opposition. To allow opposition by speech seems to indicate that you think the speech impotent, as when a man says that he has squared the circle, or that you do not care whole-heartedly for the result, or that you doubt either your power or your premises.”).

187. JOSEPH HELLER, *CATCH-22* (1955).

crazy.<sup>188</sup> And indeed, the army took the position that insane pilots could and should be grounded.<sup>189</sup> To be grounded for insanity, however, a pilot had first to ask.<sup>190</sup> This triggered “catch-22” (there’s always a catch), a rule providing that anyone with sufficient presence of mind to ask to be grounded for insanity could not be insane, and thus could not be grounded.<sup>191</sup>

The FDA and its prosecutors invoke a similar circularity. There is nothing illegal about promoting off-label drug uses. But there’s a catch (there’s always a catch). No drug may be promoted if it is misbranded. Any drug promoted for use other than a use approved by the FDA (i.e., any drug promoted for an off-label use) is, by definition, “misbranded.”<sup>192</sup> And much like the military in *Catch-22*, which claims it is not penalizing the pilot merely for *asking* to be grounded, but rather is simply using “the ask” as evidence of the pilot’s sanity, the FDA claims it is not penalizing the promoter of off-label uses for the promotion *itself*, but rather as evidence of misbranding.

While seductively clever, the government’s argument is too clever by half. Here is its flaw: the *Mitchell* evidentiary-use principle is valid *only* when the elements of the underlying crime or tort do not *themselves* require expressive activity.<sup>193</sup> In such cases it is possible to coherently separate the use of speech as evidence of a nonspeech element from the imposition of liability for the speech itself. When expressive activity is a necessary element of the crime or tort, however, no such separation is possible.<sup>194</sup> For example,

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188. *Id.* at 49.

189. *Id.*

190. *Id.*

191. *Id.*

192. See Gentry, *supra* note 35, at 443 (“It is a Catch-22 because if a manufacturer labels its product to reflect the off-label use it knows about the product becomes misbranded and subject to FDA enforcement action. However, if it does not label the product to reflect the off-label use, it is also misbranded or adulterated—since it is being shipped for an intended use not contained in the labeling.”).

193. See *Wisconsin v. Mitchell*, 508 U.S. 476, 487 (1993) (“But whereas the ordinance struck down in *R.A.V.* was explicitly directed at expression (*i.e.*, ‘speech’ or ‘messages’), the statute in this case is aimed at conduct unprotected by the First Amendment.” (citation omitted)).

194. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998) (“In claiming that the speech at issue involves ‘illegal activities,’ the FDA does not seriously press any argument that off-label prescriptions are illegal. Rather, the agency [argues that] . . . a drug or device is considered to be misbranded as a matter of law if it is promoted by the manufacturer for an off-label use. Therefore, when a manufacturer disseminates information about a drug product that diverges from the treatments included on the label, that manufacturer may be engaged in misbranding, which is illegal. However, the tautological nature of this argument exposes its shortcomings. The proper inquiry is not whether the speech violates a law or a regulation, but rather whether the conduct that the speech promotes violates the law.” (citations

libel, civil or criminal, requires publication of a defamatory statement.<sup>195</sup> Speech is an integral element of the offense, and First Amendment principles are thus brought to bear in shaping the contours of libel law. The Supreme Court made this distinction clear in *Mitchell* itself by distinguishing between the hate-crimes law it upheld in *Mitchell* and the hate-speech law it struck down in a prior case, *R.A.V. v. City of St. Paul*,<sup>196</sup> in which expression was an integral element of the offense.<sup>197</sup>

On what side of this divide does prosecution for off-label promotion of drugs fall? The answer is found in the very name of the offense: *misbranding*. Unlike the racially motivated beating in *Mitchell*, conduct that was not intrinsically linked to expression at all, it is *impossible* to conceive of a prosecution for the introduction of a misbranded drug into interstate commerce predicated on the promotion of the drug's off-label uses *without* making the expressive promotion of the off-label use an element of the crime. Distilled to its core, in all off-label prosecutions, the government's case is reduced to this: (1) The FDA requires that all approved uses of a drug be included in its branding, and only a drug listing those approved uses is legally branded; (2) a defendant is accused of promoting the drug for off-label uses, thus violating the requirement that approved uses—and only approved uses—be included in the branding, thereby rendering the defendant guilty of promoting a misbranded drug. Because the prosecution for misbranding arising from off-label promotion cannot be articulated without establishing the off-label *promotion* as a necessary element of the prosecution, the *promotion of the off-label use itself*, like the requirement of a defamatory statement in libel law, is a necessary element of the crime.

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omitted)), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *and appeal dismissed, judgment vacated in part sub nom.* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

195. See, e.g., *Celle v. Filipino Reporter Enters. Inc.*, 209 F.3d 163, 176 (2d Cir. 2000) (“Under New York law, a plaintiff must establish five elements to recover in libel: . . . 2) publication to a third party . . .”); see also 1 RODNEY A. SMOLLA, LAW OF DEFAMATION § 4:77 (2d ed. 1999) (defining “publication”).

196. 505 U.S. 377 (1992).

197. *Mitchell*, 508 U.S. at 487 (“Nothing in our decision last Term in *R.A.V.* compels a different result here. That case involved a First Amendment challenge to a municipal ordinance prohibiting the use of ‘fighting words that insult, or provoke violence, on the basis of race, color, creed, religion or gender.’ Because the ordinance only proscribed a class of ‘fighting words’ deemed particularly offensive by the city—i.e., those ‘that contain . . . messages of bias-motivated hatred,’—we held that it violated the rule against content-based discrimination. But whereas the ordinance struck down in *R.A.V.* was explicitly directed at expression (i.e., ‘speech’ or ‘messages’), the statute in this case is aimed at conduct unprotected by the First Amendment.” (citations omitted) (some internal quotation marks omitted)).

In one decision involving the FDA that did not involve statements regarding off-label drug use, but instead the boundary line between FDA regulation of “drug claims” and mere “health claims” for a product, the D.C. Circuit did appear to accept a somewhat different variation of the FDA’s evidence-of-intent argument. The case, *Whitaker v. Thompson*,<sup>198</sup> involved the promotion of saw palmetto, an extract from the pulp and seed of the dwarf American palm (*serenoa repens*) under a label that the marketers stated was merely a “health claim,” but that the FDA insisted was a “drug claim.”<sup>199</sup> The district court in the case had sided with the FDA in rejecting any First Amendment defense to the prosecution on overly simplistic logic that the D.C. Circuit in *Whitaker* correctly rejected as merely circular.<sup>200</sup> The district court had reasoned that once the FDA determined that the saw palmetto claim was in fact a drug claim, the conclusion that the promotion of the product was an unlawful health claim, not protected by the First Amendment, inexorably followed.<sup>201</sup> As the D.C. Circuit noted, this logic on its face was entirely circular.<sup>202</sup> The D.C. Circuit further ruled, however, that the apparent circularity of the FDA’s position could be rescued by invocation of the evidence-of-intent argument, reasoning that “it is constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that Whitaker’s proposed sale of saw palmetto extract would constitute the forbidden sale of an unapproved drug.”<sup>203</sup>

Whether *Whitaker* is sound on this point is far from clear, as it is not at all plain that the D.C. Circuit’s argument in fact cured the circularity problem. The Supreme Court in *Rubin v. Coors Brewing Co.*,<sup>204</sup> for example, struck down a federal law forbidding the display of alcohol content on beer labels.<sup>205</sup> Yet as the court in *Washington Legal Foundation* correctly observed, if the FDA’s approach to “illegal activity” were adopted, the statute in *Coors* “would have been a satisfactory restriction on commercial speech because

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198. 353 F.3d 947 (D.C. Cir. 2004).

199. *Id.* at 948–49.

200. *Id.* at 953.

201. *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 54 (D.D.C. 2003), *aff’d*, 353 F.3d 947 (D.C. Cir. 2004) (“Because the FDA determined that the saw palmetto claim was a drug claim for disease treatment, it concluded that the claim was an *unlawful* health claim and thus denied Plaintiffs’ petition. As there is no doubt that unlawful speech can be banned under the first step of the *Central Hudson* analysis, the FDA’s prohibition of Plaintiffs’ saw palmetto claim does not violate the First Amendment.”).

202. *Whitaker*, 353 F.3d at 953 (“So worded, the analysis appears, as *Whitaker* points out, completely circular. Because sale pursuant to the claim was ‘unlawful’ under the statute, the speech related to an unlawful activity and enjoyed no First Amendment protection.”).

203. *Id.*

204. 514 U.S. 476 (1995).

205. *Id.* at 478.

printing alcohol content on beer labels would render the product ‘misbranded.’”<sup>206</sup>

Yet even if the *Whitaker* court’s invocation of the evidence-of-intent argument to articulate the boundary between “health claims” and “drug claims” was sound, there is a fundamental difference between the use of the evidence-of-intent claim to settle what is in effect a regulatory boundary dispute and to invoke it simply to declare otherwise truthful speech about lawful activity illegal. The Second Circuit in *Caronia*, analyzing and limiting *Whitaker*, correctly saw it that way. The Second Circuit thus distinguished *Whitaker* and refused to follow its evidence-of-intent argument in the case of off-label drug promotion by observing that *Whitaker* used the speech of the defendant as evidence that the defendant was *marketing saw palmetto as a drug* when the FDA had never approved the substance *as a drug at all*.<sup>207</sup> That is quite different from discussing, truthfully, the extant off-label uses to which doctors are putting a drug that the FDA *has* approved.<sup>208</sup>

In the end, perhaps the most clinching proof that the FDA’s use of the evidence-of-intent argument is spurious is provided by the work of Professors Klasmeier and Redish, who have correctly observed that the FDA does *not* prosecute drug manufacturers for the mere marketing of a drug with the knowledge that a drug is often prescribed by doctors for an off-label use.<sup>209</sup> To the contrary, the uneasy compromise reflected in current FDA policy and practice concedes the legality of such off-label prescription—and even its social utility. To sell the drug is not a crime. To sell the drug and speak of its *approved* uses is not a crime—indeed, the law requires such expression. It is only a crime to sell the drug and speak of its *unapproved* uses. That makes the speech regarding off-label use a necessary element of the crime itself, not mere “evidence of intent.”

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206. *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *and appeal dismissed, judgment vacated in part sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

207. *United States v. Caronia*, 703 F.3d 149, 165 n.10 (2d Cir. 2012).

208. *Id.* (“In *Whitaker*, cited by the dissent, the D.C. Circuit held that the labeling of a product, which was not approved by the FDA as a drug, constituted speech about unlawful activities and therefore did not enjoy First Amendment protection because it was unlawful to sell an unapproved product pursuant to claims about disease treatment. The government does not contend that off-label promotion is in and of itself false or misleading.” (citations omitted)).

209. Klasmeier & Redish, *supra* note 43, at 343 (“[C]ontrary to its assertion, the FDA does *not* employ the fact of off-label promotion merely as *evidence* of the illegal act. Indeed, if the FDA were truly concerned with the manufacturer’s non-expressive act of sale with intent that the product be used off-label, it would logically prohibit *all* sales of a drug widely used off-label, because *any* time the manufacturer sells its drug, it would do so with knowledge that it will be used for off-label purposes.”).

As such, the heightened scrutiny of the First Amendment is activated.

## 2. *Identifying the Appropriate Level of Heightened Scrutiny*

### a. Confining the Definition of Commercial Speech

The United States Supreme Court has never resolved the question of what standard of review ought to apply to speech which, judged by its *content alone*, would surely be deemed political, cultural, religious, or scientific (that is to say, *not* “commercial”), but yet is motivated, at least in substantial part, by the commercial self-interests of the speaker.

It appeared that the Court might answer the question in *Nike, Inc. v. Kasky*,<sup>210</sup> which involved the question of whether Nike’s public statements on labor and employment conditions in third-world factories could be regulated as commercial speech.<sup>211</sup> The Supreme Court initially granted certiorari on “whether a corporation participating in a public debate may ‘be subjected to liability for factual inaccuracies on the theory that its statements are “commercial speech” because they might affect consumers’ opinions about the business as a good corporate citizen and thereby affect their purchasing decisions.”<sup>212</sup> The Court, however, dismissed the writ as improvidently granted on standing and justiciability grounds.<sup>213</sup> So, too, as previously discussed,<sup>214</sup> the Court in *Sorrell* seemed headed for resolution of the issues in the early going, but yielded to the expedient of striking down the challenged Vermont law under the *Central Hudson* commercial-speech test, pretermittting any need to decide whether some higher form of heightened scrutiny was called for.<sup>215</sup>

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210. 539 U.S. 654 (2003).

211. *Id.* at 656–57 (Stevens, J., concurring).

212. *Id.* at 657.

213. *Id.* at 655 (per curiam) (dismissing the writ as improvidently granted); *id.* at 657–58 (Stevens, J., concurring) (“In my judgment, the Court’s decision to dismiss the writ of certiorari is supported by three independently sufficient reasons: (1) the judgment entered by the California Supreme Court was not final within the meaning of 28 U.S.C. § 1257; (2) neither party has standing to invoke the jurisdiction of a federal court; and (3) the reasons for avoiding the premature adjudication of novel constitutional questions apply with special force to this case.”); *see also* Erwin Chemerinsky & Catherine Fisk, *What Is Commercial Speech? The Issue Not Decided in Nike v. Kasky*, 54 CASE W. RES. L. REV. 1143, 1143–45 (2004).

214. *See supra* text accompanying note 97.

215. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011) (“As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.” (citing *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 184 (1999); *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989))).

For multiple reasons, the soundest view of the matter is that strict scrutiny, not the intermediate-level, commercial-speech scrutiny of *Central Hudson*, ought to apply to speech that, judged by its content, is not commercial, notwithstanding the speaker's "mixed motive" of commercial and noncommercial purposes in engaging in the expression. The Supreme Court's formal commercial-speech definitions have focused heavily on whether the speech does *no more* than propose a commercial transaction.<sup>216</sup> Moreover, to the extent that Supreme Court decisions discuss commercial motivation at all, they have focused on whether the speech is *solely* driven by commercial interest.<sup>217</sup> More broadly, the Court has repeatedly insisted that the existence of a commercial motivation does not disqualify speech from the heightened-scrutiny protection it would otherwise deserve.<sup>218</sup> So, too, the Court has warned that when commercial and political elements of speech are inextricably intertwined, the heightened protection applicable to the political speech should be applied lest the political speech be chilled.<sup>219</sup> Most importantly, the constitutional policy arguments that undergird the reduction of protection for commercial speech have no persuasive force when the content of the speech is political, particularly when alternative palliatives, such as disclaimers and warnings, will suitably advance any governmental interests otherwise in play.<sup>220</sup>

Since the early 1970s, no less than twelve Supreme Court opinions have invoked the "no-more" test as the core definition of commercial speech.<sup>221</sup> Many opinions describe the no-more formulation as the "core" or "usual" test.<sup>222</sup> The Court has on one

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216. See *infra* notes 221–23 and accompanying text.

217. See *infra* note 224 and accompanying text.

218. See *infra* note 230 and accompanying text.

219. See *infra* notes 231–32 and accompanying text.

220. See *infra* notes 240–44, 246, 263 and accompanying text.

221. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002) ("Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment." (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993))); *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001) ("[C]ommercial speech, usually defined as speech that does no more than propose a commercial transaction, is protected by the First Amendment." (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976))); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 504 (1996); *United States v. Edge Broad. Co.*, 509 U.S. 418, 426 (1993); *Edenfield*, 507 U.S. at 767; *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993); *Posadas de P.R. Assocs. v. Tourism Co. of P.R.*, 478 U.S. 328, 340 (1986); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983); *Friedman v. Rogers*, 440 U.S. 1, 10 n.9 (1979); *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 98 (1977); *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 762; *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973).

222. *United Foods, Inc.*, 533 U.S. at 409 (stating that commercial speech is "usually defined" under the no-more test); *Discovery Network, Inc.*, 507 U.S. at

occasion described it as *the* test.<sup>223</sup> To be sure, there must be more to legal argument than a string cite; but this is quite a string.

In the context of discussion of off-label uses of drugs, pharmaceutical manufactures and their representatives in many cases plainly will be engaged in *more* than “proposing a commercial transaction” when discussing off-label uses. In fact, they often will be doing *much* more—describing, for the benefit of physicians and their patients, the potential therapeutic benefits and extant experiences and practices of other physicians and patients.

When commercial motivation has been imported as a factor in determining whether expression is commercial speech, the Court has erred on the side of requiring exclusivity, articulating the standard as whether it is “expression related *solely* to the economic interests of the speaker and its audience.”<sup>224</sup> Again, while economic self-interest will often be a motivating factor in the discussion of off-label uses, it strains credulity to assume that this is the *sole* interest in all cases—again for the obvious reason that the advancement of the medical knowledge of the physician and the potential balance of health benefits and risks for the patient will often be a significant animating purpose of the communication.

That the setting in which this professional speech is exchanged may include the potential for commercial sales does not itself justify treating the expression as commercial speech. As the Court explained in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>225</sup>: “Yet the speech whose content deprives it of protection cannot simply be speech on a commercial subject. No one would contend that our pharmacist may be prevented from being heard on the subject of whether, in general, pharmaceutical prices should be regulated, or their advertisement forbidden.”<sup>226</sup>

The Supreme Court has instructed that application of the commercial speech doctrine should rest on “common-sense”

422 (describing the no-more test as the “core notion of commercial speech”); *Bolger*, 463 U.S. at 66 (same).

223. *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473–74 (1989) (“[The speakers] ‘propose a commercial transaction,’ which is the test for identifying commercial speech.” (citation omitted)); *see also* *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 574–75 (2001) (Thomas, J., concurring) (invoking the no-more test as the defining characteristic of commercial speech while arguing that commercial speech should receive the same levels of protection as political speech); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 790 (1985) (Brennan, J., dissenting) (“‘Commercial speech’—defined as advertisements that ‘[do] no more than propose a commercial transaction’—may be more closely regulated than other types of speech.” (alteration in original) (citation omitted)).

224. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 561 (1980) (emphasis added).

225. 425 U.S. 748.

226. *Id.* at 761–62.

distinctions between commercial and noncommercial speech.<sup>227</sup> Accordingly, when applying common sense, it has been said that “advertising the price of a product or arguing its merits” is a “typical” example of commercial speech.<sup>228</sup> Even when narrowed to professional settings, however, the word “typical” is an understatement. The parade of Supreme Court commercial speech decisions involving professionals is entirely comprised of speech either overtly proposing commercial transactions or solely relating to economic interests.<sup>229</sup> To be sure, discussion of off-label drug uses may in some contexts amount to nothing more than meretricious discussion of the “merits” of a “product” and, in such contexts, might well be appropriately treated as pure advertising deserving only the protections of *Central Hudson* and its progeny. But surely that is not *always* the case, and surely there are instances in which even drug manufactures and their representatives, despite their commercial motivation, are best characterized as engaging in speech regarding medical practices—speech deserving heightened levels of First Amendment protection. For as the Supreme Court has emphasized in *Virginia Citizens Consumer Council, Inc.*, “[S]peech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another. Speech likewise is protected even though it is carried in a form that is ‘sold’ for profit.”<sup>230</sup>

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227. *Bolger*, 463 U.S. at 64 (quoting *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 455–56 (1978)).

228. *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 576 (1988).

229. *See, e.g., Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 234 (2010) (advertising by debt relief agencies); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 620 (1995) (attorneys sending targeted mail solicitations); *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation, Bd. of Accountancy*, 512 U.S. 136, 138, 142 (1994) (attorney’s publication of professional certifications in “Yellow Pages” listings and on business cards and other materials).

230. *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 761 (citations omitted); *see also Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 384 (1973) (“[S]peech is not rendered commercial by the mere fact that it relates to an advertisement.”); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 266 (1964) (“The publication here was not a ‘commercial’ advertisement in the sense in which the word was used in *Chrestensen*. It communicated information, expressed opinion, recited grievances, protested claimed abuses, and sought financial support on behalf of a movement whose existence and objectives are matters of the highest public interest and concern.” (emphasis added)); *Smith v. California*, 361 U.S. 147, 150 (1959) (“It is of course no matter than the dissemination takes place under commercial auspices.”); *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495, 501 (1952) (“It is urged that motion pictures do not fall within the First Amendment’s aegis because their production, distribution, and exhibition is a large-scale business conducted for private profit. We cannot agree.”); *Murdock v. Pennsylvania*, 319 U.S. 105, 111 (1943) (“[T]he mere fact that the religious literature is ‘sold’ by itinerant preachers rather than ‘donated’ does not transform evangelism into a commercial enterprise.”).

b. When Commercial and Noncommercial Elements are Intertwined

When commercial and noncommercial elements are both present in a communication, the appropriate constitutional response is to ratchet up, not ratchet down. First Amendment values are better safeguarded by treating the entirety of the message as protected by the First Amendment's demanding strict-scrutiny standard. As the Supreme Court explained in *Riley v. National Federation of the Blind of North Carolina, Inc.*<sup>231</sup>:

It is not clear that a professional's speech is necessarily commercial whenever it relates to that person's financial motivation for speaking. But even assuming, without deciding, that such speech in the abstract is indeed merely "commercial," we do not believe that the speech retains its commercial character when it is inextricably intertwined with otherwise fully protected speech. Our lodestars in deciding what level of scrutiny to apply to a compelled statement must be the nature of the speech taken as a whole and the effect of the compelled statement thereon.<sup>232</sup>

While Justice Breyer may not have been persuasive in his dissenting opinion in *Sorrell*, Justice Breyer's dissent from the dismissal of the *Nike* case, joined by Justice O'Connor, was highly insightful on the issue of how best to treat speech that combines commercial and noncommercial elements. The *Nike* case involved the appropriate constitutional test to be applied to Nike's defense of its labor practices.<sup>233</sup> Justice Breyer observed that the First Amendment "favors application of the . . . public-speech principle, rather than the . . . commercial-speech principle."<sup>234</sup> He noted that "the communications at issue are not purely commercial in nature. They are better characterized as involving a mixture of commercial

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231. 487 U.S. 781 (1988).

232. *Id.* at 795–96 (citation omitted); see also *Greater Balt. Ctr. for Pregnancy Concerns, Inc. v. Mayor of Balt.*, 683 F.3d 539, 560 (4th Cir. 2012) ("[E]ven if some speech of regulated pregnancy centers included commercial elements, strict scrutiny would still apply because those elements would be 'inextricably intertwined' with otherwise fully protected speech."); *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 456 (D.C. Cir. 2012) ("Thus, when the government seeks to restrict *inextricably intertwined* commercial and noncommercial speech, courts must subject the restriction to the test 'for fully protected expression.'" (quoting *Riley*, 487 U.S. at 796)); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 793 (3d Cir. 1999) ("Where the commercial and noncommercial elements of speech are 'inextricably intertwined,' the court must apply the 'test for fully protected expression.'" (quoting *Riley*, 487 U.S. at 796)).

233. *Nike, Inc. v. Kasky*, 539 U.S. 654, 656–57 (2003) (Stevens, J., concurring).

234. *Id.* at 676 (Breyer, J., dissenting).

and noncommercial (public-issue-oriented) elements.”<sup>235</sup> He then noted that even the *least* political of the statements at issue in the case involved commercial and noncommercial elements that were “inextricably intertwined.”<sup>236</sup> After examining the form, content, and regulatory regime, Justice Breyer concluded that heightened scrutiny—not commercial-speech, intermediate scrutiny—should apply:

These three sets of circumstances taken together—circumstances of format, content, and regulatory context—warrant treating the regulations of speech at issue differently from regulations of purer forms of commercial speech, such as simple product advertisements, that we have reviewed in the past. And, where all three are present, I believe the First Amendment demands heightened scrutiny.<sup>237</sup>

### c. The Rationales for the Commercial Speech Doctrine

Finally, in assessing whether all discussion of off-label drug uses by pharmaceutical companies and their agents should be deemed commercial speech, courts should be informed by the rationales for treating commercial speech as deserving of only intermediate scrutiny. When the animating purposes for reduced protection of commercial speech are not germane, reduction of First Amendment protection is not justified.<sup>238</sup> Indeed, precisely because regulators appear so incorrigible in seeking to stretch the application of commercial-speech principles beyond their legitimate bounds, a number of Supreme Court Justices have openly suggested that *Central Hudson* and its progeny be abandoned altogether, thereby providing commercial speech with full First Amendment protection.<sup>239</sup> Even short of that project succeeding, however, the

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235. *Id.*

236. *Id.* at 677.

237. *Id.* at 678–79.

238. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418–19, 424 (1993) (“The major premise supporting the city’s argument is the proposition that commercial speech has only a low value . . . . In our view, the city’s argument attaches more importance to the distinction between commercial and noncommercial speech than our cases warrant and seriously underestimates the value of commercial speech . . . . Not only does Cincinnati’s categorical ban . . . place too much importance on the distinction between commercial and noncommercial speech, but in this case, the distinction bears no relationship *whatsoever* to the particular interests that the city has asserted. It is therefore an impermissible means of responding to the city’s admittedly legitimate interests.”).

239. *See, e.g.*, 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518 (1996) (Thomas, J., concurring in part and concurring in judgment); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 493 (1995) (Stevens, J., concurring in judgment). At various times, as many as four different Justices have expressed doubts about adhering to *Central Hudson*. *See, e.g.*, *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 197 (1999) (Thomas, J., concurring in judgment);

carte blanche application of the commercial speech doctrine to all expressive activity regarding off-label drug uses by pharmaceutical companies and their agents cannot be justified.

The two rationales traditionally invoked to justify the diminished level of First Amendment protection applicable to commercial speech are that the truth of commercial speech is allegedly more “verifiable” than the truth of other forms of expression, and that the economic self-interest of commercial speakers renders commercial speech more “hardy” and thus impervious to being crushed by government regulation.<sup>240</sup> There are good reasons to doubt the cogency of these rationales as general propositions.<sup>241</sup> At the very least, the rationales should have no application when the regulation of the speech in question is paternalistic, as “neither of these rationales provides any basis for permitting government to keep citizens ignorant as a means of manipulating their choices in the commercial or political marketplace.”<sup>242</sup> In the words of Justice Stevens:

Any “interest” in restricting the flow of accurate information because of the perceived danger of that knowledge is anathema to the First Amendment; more speech and a better informed citizenry are among the central goals of the Free Speech Clause. Accordingly, the Constitution is most skeptical of supposed state interests that seek to keep people in the dark for what the government believes to be their own good.<sup>243</sup>

Moreover, however one regards the cogency or coherence of the traditional rationales for reduced protection of commercial speech,<sup>244</sup>

44 *Liquormart, Inc.*, 517 U.S. at 501, 510–14 (majority opinion); *id.* at 517–18 (Scalia, J., concurring in part and concurring in judgment); *id.* at 518 (Thomas, J., concurring in part and concurring in judgment).

240. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 564 n.6 (1980) (“Two features of commercial speech permit regulation of its content. First, commercial speakers have extensive knowledge of both the market and their products. Thus, they are well situated to evaluate the accuracy of their messages and the lawfulness of the underlying activity. In addition, commercial speech, the offspring of economic self-interest, is a hardy breed of expression that is not ‘particularly susceptible to being crushed by overbroad regulation.’” (citation omitted) (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 381 (1977))).

241. *See 44 Liquormart, Inc.*, 517 U.S. at 523 n.4 (Thomas, J., concurring in part and concurring in judgment) (“The degree to which these rationales truly justify treating ‘commercial’ speech differently from other speech (or indeed, whether the requisite distinction can even be drawn) is open to question, in my view.” (citing Alex Kozinski & Stuart Banner, *Who’s Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 634–50 (1990) (questioning the basis and coherence of the distinction))).

242. *Id.*

243. *Rubin*, 514 U.S. at 497 (Stevens, J., concurring in judgment).

244. *See generally* Kozinski & Banner, *supra* note 241, at 652–53 (arguing for strong commercial speech protection); Burt Neuborne, *A Rationale for*

when the rationales plainly do not apply within a specific regulatory regime that appears to sweep within its ambit speech that has a blend of commercial and noncommercial content, there is special force to the argument that the level of First Amendment protection ought not to be reduced below strict scrutiny.

In the context of off-label drug uses, the “truth” that really matters is the safety and efficacy of the drug in treating an off-label malady. This is often a truth extremely difficult to “verify” in the sense that law knows “truth” and “verification,” for resolution often involves complex and nuanced interpretation of medical results and assessments of potential medical risks and benefits, as measured by the physician’s personal judgment regarding the condition of his or her specific patient and the often subjective judgment that enters into the *art* of the healing arts.<sup>245</sup> That a particular off-label use might well be the best possible medical practice in a given situation will often elude “verification” in the cold, hard sense that the Supreme Court apparently contemplated when it touted the peculiar hardness of commercial speech.

Moreover, there has always been a tautological weakness to the argument that commercial speech is uniquely “hardy.” In fact, commercial speech may only be as hardy as the law empowers it to be, and when the government engages in draconian restrictions on speech backed by highly punitive *in terrorem* sanctions, the speech

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*Protecting and Regulating Commercial Speech*, 46 BROOK. L. REV. 437, 447–53 (1980) (arguing that commercial speech deserves greater protection than it currently receives to ensure that the data necessary for economic and political decisionmaking is available); Martin H. Redish, *First Amendment Theory and the Demise of the Commercial Speech Distinction: The Case of the Smoking Controversy*, 24 N. KY. L. REV. 553 (1997) (arguing in favor of commercial speech protection); Martin H. Redish, *The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression*, 39 GEO. WASH. L. REV. 429, 431 (1971) (arguing that certain commercial speech should receive heightened protection); Martin H. Redish & Howard M. Wasserman, *What’s Good for General Motors: Corporate Speech and the Theory of Free Expression*, 66 GEO. WASH. L. REV. 235 (1998) (arguing against the exclusion of corporate speech from First Amendment protection); Jeffrey M. Shaman, *Revitalizing the Clear-and-Present-Danger Test: Toward a Principled Interpretation of the First Amendment*, 22 VILL. L. REV. 60 (1976) (arguing in favor of treating all speech as protected under rigorous heightened review standards, without regard to categories such as “commercial speech” or “libel”); Rodney A. Smolla, *Information, Imagery, and the First Amendment: A Case for Expansive Protection of Commercial Speech*, 71 TEX. L. REV. 777 (1993) (arguing for strong commercial speech protection).

245. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 70 (D.D.C. 1998) (“A physician’s livelihood depends upon the ability to make accurate, life-and-death decisions based upon the scientific evidence before them. They are certainly capable of critically evaluating journal articles or textbook reprints that are mailed to them, or the findings presented at CME seminars.”), *amended by* 36 F. Supp. 2d 16 (D.D.C. 1999), *and appeal dismissed, judgment vacated in part sub nom.* *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

is hardly hardy at all.<sup>246</sup> As Judge Lamberth colorfully put it in *Washington Legal Foundation*, “In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, [the] FDA exaggerates its overall place in the universe.”<sup>247</sup> Judge Lamberth is correct, but unless and until that self-appointed, exaggerated place in the universe is placed in check by courts, the speech of those who dare defy the FDA is precarious at best, and not well characterized as “hardy.”

### C. *A Tiered Approach to Determining the Level of Scrutiny*

In the final analysis, determination of the proper level of First Amendment heightened scrutiny, as applied to the discussion of off-label drug uses, may best be resolved through the recognition that one size does not fit all and differing tiers of First Amendment protection may apply in differing circumstances. When the content of the speech is the reproduction of scientific discourse in its traditional sense—the sort of discussion at issue in the *Washington Legal Foundation* case involving distribution of medical journal and treatise articles and similar scientific data<sup>248</sup>—the speech should surely be treated as scientific discourse receiving the highest levels of First Amendment protection, the regulation of which must withstand traditional strict-scrutiny judicial review.<sup>249</sup> And indeed, the government’s concession of defeat on the appeal in *Washington Legal Foundation*<sup>250</sup> and its issuance of new guidance<sup>251</sup> (including its new proposed draft guidance<sup>252</sup>) appear to acknowledge, however grudgingly, that the highest levels of First Amendment protection must apply to such speech.<sup>253</sup>

A second tier of First Amendment protection, to which strict scrutiny also ought to apply, involves promotional discussion of off-label drug uses *for which government reimbursement is currently provided* under government health care programs such as Medicare and Medicaid. When the U.S. government, through one of its voices,

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246. See Rodney A. Smolla, *Free the Fortune 500! The Debate over Corporate Speech and the First Amendment*, 54 CASE W. RES. L. REV. 1277, 1290 (2004) (“There is an arguable element of question-begging to this point, however, for advertisers might just as plausibly assert that commercial speech is only as hardy as the law empowers it to be, and that if certain advertising practices are prohibited by law and the sanctions sufficiently enforceable, no degree of perceived hardness will enable the speech to persevere.”).

247. *Wash. Legal Found.*, 13 F. Supp. 2d at 67.

248. See *supra* text accompanying notes 114–36.

249. See *supra* text accompanying notes 72–74, 87.

250. See *supra* text accompanying notes 131–36.

251. See *supra* text accompanying note 38.

252. See *supra* note 37.

253. See *supra* notes 38, 42–43 and accompanying text.

recognizes that a particular drug use is sufficiently appropriate as accepted medical practice to warrant reimbursement, it cannot, through another voice, seek to chill the free flow of information regarding that use, even though the pharmaceutical company or its agents engaging in the distribution of that information may have commercial motivations.

Congress, for example, has recognized (and even encouraged) off-label prescription by requiring Medicare and Medicaid to reimburse when drugs are prescribed for unapproved but “medically accepted” uses.<sup>254</sup> Particularly when discussion of such accepted uses is directed to a sophisticated audience, such as prescribing physicians or payers, the government’s interest in restricting truthful and non-misleading speech is at its lowest ebb, and the corresponding First Amendment interests in allowing the free flow of information is at its highest. In such instances, the commercial and noncommercial elements of the communication ought to be deemed inextricably intertwined,<sup>255</sup> and strict scrutiny applied.<sup>256</sup>

The third tier of heightened scrutiny, in which the *Central Hudson* commercial-speech standard is appropriately applied, should be limited to stripped-down sound bites describing off-label uses with little additional medical or scientific elaboration, in which there is no additional validation, such as that existing in the case of governmental recognition of the appropriateness of reimbursement. Courts faced with expression in this tier may be more inclined to treat the speech as commercial and test the regulation under *Central Hudson*.

As set forth below in Subpart II.D, however, when such speech is truthful and not misleading, the near-absolute restrictions

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254. See 42 U.S.C. § 1395x(t) (2012) (Medicare); 42 U.S.C. § 1396r-8(d)(1)(B)(i), (g)(1)(B) (2012) (Medicaid). In *United States ex rel. Simpson v. Bayer Corp.*, the court held that reimbursement decisions depend not on whether a drug is prescribed for an off-label use, but rather on whether a use is “medically accepted,” and that off-label use is “medically accepted,” and government healthcare programs are required to provide reimbursement, if the use is supported by any of the government-designated compendia or peer-reviewed medical literature. No. 05-3895 (JLL) (JAD), 2014 WL 1418293, at \*8 (D.N.J. Apr. 11, 2014).

The Court agrees with Bayer. Indeed, the above quoted [Medicare Benefit Policy Manual] language states *only* that a carrier should consider the major drug compendia, and Simpson cites to no binding authority supporting her restrictive reading of that language. Moreover, an off-label drug use is considered medically accepted under the Medicaid statute if that use is supported by “one or more citations” in the major drug compendia.

*Id.* (citing § 1396r-8(k)(6)); see also *United States ex rel. Worsfold v. Pfizer Inc.*, No. 09-11522-NMG, 2013 WL 6195790, at \*3 (D. Mass. Nov. 22, 2013) (noting that medical acceptance of an off-label use depends on whether that particular use is included in one of the compendia).

255. See *supra* note 232 and accompanying text.

256. See *supra* notes 231–32 and accompanying text.

imposed by the current FDA regime cannot withstand First Amendment scrutiny under *Central Hudson* and still ought to be struck down.

#### D. *Central Hudson Cannot Save the FDA*

##### 1. *Overview*

The commercial-speech standard emanating from *Central Hudson* may be applied to the FDA's effective proscription of off-label drug promotion, either because a court determines, on the merits, that the speech is commercial, or because the court avoids the issue by deciding the speech is protected by the First Amendment under *Central Hudson* in any event. If *Central Hudson* is applied, the FDA's current draconian approach to banning off-label uses should be held unconstitutional.

The Supreme Court's holdings in *Western States* and *Sorrell* and the various lower court rulings that have touched on the issue have already been thoroughly canvassed in this Article and are enough to make a convincing case that the FDA's regime is unconstitutional under *Central Hudson*.<sup>257</sup> The holdings of those judicial decisions will not be repeated here. Rather, by way of conclusion, the key conclusions of those cases, and the larger First Amendment principles they apply, will be distilled and summarized.

##### 2. *Lawful and Not Misleading*

The first critical point involves the application of the first prong of *Central Hudson*, requiring that the speech be about lawful activity and not be false or misleading.<sup>258</sup> As previously discussed, courts have uniformly seen through the circular and spurious argument that discussion of off-label uses involves "illegal activity," which is simply a variant of the equally spurious evidence-of-intent argument.<sup>259</sup>

The requirement that the speech not be misleading, however, deserves more serious comment. *Some* promotion of off-label uses might well prove false or misleading, as when the promoter of an off-label use misrepresents scientific data. The indictment in *Harkonen* charged such fraudulent marketing, for example, and for that reason was not dismissed.<sup>260</sup> The argument advanced in this Article is that the First Amendment should be brought to bear against the FDA's blanket, across-the-board regime when, as in *Caronia*, the speech is not false or misleading.

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257. See *supra* text accompanying note 52.

258. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

259. See *supra* text accompanying notes 119, 172–209.

260. *United States v. Harkonen*, No. C 08-00164 MHP, 2009 WL 1578712, at \*8 (N.D. Cal. June 4, 2009); see also *supra* text accompanying notes 144–50.

### 3. *Substantial Interests*

It is a rare case under *Central Hudson* in which the government loses under prong two of the test, requiring that the government regulation be based on a substantial governmental interest. Indeed, parties challenging government regulation under *Central Hudson* almost never bother to contest prong two. When the governmental interest advanced is stated at a high enough level of abstraction or generality, it will invariably have a sufficiently “mom-and-apple-pie” aura about it as to be essentially inoculated against attack. In any case involving FDA regulation, for example, no court will fuss over the claim that protecting “public health” is a substantial governmental interest.<sup>261</sup> It is when the *Central Hudson* test moves to prongs three and four—and the government is forced to descend from such gauzy formulations as “public health” to a bill of particulars that explains exactly how its regime directly and materially advances that interest and how it is narrowly tailored to effectuate it—that the rubber meets the road.

### 4. *Direct and Material Advancement*

FDA regulation of off-label uses fails prong three of *Central Hudson* to the extent that the FDA’s real motivation is simply paternalistic—an effort to influence the behavior of physicians and patients by manipulating the free flow of information to them. The entire projection of modern commercial-speech jurisprudence stands against such paternalism.<sup>262</sup> And in opinion after opinion germane to off-label advertising, such paternalism has been condemned.<sup>263</sup>

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261. See, e.g., *United States v. Caronia*, 703 F.3d 149, 165–66 (2d Cir. 2012) (“[T]he government’s asserted interests in drug safety and public health are substantial.”).

262. See *supra* text accompanying note 60.

263. See, e.g., *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011) (“[A] State’s failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction.”); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 370–71 (2002) (striking down a prohibition on advertising compounded drugs as more extensive than necessary to achieve the government’s interests); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553–71 (2001) (striking down some restrictions on tobacco advertising and sustaining others); *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 183–96 (1999) (striking down casino gambling advertising limitations); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996) (striking down liquor advertisement restrictions); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 480–91 (1995) (striking down beer advertising regulations); *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation*, 512 U.S. 136, 142–49 (1994) (striking down restrictions on accountancy advertising); *Edenfield v. Fane*, 507 U.S. 761, 765–77 (1993) (striking down commercial speech limitations on accountants); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416–31 (1993) (striking down restrictions on news racks for commercial flyers and publications); *Peel v. Att’y Registration & Disciplinary Comm’n*, 496 U.S. 91, 110–11 (1990) (declaring unconstitutional a regulation

Even the one governmental interest that some courts have found attractive—the interest of the FDA in encouraging pharmaceutical manufacturers to move drugs along from off-label uses to on-label uses<sup>264</sup>—is not “directly and materially advanced” in the manner required under *Central Hudson* by the FDA’s current near-absolutist regime. Given the extremely demanding and onerous process for obtaining approval of on-label uses,<sup>265</sup> accepting this argument as enough to trump the First Amendment rights of drug companies would effectively eviscerate *Central Hudson*. Because it is plain that off-label prescription of drugs is often the appropriate standard of medical care,<sup>266</sup> particularly for certain diseases such as cancer,<sup>267</sup> courts have properly seen a powerful and telling “disconnect,” articulated in this Article as grounded in principles of federalism, between the FDA’s lack of authority to regulate medical practice and its manipulation of information regarding off-label use, which amounts to a back-handed and paternalistic intrusion into medical practice.<sup>268</sup> In short, the FDA

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banning lawyer advertisement of certification by the National Board of Trial Advocacy as misleading); *Shapero v. Ky. Bar Ass’n*, 486 U.S. 466, 472–78 (1988) (declaring unconstitutional a regulation banning solicitation for legal business mailed on a personalized or targeted basis to prevent potential clients from feeling undue duress to hire the attorney); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637–56 (1985) (striking down some restrictions on lawyer advertising and upholding others); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64–75 (1983) (declaring unconstitutional a statute banning unsolicited mailings advertising contraceptives to aid parental authority over teaching their children about birth control); *In re R. M. J.*, 455 U.S. 191, 199–207 (1982) (declaring unconstitutional regulations limiting the precise names of practice areas lawyers can use in ads and identifying the jurisdictions a lawyer is licensed in as misleading); *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 561–72 (striking down restrictions on advertising statements by public utilities); *In re Primus*, 436 U.S. 412, 421–39 (1978) (striking down restrictions on the solicitation of legal business on behalf of the ACLU); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 363–84 (1977) (declaring unconstitutional a regulation banning lawyer advertisement of prices for routine legal services as misleading); *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 91–98 (1977) (declaring unconstitutional a regulation banning the placement of “for sale” signs in the front lawns of houses in order to prevent the town from losing its integrated racial status); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–73 (1976) (striking down restrictions on pharmaceutical advertising); *Bigelow v. Virginia*, 421 U.S. 809, 818–29 (1975) (striking down restrictions on abortion advertising).

264. See *supra* text accompanying note 123.

265. See *supra* text accompanying notes 3–4, 30; see also *supra* Subpart I.C.

266. See *supra* text accompanying notes 31–35.

267. See *supra* text accompanying note 33.

268. See *44 Liquormart, Inc.*, 517 U.S. at 520 (Thomas, J., concurring in part and concurring in judgment) (“In case after case following *Virginia Bd. of Pharmacy*, the Court, and individual Members of the Court, have continued to stress the importance of free dissemination of information about commercial choices in a market economy; the antipaternalistic premises of the First

cannot admit, as it must, that off-label uses are often appropriate and valuable and, at the same time, argue persuasively that its limits on expression regarding off-label use directly and materially advance its overall drug-approval process.

##### 5. *Narrow Tailoring*

Finally, and perhaps most significantly, the FDA's current, effective prohibition on off-label uses fails prong four of *Central Hudson* because there are so many readily available alternatives to what is in actual operation a blanket ban that courts will inevitably, and appropriately, find the current FDA position untenable.

The narrow-tailoring requirement applicable under prong four of *Central Hudson* is not as demanding as the similarly worded "narrow tailoring" associated with strict scrutiny, which often requires that the government employ the "least restrictive means" of regulation at its avail.<sup>269</sup> Rather, in commercial-speech cases, what is required is a reasonable or proportionate "fit" between means and ends:

What our decisions require is a "fit" between the legislature's ends and the means chosen to accomplish those ends—a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is "in proportion to the interest served"; that employs not necessarily the least restrictive means but, as we have put it in the other contexts discussed above, a means narrowly tailored to achieve the desired objective. Within those bounds we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.<sup>270</sup>

Despite the seemingly permissive and generous nature of this standard, the reality on the ground is that prong four of *Central Hudson* is often invoked to strike down regulation of commercial speech and, as demonstrated previously in this Article, has often been invoked to strike down the FDA's off-label marketing restrictions because courts are able to readily identify alternatives that burden less speech.<sup>271</sup>

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Amendment; the impropriety of manipulating consumer choices or public opinion through the suppression of accurate 'commercial' information; the near impossibility of severing 'commercial' speech from speech necessary to democratic decisionmaking; and the dangers of permitting the government to do covertly what it might not have been able to muster the political support to do openly.").

269. See *Bernal v. Fainter*, 467 U.S. 216, 219 (1984).

270. *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989) (citations omitted).

271. See *supra* text accompanying notes 166–70.

Disclaimers and warnings are the most obvious cures, and the cures heavily favored in First Amendment doctrine.<sup>272</sup> In *Pearson v. Shalala*,<sup>273</sup> for example, the District of Columbia Circuit struck down FDA restrictions on health claims by dietary supplement manufacturers, holding that the FDA's restrictions failed the final prong of *Central Hudson* because disclaimers, such as "The FDA does not approve this claim," would accomplish the government's

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272. See, e.g., *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 n.14 (1985) ("We reject appellant's contention that we should subject disclosure requirements to a strict 'least restrictive means' analysis under which they must be struck down if there are other means by which the State's purposes may be served. Although we have subjected outright prohibitions on speech to such analysis, all our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech. Because the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed, we do not think it appropriate to strike down such requirements merely because other possible means by which the State might achieve its purposes can be hypothesized." (citation omitted)); *Borgner v. Brooks*, 284 F.3d 1204, 1214 (11th Cir. 2002) ("Disclaimers are significantly different than outright bans on commercial speech; they are not as broad and less likely to be disproportionate to the ends the government seeks. Courts have been more tolerant of regulations mandating disclosure requirements than they have been of regulations that impose a total ban on commercial speech." (citing *Zauderer*, 471 U.S. at 651)); *Commodity Trend Serv., Inc. v. Commodity Futures Trading Comm'n*, 233 F.3d 981, 994 (7th Cir. 2000) ("The government can impose affirmative disclosures in commercial advertising if these are reasonably related to preventing the public from being deceived or misled."); *Commodity Futures Trading Comm'n v. Vartuli*, 228 F.3d 94, 108 (2d Cir. 2000) (sustaining disclosure requirements when they are "reasonably related to the government's interest in preventing consumers from being deceived"); *Abramson v. Gonzalez*, 949 F.2d 1567, 1577 (11th Cir. 1992) ("Admittedly, some danger exists that the public will be misled if the plaintiffs are permitted to hold themselves out as psychologists. Yet when the first amendment is at issue, 'the preferred remedy is more disclosure, rather than less.'" (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977))); *Bingham v. Hamilton*, 100 F. Supp. 2d 1233, 1240-41 (E.D. Cal. 2000) ("Even assuming that the Dental Board had made an adequate evidentiary showing of the potential for deception, it has failed to show that a total prohibition is necessary. The Dental Board's concern as to sponsorship could be addressed by requiring disclosure in the advertisement . . ."); *Bulldog Investors Gen. P'ship v. Sec'y of the Commonwealth*, 953 N.E.2d 691, 704 (Mass. 2011) ("[T]he Supreme Court . . . views 'as dubious any justification that is based on the benefits of public ignorance,' and it has prescribed that the 'preferred remedy' for the risk to the public of inaccurate or incomplete information 'is more disclosure, rather than less.'" (quoting *Bates*, 433 U.S. at 375)); *Walker v. Bd. of Prof'l Responsibility of the Supreme Court of Tenn.*, 38 S.W.3d 540, 545 (Tenn. 2001) ("This regulation does not prohibit or limit speech; instead it requires more speech by way of an explanatory disclaimer. The fact that the regulation requires disclosure rather than prohibition tends to make it less objectionable under the First Amendment.").

273. 164 F.3d 650 (D.C. Cir. 1999).

goals.<sup>274</sup> And as the court in *Caronia* explained, there are numerous alternative regulatory avenues available to the FDA that would advance its interest in the integrity of its drug-approval process and in better informing physicians and patients without running afoul of the First Amendment.<sup>275</sup>

#### CONCLUSION

Assume, for the sake of argument, that the FDA could, if authorized by Congress under its Commerce Clause power, actually take the extreme step of banning outright all off-label drug prescriptions. Off-label prescriptions would then be illegal contraband, like marijuana or cocaine,<sup>276</sup> and advertising of such illegal drugs would not be protected under the First Amendment.<sup>277</sup>

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274. *Id.* at 659 (“The government’s general concern that, given the extensiveness of government regulation of the *sale* of drugs, consumers might assume that a claim on a supplement’s label is approved by the government, suggests an obvious answer: The agency could require the label to state that ‘The FDA does not approve this claim.’ Similarly, the government’s interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied—at least ordinarily—by inclusion of a prominent disclaimer setting forth those adverse effects.”).

275. *United States v. Caronia*, 703 F.3d 149, 167–68 (2d Cir. 2012).

276. *See Gonzales v. Raich*, 545 U.S. 1, 22 (2005) (upholding the power of Congress, under the Commerce Clause, to ban the local cultivation and use of marijuana, even in states in which such use is legal for medical purposes).

277. *Central Hudson’s* first prong requires that the speech concern *legal* activity. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 563–64 (1980). Prohibitions on the use of paraphernalia for illegal drug use are routinely upheld by courts. *See, e.g., Wash. Mercantile Ass’n v. Williams*, 733 F.2d 687 (9th Cir. 1984) (upholding a state’s ban on advertisements for the sale of drug paraphernalia and holding that the government may restrict commercial speech when the activity referred to is illegal); *Nova Records, Inc. v. Sendak*, 706 F.2d 782 (7th Cir. 1983) (upholding an Indiana drug paraphernalia statute and finding that the law did not offend the First Amendment by failing to include a scienter requirement in the forfeiture provision); *Camille Corp. v. Phares*, 705 F.2d 223 (7th Cir. 1983) (upholding a city ordinance that banned drug paraphernalia advertising, finding that the “should reasonably know” language and the “legitimate supplier” distinction of the ordinance withstood First, Fifth, Eighth and Fourteenth Amendment challenges); *Stoianoff v. Montana*, 695 F.2d 1214 (9th Cir. 1983) (upholding the Montana Drug Paraphernalia Act, finding that First Amendment rights do not apply when speech is of a commercial nature and promotes or encourages unlawful activity); *Weiler v. Carpenter*, 695 F.2d 1348 (10th Cir. 1982) (upholding a New Mexico drug paraphernalia act under the commercial speech doctrine); *Kan. Retail Trade Coop. v. Stephan*, 695 F.2d 1343 (10th Cir. 1982) (upholding a Kansas ban on drug paraphernalia advertising under the commercial speech doctrine); *Gen. Stores, Inc. v. Bingaman*, 695 F.2d 502 (10th Cir. 1982) (holding that the right of the government to regulate commercial speech through a New Mexico drug paraphernalia statute outweighed the incidental effect on protected First Amendment speech); *Tobacco Accessories & Novelty Craftsman Merchs. Ass’n of La. v. Treen*, 681 F.2d 378 (5th Cir. 1982) (holding a Louisiana drug paraphernalia law constitutional because the statute was supported by

There was a brief moment in the history of evolving First Amendment doctrine in which the Supreme Court employed the maxim that a “greater power includes the lesser” to threaten the very underpinnings of constitutionally protected speech motivated by commercial interests. In *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*,<sup>278</sup> the Court, in a highly paternalistic mood, upheld a ban on advertising by casinos within Puerto Rico, even though casino gambling was legal in Puerto Rico, and, indeed, even though Puerto Rican casinos were allowed to advertise on the American mainland.<sup>279</sup> The government of Puerto Rico could have banned casino gambling altogether, the Court reasoned, and “the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling.”<sup>280</sup>

If the “greater-power-includes-the-lesser-power” notion of *Posadas* were still good law, the FDA’s ban on off-label drug uses would not violate the First Amendment, even though it has chosen *not* to prohibit off-label use of prescriptions, because it *could* prohibit those uses if it chose. The greater power to ban off-label use would necessarily include the lesser power to ban advertising regarding such use.

The theory of *Posadas*, however, has been repudiated and is no longer good law.<sup>281</sup> More contemporary free-speech decisions have rejected the paternalism of *Posadas*, and First Amendment theory

legitimate state interests and was neither vague nor overbroad); *Record Head Corp. v. Sachen*, 682 F.2d 672 (7th Cir. 1982) (holding that a Wisconsin drug paraphernalia ordinance was unconstitutionally vague in its provisions, but that such ordinances do not violate the Equal Protection Clause or the First Amendment under the commercial speech doctrine); *New Eng. Accessories Trade Ass’n, Inc. v. City of Nashua*, 679 F.2d 1 (1st Cir. 1982) (holding that a New Hampshire drug paraphernalia statute should be evaluated under the commercial speech doctrine, which did not protect speech regarding an illegal act); *Fla. Businessmen for Free Enter. v. City of Hollywood*, 673 F.2d 1213 (11th Cir. 1982) (holding that a Florida law concerning drug paraphernalia was tailored narrowly enough to be construed constitutionally under the commercial speech doctrine, which did not protect the dissemination of products used in illegal acts); *High Gear & Toke Shop v. Beacom*, 689 P.2d 624 (Colo. 1984) (upholding a statute prohibiting advertising intended to promote the sale of equipment, products, or materials designed and intended for use as drug paraphernalia); *State v. Newman*, 696 P.2d 856 (Idaho 1985) (holding that a drug paraphernalia act banning sales of drug paraphernalia was constitutional because illegal commercial acts are not protected by the First Amendment).

278. 478 U.S. 328 (1986).

279. *Id.* at 330–33.

280. *Id.* at 345–46.

281. 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 511–12 (1996) (plurality opinion); *Coyote Publ’g, Inc. v. Miller*, 598 F.3d 592, 600 (9th Cir. 2010) (“Subsequent decisions, however, have cast severe doubt on the [*Posadas*] rule that restrictions on advertising of vice activity may escape the intermediate scrutiny of *Central Hudson* simply by virtue of the fact that they target vice.”).

and doctrine have passed it by. Justice Stevens, in his opinion in *44 Liquormart, Inc. v. Rhode Island*,<sup>282</sup> elegantly explained why:

Although we do not dispute the proposition that greater powers include lesser ones, we fail to see how that syllogism requires the conclusion that the State's power to regulate commercial *activity* is "greater" than its power to ban truthful, nonmisleading commercial *speech*. Contrary to the assumption made in *Posadas*, we think it quite clear that banning speech may sometimes prove far more intrusive than banning conduct. As a venerable proverb teaches, it may prove more injurious to prevent people from teaching others how to fish than to prevent fish from being sold. Similarly, a local ordinance banning bicycle lessons may curtail freedom far more than one that prohibits bicycle riding within city limits. In short, we reject the assumption that words are necessarily less vital to freedom than actions, or that logic somehow proves that the power to prohibit an activity is necessarily "greater" than the power to suppress speech about it.<sup>283</sup>

Why tell this story here? The answer is plain. The FDA seeks to do what the Supreme Court once permitted in *Posadas*, but now does not permit. As demonstrated in this Article, this is evidenced by a long train of Supreme Court and lower-court decisions, particularly the decisions in *Sorrell*<sup>284</sup> and *Western States*.<sup>285</sup> The First Amendment no longer tolerates governmental restrictions on the free flow of information about activity that the government conceivably could prohibit, but has not. There is a "put-up-or-shut-up" dynamic at work—when the government lacks the political will to ban an activity, it concomitantly lacks the First Amendment authority to ban truthful and non-misleading speech regarding that activity.<sup>286</sup>

The FDA, of course, is not about to ban off-label uses of prescription drugs. This would be bad medicine, bad public policy, bad politics, and bad federalism. The FDA may certainly punish demonstrably false or misleading claims about off-label uses. It may require disclaimers, warnings, or employ other regulatory devices that advance public health without restricting the free flow of

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282. 517 U.S. 484.

283. *Id.* at 511 (plurality opinion) (footnote omitted).

284. *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011).

285. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

286. *See United States v. Caputo*, 517 F.3d 935, 939 (7th Cir. 2008) ("The Court once held that gambling is a special case, but the status of that rule is doubtful. The Court suggested in *Western States Medical* that Congress either adopt a substantive rule prohibiting compounding (or, here, prohibiting off-label uses) or allow the FDA to supply warnings via its own speech. Compelling private persons to toe the government's line, or shut up, is unconstitutional, the Court held." (citations omitted)).

constitutionally protected information. It may not, however, continue to enforce its current policies, which amount to an outright ban on trafficking in information about off-label uses by pharmaceutical companies. "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."<sup>287</sup>

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287. *W. States Med. Ctr.*, 535 U.S. at 373.