

# Sex, Drugs, and Commercial Speech: The Contested Discourse of Truvada

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*In January 2016, Michael Weinstein, president of the AIDS Healthcare Foundation (AHF), a globally influential HIV/AIDS policy organization, urged the Food and Drug Administration (FDA) to take legal action against Gilead Sciences, manufacturer of the HIV-prophylactic medication Truvada, for violations of the Food, Drug, and Cosmetic Act (FDCA). The violations the letter enumerated were in reference to a Gilead-sponsored video advertising campaign that, per the allegations, misrepresented the proper usage regimen of Truvada. Under constitutional precedent governing commercial speech vis-à-vis pharmaceutical marketing, such misrepresentation of a drug's constitutes "off-label" speech, a form of promotional advertising subject to criminal sanctions. This Comment explores the implications of AHF's claims in the context of recent changes to commercial speech doctrine. It contends that should the FDA act upon the allegations contained in AHF's letter it would require the agency to argue in favor of a significant misapplication of commercial-speech doctrine, particularly with regard to the branding provisions of the FDCA. Because the FDA continues to harden its stance on off-label use and speech, and in light of policy changes potentially encouraged by the new presidential administration, an examination of how the FDA might respond to allegations of FDCA violation is crucial. This Comment concludes by observing that the significance of this analysis is only heightened when the drug under legal scrutiny is one like Truvada — a prophylactic medication potentially able to drastically reduce the rate of HIV contraction if rendered more widely available.*

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## I. INTRODUCTION

In January 2016, Michael Weinstein, president of the AIDS Healthcare Foundation (AHF), the world's largest and most influential HIV/AIDS advocacy organization,<sup>1</sup> wrote a letter to the Food and Drug Administration (FDA) urging the agency to take legal action against Gilead Sciences (Gilead), the biopharmaceutical company that maintains exclusive patent rights over the drug Truvada, for misbranding and promoting false information regarding the drug's proper medical use.<sup>2</sup> AHF's primary allegations referenced a video advertising campaign that, per the organization, misrepresented the proper usage regimen of Truvada, in violation of the Food, Drug, and Cosmetic Act (FDCA).<sup>3</sup> This misrepresentation would, under commercial-speech precedent vis-à-vis pharmaceutical drugs, constitute "off-label" speech, a form of promotional advertising subject to criminal sanctions.<sup>4</sup> A pharmaceutical company engages in off-label speech when it encourages the use of a drug in a manner inconsistent with that

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1. *AHF Marks World AIDS Day with HIV Testing & Awareness Events in 32 Countries; Celebrates Milestone: 500,000 Lives in Care*, BUS. WIRE (Dec. 1, 2015, 12:59 AM), <http://www.businesswire.com/news/home/20151130006475/en/AHF-Marks-World-AIDS-Day-HIV-Testing> [<https://perma.cc/BF9D-HJ4Y>] (describing AHF as "the largest global AIDS organization" that services over 500,000 persons in thirty-six countries around the world).

2. Letter from Michael Weinstein, Pres., AIDS Healthcare Foundation, to Stephen Ostroff, Acting Comm'r, Food and Drug Administration 3 (Jan. 13, 2016) [hereinafter AHF Letter], available at <http://www.fdanews.com/ext/resources/files/2016/01/01-27-16-Letter.pdf> [<https://perma.cc/45AT-FSTN>] ("In contravention of statute and regulations, Gilead launched an ad campaign to mislead viewers into believing that Truvada is safe . . . for use on a situational basis despite knowing that the drug is not approved for such use.").

3. See 21 U.S.C. § 331(a) (2012) (prohibiting the introduction "into interstate commerce of any . . . drug . . . that is adulterated or misbranded"); 21 U.S.C. § 352(a) (2012) (stating a drug shall be deemed misbranded if "its labeling is false or misleading in any particular").

4. See, e.g., 21 U.S.C. § 333(a)(2) (2012) ("[I]f any person commits such a violation . . . such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both."); U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: DISTRIBUTING SCIENTIFIC AND MEDICAL PUBLICATIONS ON UNAPPROVED NEW USES — RECOMMENDED PRACTICES 4 (2014) [hereinafter FDA GUIDANCE] (stating an approved drug intended for an unapproved use "would be considered misbranded, because the drug does not meet the regulatory exemptions from the requirement that its labeling bear 'adequate directions for use'" (footnote omitted)); Joseph Leghorn et al., *The First Amendment and FDA Restrictions on Off-Label Uses: The Call for a New Approach*, 63 FOOD & DRUG L.J. 391, 393 (2008) (defining off-label use as the prescribing of a drug "for an indication, dosage and/or population that has not been approved by FDA and is therefore not listed on the approved product labeling" (footnote omitted)).

approved by the FDA and presented on the drug's labeling.<sup>5</sup> Based on Gilead's putative off-label advertising, AHF insisted the FDA admonish Gilead publically, mandate that Gilead correct the misinformation it has spread, and issue any and all legally permissible sanctions.<sup>6</sup>

This Comment will explore the implications of the claims AHF proffers in its letter to the FDA; if heeded by the agency, AHF's call to action would require significant misapplication of commercial-speech doctrine by the FDA, particularly with regard to the branding provisions of the FDCA. As one of the most influential voices on HIV/AIDS advocacy globally, AHF is in a unique and potent position to propel or strain policy narratives based on their alignment with the organization's political agenda. It is because of AHF's position as a central actor within policy debates and legal discourse addressing HIV/AIDS that its demand for legal intervention against Gilead, however misled, cannot be dismissed as facile pandering or hyperbole. Indeed, as the FDA continues to harden its stance on off-label use and off-label speech under the new presidential administration,<sup>7</sup> the question of whether a drug as important as Truvada — a prophylactic medication able to drastically reduce the rate of HIV contraction — may be forcibly removed from interstate commerce is one that echoes throughout the nodal point of commercial speech doctrine and health law.

## II. AHF AND THE LEGAL ASSAULT ON GILEAD AND TRUVADA

### A. THE HIV/AIDS EPIDEMIC AND PARADIGMS OF TREATMENT

In 1982, a crisis emerged that permanently altered the juncture at which queer male bodies and American law met. Throughout the first five months of 1982, physicians documented a constellation of physiological symptoms primarily affecting individuals in urban settings that bore no relationship to preexist-

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5. Leghorn et al., *supra* note 4, at 393.

6. AHF Letter, *supra* note 2, at 3.

7. Benjamin A. Zegarelli, *FDA Hardens Its Stance on Intended Use and Off-Label Use and Industry Responds*, NAT'L L. REV. (Feb. 17, 2017), <http://www.natlawreview.com/article/fda-hardens-its-stance-intended-use-and-label-use-and-industry-responds> [<https://perma.cc/Y5C9-3AQX>] (noting "recent rule-making and public comments suggest that FDA is becoming more sclerotic instead of flexible" with regard to off-label promotion and use of drugs).

ing diseases.<sup>8</sup> Clinical reports stated that the symptoms from which these persons suffered engendered a complete disintegration of the immune system, leaving patients' bodies susceptible to rare forms of cancer and serious infections.<sup>9</sup> Nearly all who presented this symptomatic mosaic self-identified as gay men, leading researchers to call the anomalous collective Gay-Related Immunodeficiency (GRID).<sup>10</sup> It was not until September 1982, as rates of infection continued to grow exponentially, that the Centers for Disease Control (CDC) named the cluster of mysterious and fatal symptoms intimately associated with queer death Acquired Immune Deficiency Syndrome (AIDS).<sup>11</sup> Subsequent epidemiological investigation revealed that the ailments symptomatic of AIDS were caused by sustained viral infection.<sup>12</sup> By May 1986, there was near-universal consensus among the international scientific community that the pathological agent causing AIDS was a virus; the International Committee on the Taxonomy of Viruses soon convened to confirm this consensus, naming the AIDS-causing pathogen the Human Immunodeficiency Virus (HIV).<sup>13</sup>

On the biopharmaceutical frontier, research for treatments of HIV/AIDS would remain reactive in nature until the publication of a 2010 multinational study that evaluated the efficacy of a

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8. See Lawrence K. Altman, *New Homosexual Disorder Worries Health Officials*, N.Y. TIMES (May 11, 1982), <http://www.nytimes.com/1982/05/11/science/new-homosexual-disorder-worries-health-officials.html> [<https://perma.cc/S3DL-NUJY>] (reporting a "disorder of the immune system that ha[d] been known to doctors for less than a year — a disorder that appears to affect primarily male homosexuals — has now afflicted at least 335 people, of whom it has killed 136").

9. See *id.* (explaining that the breakdown in immune system that the pathogen causes "seems to invite in its wake a wide variety of serious infections and other disorders").

10. *Id.* (stating that, although the etiology of the disease remains unknown, researchers named it "GRID, for gay-related immunodeficiency").

11. AIDS.GOV, 30 YEARS OF HIV/AIDS TIMELINE 1 (2015), <https://www.aids.gov/pdf/aidsgov-timeline.pdf> [<https://perma.cc/XKC6-JBK7>] (noting on September 24, 1982, the CDC first used the acronym AIDS to accompany a provisional case definition: "a disease at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known case for diminished resistance to that disease").

12. See Jean L. Marx, *Strong New Candidate for AIDS Agent*, 224 SCI. 475, 475 (1984) (noting "a newly discovered subgroup of the human T-cell leukemia virus family, designated HLTV-III," was closely linked to the development of the symptoms characterizing AIDS); *id.* at 476 (commenting on a then-recently-published study in which "100 percent of the AIDS patients [tested] positive" for the presence of HLTV-III).

13. AIDS.GOV, 30 YEARS OF HIV/AIDS TIMELINE, *supra* note 11, at 3 ("In May [1985], the International Committee on the Taxonomy of Viruses declares that the virus that causes AIDS will officially be known as Human Immunodeficiency Virus (HIV)." (emphasis removed)).

once-daily oral antiretroviral treatment to proactively reduce the likelihood of HIV acquisition.<sup>14</sup> Named the Preexposure Prophylaxis Initiative (iPrEx), the study enrolled 2500 HIV-negative subjects across six countries,<sup>15</sup> each of whom received chemoprophylactic therapy in the form of an antiretroviral composite pill. The study concluded that, although “[t]he protective effect of [the composite antiretroviral] was . . . not as high as originally hypothesized . . .,”<sup>16</sup> ingestion of the once-daily oral pill “provided 44% additional protection from HIV [acquisition] among men . . . who have sex with men . . .”<sup>17</sup> The discussion the iPrEx study began continued in 2011, when two additional studies confirmed the efficacy of the composite antiretroviral in reducing HIV acquisition.<sup>18</sup>

The composite pill would be named Truvada, and it was subsumed within the general preventative HIV treatment known as Pre-Exposure Prophylaxis (PrEP) as its bio-chemical component. Gilead, the biopharmaceutical company that maintained exclusive rights over the patents covering Truvada, immediately sought to introduce the medication into the United States market following the success of these international studies.<sup>19</sup> Although Gilead successfully petitioned the FDA to begin sales of Truvada

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14. Robert M. Grant et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*, 363 N. ENG. J. MED. 2857, 2587 (2010) (concluding that subjects chosen to ingest daily a composite pill containing two antiretroviral medications, emtricitabine and tenofovir disoproxil fumarate (FTC-TDF), were increasingly less likely to acquire HIV in positive correlative relation to the presence of the antiretrovirals in the subjects' blood).

15. *Id.* at 2587–88. Inclusion criteria for subjects in the study “were male sex at birth, an age of 18 years or older, HIV-seronegative status, and evidence of high risk for acquisition of HIV infection.” *Id.* at 2588.

16. *Id.* at 2597.

17. *Id.*

18. See Press Release, Univ. Wash. Int'l Research Ctr., Pivotal Study Finds that HIV Medications are Highly Effective as Prophylaxis against HIV Infection in Men and Women in Africa (July 13, 2011), available at <http://www.thebodypro.com/content/62919/pivotal-study-finds-that-hiv-medications-are-highl.html> [<https://perma.cc/86PR-KQWW>] (documenting that among those persons who were HIV negative but had an HIV-positive partner, once-daily use of Truvada reduced the likelihood of transmission by 73%); *TDF2 Study of Pre-Exposure Prophylaxis (PrEP) Among Heterosexual Men and Women in Botswana: Key Facts*, CTRS. FOR DISEASE CONTROL (2011), <https://www.cdc.gov/nchhstp/newsroom/docs/prep-heterosexuals-factsheet.pdf> [<https://perma.cc/SUT3-8PXW>] (finding once-daily ingestion of Truvada reduced the likelihood of HIV acquisition by nearly 63% in the targeted population).

19. See Liz McKenzie, *Gilead Sues Teva over Truvada ANDA*, LAW360 (Dec. 16, 2008, 12:00 AM), <http://www.law360.com/articles/80464/gilead-sues-teva-over-truvada-anda> [<https://perma.cc/L29Z-SY3M>] (noting Gilead's intellectual property rights over all ten patents related to Truvada).

in July 2012,<sup>20</sup> the medication immediately incited controversy. Truvada's most vocal opponent was Michael Weinstein, president of the AIDS Healthcare Foundation. Both prior and subsequent to the FDA's approval of Truvada, Weinstein employed AHF's influential marketing apparatus to sustain a lobbying campaign intended to discredit Truvada as false science.<sup>21</sup>

#### B. AHF'S LETTER TO THE FDA AND THE THREAT TO TRUVADA

AHF's campaign against Truvada took on a legal dimension in January 2016, when Weinstein wrote a letter to the FDA urging legal action against Gilead for misbranding Truvada and for promoting false information about the medication's use through a video advertisement campaign.<sup>22</sup> The letter stated that, despite the restrictions on Truvada that the FDA clearly articulated, Gilead had "launched a brazen new ad campaign to promote situational use of the anti-retroviral as a 'party drug.'"<sup>23</sup> It further alleged that Gilead's advertisements "misleadingly impl[ie]d that Truvada can be effectively used exclusively on a situational basis to prevent HIV infection on occasions when an individual decides to [be sexually active]."<sup>24</sup> AHF's letter described with particular invective a moment in one of the three advertisements<sup>25</sup> wherein an actor stated that he "'like[s] to party[ ]' as the video shows him reaching for Truvada the morning *after* he presumably engaged in sex."<sup>26</sup> Per AHF, because the campaign "entirely contradicts the scientific evidence for the drug's effectiveness[, it] constitutes

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20. See U.S. FOOD AND DRUG ADMIN., APPROVAL LETTER NDA 21752/S-030 1 (2012), available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2012/021752Orig1s030Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/021752Orig1s030Approv.pdf) [<https://perma.cc/E44F-68L8>] (approving the introduction of Truvada into interstate commerce on July 16, 2012).

21. See Sam Spokony, *AIDS Healthcare Foundation lobbies against fed PrEP approval*, AIDS HEALTHCARE FOUND. (Aug. 11, 2011), <http://www.aidshealth.org/#/archives/2203> (including statements of AHF President Michael Weinstein that characterize Truvada as "a catastrophe for HIV prevention").

22. AHF Letter, *supra* note 2, at 3 ("In contravention of statute and regulations, Gilead launched an ad campaign to mislead viewers into believing that Truvada is safe . . . for use on a situational basis despite knowing that the drug is not approved for such use.").

23. *Id.* at 2.

24. *Id.*

25. For access to the videos referenced in the AHF Letter, see Public Health Solutions, *It's Time 2 PrEP . . . For the Party, For a Date, or For Love, HIV Big Deal*, <http://www.hivbigdeal.org/HIVBIGDEAL/time2prep.html> [<https://perma.cc/7XLJ-372X>] (last visited Apr. 29, 2017).

26. AHF Letter, *supra* note 2, at 2 (emphasis in original).

advertising for an unapproved and off-label use.”<sup>27</sup> AHF even expands its criticism of the videos beyond the boundaries of adherence to a regimen of Truvada use. As Weinstein comments:

It is also worth noting that the ad goes even further than promoting off-label usage of Truvada and essentially promotes illicit drug use as part of an “I Like to Party” lifestyle. At one point, one of the ads clearly shows the primary actor reaching for recreational drugs as he leaves his home for an evening of “partying.” It is precisely this cavalier attitude toward complying with the established PrEP regimen, consistent condom use, and regular testing that undermines the effectiveness of Truvada and expressly contradicts the approved usage of the drug.<sup>28</sup>

AHF found that the videos in question excluded “any references to the side effects associated with Truvada,” a transgression compounded by the absence of any reference to Truvada by its name.<sup>29</sup> The videos, AHF noted, concluded with a slate that made unmistakable the financial support of Gilead in the production of the advertisements, which AHF found to “clearly establish[ ] a link between the manufacturer of Truvada and the inappropriate off-label promotion of the drug.”<sup>30</sup> Because AHF believed that Gilead launched this campaign in purposeful contravention of statutes and regulations, its letter urged the FDA to take immediate action by halting Gilead’s off-label promotion, requiring Gilead to publically correct the false claims disseminated by its advertisements, and imposing any sanctions permissible under law.<sup>31</sup>

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27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.* at 3.

### III. THE DOCTRINE OF COMMERCIAL SPEECH IN THE CONTEXT OF PHARMACEUTICAL EXPRESSION — SITUATING THE CONSTITUTIONAL BOUNDARY

AHF's primary allegation in its letter to the FDA is that Gilead, by financially supporting the production of the aforementioned advertising videos, launched a campaign "to mislead viewers into believing that Truvada is safe and effective for use on a situational basis despite knowing that the drug is not approved for such use."<sup>32</sup> Consequently, the advertisement campaign "constitutes impermissible off-label promotion" of Truvada contravening the FDCA and regulations the FDA has passed pursuant to its delegated power.<sup>33</sup> Because the FDA continues to vacillate on the policy position it will adopt with regard to the off-label promotion of pharmaceuticals,<sup>34</sup> the legal inquiry raised by AHF's letter addresses more than its conflict with Gilead — it speaks to the continued viability of the constitutional proscription of commercial speech on behalf of drug manufacturers. The broader scope the AHF-Gilead conflict implicates sharpens in clarity when situated within the context of a January 2017 rule promulgated by the FDA,<sup>35</sup> which dealt directly with the threshold of liability required to hold a pharmaceutical company responsible

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32. *Id.* at 3; *see also id.* at 3 n.3 (citing 21 U.S.C. § 355(a) (2012) and 21 U.S.C. § 331(d) (2012) in support of its argument that Gilead had violated FDA regulations and federal law).

33. *Id.* at 3. In addition to possible criminal sanctions pursuant to the FDCA, Gilead, like any drug manufacturer alleged to promote a drug for off-label use, could face a civil suit under the False Claims Act on the theory that, in the course of the company's misbranding, it caused false claims to be submitted to the federal government for reimbursement through its various healthcare programs. *See generally* 31 U.S.C. § 3729–3733 (2012). Within the last decade, the government "has brought [False Claims Act] claims on this theory, often in conjunction with criminal prosecutions under the FDCA for misbranding." *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 205 (2015) (footnote omitted).

34. *See Zegarelli, supra* note 7 ("From 2015 to 2016, FDA appeared to open the door to loosening the standards around intended use and off-label use, but recent rule-making and public comments suggest that FDA is becoming more sclerotic instead of flexible.").

35. *See* Eli Greenspan & Benjamin M. Zegarelli, *Beyond the Eleventh Hour: FDA Prepares to Finalize Intended Use Amendments Despite Midnight Rule Relief Act*, NAT'L L. REV. (Jan. 11, 2017), <http://www.natlawreview.com/article/beyond-eleventh-hour-fda-prepares-to-finalize-intended-use-amendments-despite> (commenting on FDA's recently promulgated rule intended to address "established definitions of 'intended use' for drugs and devices, the primary consideration in determining whether a product is regulated for a particular use and what regulations apply").

for the promotion of off-label uses of FDA-approved medications.<sup>36</sup> In consideration of these issues, this Part will examine the interstices of overlap between FDCA law and commercial-speech doctrine as related to the regulation of pharmaceutical speech. This examination will provide a normative foundation upon which an analysis of AHF's misbranding allegations and its subsequent request that the FDA restrict Gilead's speech may be constructed.

#### A. THE CONSTITUTIONAL TERRAIN OF COMMERCIAL SPEECH IN THE PHARMACEUTICAL CONTEXT

The FDCA empowers the FDA to police the "introduction . . . into interstate commerce . . . any . . . drug . . . that is adulterated or misbranded."<sup>37</sup> A drug is misbranded if it lacks "adequate warnings . . . against unsafe dosage . . . as are necessary for the protection of users . . ."<sup>38</sup> The misbranding provision ties intimately to the labeling mandate of the FDCA; when a pharmaceutical company submits a New Drug Application (NDA) for evaluation, it must include "the labeling proposed to be used for such drug" so the FDA may evaluate the label's accuracy.<sup>39</sup> The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter . . . accompanying such [drug]."<sup>40</sup> This provision has been broadly interpreted so as to include information entirely separated from the medication itself as supplementary labeling.<sup>41</sup> What the FDA legally approves, then, is not the drug *itself*, but

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36. See Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193, 2204 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts. 201, 801, 1100) ("Second, as discussed previously, the Agency does not, absent extraordinary circumstances, regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that the product was being prescribed or used by doctors for such use" (reference omitted)); *but see id.* ("These changes do not reflect a change in FDA's approach regarding evidence of intended use for drugs and devices. These clarifying changes to the intended use regulations apply to drugs and devices generally . . ."). For a discussion of this rule's potential impact on AHF's misbranding allegations, see Part IV, *infra*.

37. 21 U.S.C. § 331(a) (2012).

38. 21 U.S.C. § 352(f) (2012).

39. 21 U.S.C. § 355(b)(1)(F) (2012).

40. 21 U.S.C. § 321(m) (2012) (defining labeling to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article").

41. See *Kordel v. United States*, 335 U.S. 345, 350 (1948) (noting an "article or thing is accompanied by another when it supplements or explains it," which requires the conclusion that, while "physical attachment one to the other" is not necessary, it can only be the "textual relationship" that animates a relation of accompaniment).

the drug's specific medical use, known as the drug's "indication."<sup>42</sup> For a label to be sufficient, it must dictate the proper conditions under which the drug should be prescribed. A label that does not focus on a specific treatment or on a narrow constituency of patients might fail to meet this high threshold, thereby precluding the drug from entering interstate commerce.<sup>43</sup> Once a product is approved to enter interstate commerce, however, a physician may prescribe such medication to treat any illness.<sup>44</sup> Thus, because doctors may speak about off-label uses and promote medications for such uses while pharmaceutical companies cannot, two forms of drug-related speech begin to circulate — on-label speech and off-label speech.<sup>45</sup>

Despite its legal prohibition against the off-label marketing of medication, the FDA does not regulate the prescription of medication by doctors for off-label purposes.<sup>46</sup> In fact, once the FDA approves a drug for a specific treatment, the use of that drug in alternative and unconventional contexts is left to the discretion of

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42. Ralph F. Hall & Elizabeth S. Sobotka, *Inconsistent Government Policies: Why FDA Off-Label Regulation Cannot Survive First Amendment Review under Greater New Orleans*, 62 FOOD & DRUG L.J. 1, 4 (2007) (stating the "FDA approves a specific use, or 'indication,' for the [drug], not the [drug] in general").

43. See Marc J. Scheineson & Guillermo Cuevas, *United States v. Caronia: The Increasing Strength of Commercial Free Speech and Potential New Emphasis on Classifying Off-Label Promotion as "False and Misleading,"* 68 FOOD & DRUG L.J. 201, 204 (2013) ("On-label uses tend to be very specific and quite narrow. This is due . . . [to] the judgments of drug reviewers in the FDA Center for Drug Evaluation and Research (CDER) that are tied to the specific parameters of the [research] data presented.").

44. *Id.* at 202 ("FDA maintains a stated policy of not regulating or interfering with physicians' practice of medicine in the prescribing of drugs.").

45. See, e.g., FDA GUIDANCE, *supra* note 4, at 4 (2014) (stating an approved drug intended for an unapproved use "would be considered misbranded, because the drug does not meet the regulatory exemptions from the requirement that its labeling bear 'adequate directions for use'"); Joseph Leghorn et al., *The First Amendment and FDA Restrictions on Off-Label Uses: The Call for a New Approach*, 63 FOOD & DRUG L.J. 391, 393–94 (2008) (defining off-label use as the prescribing of a drug "for an indication, dosage and/or population that has not been approved by FDA and is therefore not listed on the approved product labeling").

46. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998) ("Once a drug has been approved by the FDA for marketing for *any* use, the actual prescription choices regarding those drugs are left to the discretion of the physician."), *vacated in part, sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. 2000); see also Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193, 2204 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts. 201, 801, 1100) (noting the FDA "does not, absent extraordinary circumstances, regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that the product was being prescribed or used by doctors for such use").

the prescribing physician.<sup>47</sup> Further, restrictions on the dissemination of scientific literature discussing off-label uses apply only to the commercial entities that manufacture the medication; a physician's request for such literature is inoculated against legal indictment.<sup>48</sup> An asymmetry of permissible speech thus materializes, the axis of which separates the physician, whose charge is the treatment of the individual patient, from the FDA, whose statutory purpose is to protect public health.<sup>49</sup> When challenged as improper or unconstitutional, this asymmetry triggers the protections offered by the First Amendment.<sup>50</sup> Specifically, such challenges are filtered through the doctrine of commercial speech, as they ask whether it is permissible to proscribe drug manufacturers from disseminating information regarding off-label uses for their medication,<sup>51</sup> and whether the labeling requirements of

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47. See, e.g., *Wash. Legal Found.*, 13 F. Supp. 2d at 55 (“A physician may prescribe an approved drug for any medical condition, irrespective of whether FDA has determined that the drug is safe and effective with respect to that illness.”); 21 U.S.C. § 396 (2012) (“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.” (emphasis added)).

48. See *Wash. Legal Found.*, 13 F. Supp. 2d at 58 (“Notably, these restrictions on the dissemination [of literature] apply only when the drug manufacturer . . . seeks to initiate distribution . . . . Dissemination of article reprints and reference texts that would otherwise violate the [law] are permissible when that distribution is responsive to a physician’s inquiry.”).

49. Compare *Bioethics: Hippocratic Oath, Modern Version*, JOHNS HOPKINS: SHERIDAN LIBRARIES & UNIV. MUSEUMS (Apr. 14, 2016, 2:08 PM), <http://guides.library.jhu.edu/c.php?g=202502&p=1335759> (requiring physicians to “remember that [they] do not treat a fever chart, a cancerous growth, but a *sick human being*, whose illness may affect the person’s family and economic stability” (emphasis added)), with 21 U.S.C. § 393 (2012) (articulating the mission of the FDA, which is to “promote the *public health* by promptly and efficiently reviewing clinical research and taking appropriate action on the marking of regulated products in a timely manner” (emphasis added)).

50. See *Wash. Legal Found.*, 13 F. Supp. 2d at 59 (stating the threshold inquiry in a case that deals with a challenge to the FDA’s proscription against off-label marketing concerns “how to classify the ‘speech’ at issue”). In this case, Judge Lamberth dismisses outright the FDA’s suggestion that the prohibition against disseminating literature concerning off-label uses for medication could be classified as conduct instead of speech. He renders explicit that, though “[t]here may certainly be a ‘line’ between education and promotion as regards a drug manufacturer’s marketing activities . . . , [that] line [is] between pure speech and commercial speech, not between speech and conduct.” *Id.* As such, questions of labeling, misbranding, and marketing all fall within the scope of First Amendment analysis.

51. See Joseph Leghorn et al., *supra* note 45, at 396 (noting that, “[t]o date, First Amendment analysis of off-label speech restrictions has been performed under the commercial speech doctrine”).

the FDCA are too onerous for even the largest of biopharmaceutical companies to meet.<sup>52</sup>

Although the seminal case establishing the doctrinal analysis of commercial speech regulation is *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*,<sup>53</sup> the questions of off-label commercial speech and FDA proscriptions on that speech were first prominently addressed in a series of D.C. Circuit cases now taken as a significant authority on these inquiries.<sup>54</sup> Thus, while *Central Hudson* provides the overarching normative framework for commercial-speech constitutional analysis, the decisions issued by the D.C. courts in the *Washington Legal Foundation* cases illuminate how *Central Hudson's* structure should be applied in the context of FDA-based restrictions on manufacturers' speech.

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52. See Scheineson & Cuevas, *supra* note 43, at 204 (suggesting that, because labeling negotiations occur at the end of a highly uncertain regulatory review process, the "barrage of reviewer questions, criticisms and requests for additional data can wear down even the largest drug sponsors . . . , creat[ing] an incentive to agree to more restrictive labeling in order to get drugs onto the U.S. market as expeditiously as possible").

53. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980) (describing the "four-part analysis" the Court has developed in commercial speech cases to determine whether a restricted form of commercial expression merits constitutional protection).

54. See, e.g., Hall & Sobotka, *supra* note 42, at 11 (noting the D.C. trial court's interpretation of off-label promotion as commercial speech and its subsequent analysis under that doctrinal framework were accepted "without question or comment" by the D.C. Circuit Court of Appeals, and, since this pronouncement, in "essentially every legal challenge to off-label speech, the activity has been viewed as speech," per the trial court's analysis). After the district court declared the restrictions articulated in the FDA's Guidance Documents unconstitutional, the Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296, became effective; it contained provisions addressing the promotion of off-label uses and thereby superseded the materials the district court had found unconstitutional. The district court requested supplemental briefing on the constitutionality of those provisions of the FDAMA addressing manufacturer promotion of off-label uses, and, in a subsequent opinion, the court held that those provisions, like the Guidance Documents preceding them, violated the First Amendment. See *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81, (D.D.C. 1999) (holding the FDAMA, along with its implementing regulations, unconstitutionally violates the First Amendment because its procedural requirements "burden[] substantially more speech than necessary to advance the government's legitimate interest" of encouraging supplemental drug applications for off-label uses). On appeal, the circuit court vacated both the district court's decision and the injunctions regarding the unconstitutionality of the FDAMA provisions and the Guidance documents, on the grounds that neither the statute nor the documents "facially violate the First Amendment." *Wash. Legal Found. v. Henney*, 202 F.3d 331, 336 (D.C. 2000). The circuit court made clear, however, that its dismissal and vacatur *did not* impugn or overrule the reasoning of the district court in evaluating the First Amendment questions with which it was presented. See *id.* at 337 n.7 ("In disposing of this case in this manner, we certainly do not criticize the reasoning or conclusions of the district court. As we have made clear, we do not reach the merits of the district court's First Amendment holdings and part of its injunction still stands.").

At issue in *Washington Legal Foundation* were FDA policies articulated within Guidance Documents the agency had published, which concerned “manufacturer distribution of reprints of medical textbooks and peer-reviewed journal articles . . . , and manufacturer involvement in continuing medical education seminars and symposia . . . .”<sup>55</sup> The Washington Legal Foundation (WLF), a public-interest law firm whose mission is “to preserve and defend America’s free-enterprise system by litigating, educating, and advocating for free-market principles,”<sup>56</sup> sought a declaratory judgment that the FDA policies expressed in the Guidance Documents violated rights under the First Amendment. Specifically, the interest group argued that the portions of the Guidance Documents (1) restricting the distribution of medical textbooks and peer-reviewed journal articles and (2) narrowing the permissible scope of manufacturer involvement in medical educational symposia unconstitutionally burdened pharmaceutical companies’ speech.<sup>57</sup> Such materials and actions, the FDA contended, must generally aim to “strike the proper balance between the need for an exchange of reliable scientific data and information within the health care community[ ] and the statutory requirements that prohibit companies from promoting products for unapproved uses.”<sup>58</sup> When the content of materials or the information provided at a medical symposium is heavily influenced by drug manufacturers, their scientific accuracy risks adulteration and thus, per the FDA, necessarily becomes subject to increased scrutiny.<sup>59</sup>

The pivotal *Washington Legal Foundation* case, decided in 1998 at the district-court level, characterized the threshold inquiry demanding resolution as “how to classify the ‘speech’ at issue [in the instant case],”<sup>60</sup> that is, whether the speech in ques-

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55. *Wash. Legal Found.*, 13 F. Supp. 2d at 54 (D.D.C. 1998).

56. *WLF Mission*, WASH. LEGAL FOUND., <http://www.wlf.org/org/mission.asp> (last visited Feb. 20, 2017).

57. *Wash. Legal Found.*, 13 F. Supp. 2d at 54 (listing the policies at issue and characterizing plaintiff’s prayer for relief as requesting the entry of “preliminary and permanent injunctions against defendants, preventing them from enforcing, relying upon, or otherwise giving effect to the Guidance Documents”).

58. *Id.* at 58 (quoting Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800, 52,800 (Oct. 8, 1996)).

59. *Id.* at 57–58 (describing various criteria FDA developed to determine whether educational training programs and reprints of scientific journal articles were “attempts by the supporting company to influence content”).

60. *Id.* at 59. Prior to describing its rationale for distinguishing between pure and commercial speech, the court considered whether the FDA’s regulations addressed speech

tion is ultimately more properly taxonomized as “pure speech or commercial speech.”<sup>61</sup> Commercial speech, the court noted, is typically “authored and/or uttered directly by the commercial entity that wishes to financially benefit from the message.”<sup>62</sup> With regard to the prescription drug industry, the “dissemination of scientific research results [represents] an especially important and prevalent marketing tool,”<sup>63</sup> leading manufacturers to “want to get scientific information demonstrating the efficacy of their products in the hands of physicians”;<sup>64</sup> statements meant to market pharmaceuticals therefore present the question of whether academic speech articulated in the service of commercialism dilutes the level of First Amendment protection to which the speech is entitled.<sup>65</sup> The Supreme Court first articulated a doctrinal framework to determine whether the communication under scrutiny constitutes commercial speech in *Bolger v. Youngs Drug Products Corporation*, the three prongs of which are: (1) whether the speech is “conceded to be [an] advertisement[ ]”;<sup>66</sup> (2) whether the speech makes “reference to [the] specific product”;<sup>67</sup> and (3) whether the speaker “has an economic motivation” for the speech that would “turn [it] into commercial speech.”<sup>68</sup> In its application of each of the *Bolger* factors to both manufacturers’ influence over medical symposia and the dissemination of medical journal articles by pharmaceutical companies, the district court in *Washington Legal Foundation* held that such speech “is properly classified as commercial speech” and thus subject to the four-part test articulated in *Central Hudson*.<sup>69</sup>

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or conduct and whether the speech regulated by the Guidance Documents falls outside of the ambit of the First Amendment because of the federal government’s power to regulate the pharmaceutical industry. The court dismisses these two avenues of argument as inapposite, and, because the court’s conclusions are applicable to this Comment’s subsequent discussion of Gilead’s putative “promotional” speech acts, this Comment will not address them here.

61. *Id.* at 62.

62. *Id.*

63. *Id.* at 63.

64. *Id.*

65. The court phrases the question as follows: “does speech that would be fully protected as scientific and/or educational speech become transformed into commercial speech, with its reduced level of protection, by the mere fact that a commercial entity seeks to distribute it in order to increase its sales of the product addressed in speech?” *Id.* at 64.

66. *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66 (1983).

67. *Id.*

68. *Id.* at 67.

69. *Wash. Legal Found.*, 13 F. Supp. 2d at 65.

In *Central Hudson*, the Court described its constitutional analysis of commercial-speech restrictions as follows:

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>70</sup>

Although the district court in *Washington Legal Foundation* was, at the time of its decision, applying the full scope of jurisprudential precedent then available,<sup>71</sup> the Supreme Court has since intervened in the domain of commercial pharmaceutical communications.<sup>72</sup> This intervention has resulted in a multilayered constitutional analysis that has been modeled by the Second Circuit Court of Appeals and a district court within its jurisdiction.<sup>73</sup> These three cases — *Sorrell v. IMS Health Inc.*, *United States v. Caronia*, and *Amarin Pharma, Inc. v. FDA* — illustrate the more robust analysis now expected of federal courts considering restrictions on commercial pharmaceutical speech. Of importance in *Sorrell* was the Supreme Court’s articulation of the relationship between the First Amendment and pharmaceutical marketing: “[s]peech in aid of pharmaceutical marketing . . . is a form of

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70. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 566 (1980).

71. *See Wash. Legal Found.*, 13 F. Supp. 2d at 65–74 (analyzing the constitutionality of FDA’s guidance documents “under *Central Hudson’s* four-prong test” after determining that the manufacturers’ communications are properly classified as commercial speech).

72. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) (stating speech “in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment,” and, as a consequence, laws restricting such speech “must be subjected to heightened judicial scrutiny”).

73. *See, e.g., U.S. v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012) (“We review the government’s theory of prosecution under the *Sorrell* Court’s two-step analysis to determine whether it runs afoul of the First Amendment. . . . Second, we conclude the government cannot justify a criminal prohibition of off-label promotion even under *Central Hudson’s* less rigorous intermediate test.”); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 225 (S.D.N.Y. 2015) (construing the analysis of the Second Circuit in *Caronia* as requiring first the application of *Sorrell’s* heightened standard of protection for commercial speech and then *Central Hudson’s* four-prong test “used to determine [whether] a restriction upon commercial violates the First Amendment”).

expression protected by the Free Speech Clause of the First Amendment. As a consequence, [statutory restrictions on such speech] must be subjected to heightened judicial scrutiny.”<sup>74</sup> This determination would undergird the reasoning articulated in both *Caronia* and *Amarin* and as well as propel a shift in the FDA’s regulatory regime in 2017.<sup>75</sup>

B. CONSTELLATING THE EFFECTS OF SORRELL IN THE SECOND CIRCUIT — *UNITED STATES v. CARONIA AND AMARIN PHARMA, INC. v. U.S. FOOD & DRUG ADMINISTRATION*

AHF’s letter alleges that Gilead’s video campaign, the contents of which will be discussed *infra*, misleads “viewers into believing that Truvada is safe and effective for use on a situational basis despite [Gilead’s] knowing that the drug is not approved for such use.”<sup>76</sup> Such promotion, AHF argues, is proscribed by the FDCA.<sup>77</sup> This question of the FDCA’s proscriptive jurisdiction was left unanswered in *Sorrell*, as the object of the Court’s consideration therein was the constitutionality of a state statute.<sup>78</sup> However, in *United States v. Caronia*, the Second Circuit Court of Appeals addressed directly “whether . . . prosecution . . . under the FDCA only for promoting an FDA-approved drug for off-label use [could be] constitutionally permissible.”<sup>79</sup> While the FDCA criminalizes misbranding or conspiring to misbrand a drug, the statute and its corresponding regulations do not explicitly proscribe off-label promotion. Instead, 21 C.F.R. § 201.128, which addresses how a manufacturer’s intent may be evinced during a prosecution pursuant to the FDCA’s misbranding provisions, emphasizes an objective evaluation that “may, for example, be [but-

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74. *Sorrell*, 564 U.S. 552 at 557.

75. See *infra* Part IV.B.

76. AHF Letter, *supra* note 2, at 3.

77. *Id.*; see also *id.* at 3 n.3 (citing 21 U.S.C. § 355(a) (2012) (proscribing the “introduc[tion] or deliver[y] for introduction into interstate commerce any new drug” that has not satisfied the conditions of § 355(b), which includes references to proper labeling and proscriptions against misbranding)); 21 U.S.C. § 352(f) (2012) (“A drug or device shall be deemed to be misbranded [u]nless its labeling bears . . . such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . .”).

78. *But see Sorrell*, 564 U.S. at 586 (Breyer, J., dissenting) (noting the First Amendment standards applied to the state statute “would apply to similar regulatory actions taken by other States or by the Federal Government acting, for example, through [the] Food and Drug Administration” (emphasis added)).

79. *Caronia*, 703 F.3d at 160.

tressed] by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.”<sup>80</sup> Such analysis of the mens rea element of the misbranding offense necessarily implicates speech, which, as the *Caronia* court acknowledged, raises significant First Amendment concerns.<sup>81</sup>

Recognizing that construing the FDCA as criminalizing the mere promotion of a drug’s off-label use would pose a grave constitutional difficulty, the court offered a narrow interpretation of the statute as, pursuant to the doctrine of constitutional avoidance,<sup>82</sup> “not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs.”<sup>83</sup> The court began its analysis by considering the two-step inquiry articulated in *Sorrell*, wherein a court is first to consider “whether the government regulation restricting speech [is] content- and speaker-based”<sup>84</sup> and then “whether the government ha[s] shown that the restriction on speech [is] consistent with the First Amendment under the applicable level of heightened scrutiny.”<sup>85</sup> Importantly, the *Sorrell* Court did not flesh out the contours of this “heightened scrutiny,” instead noting only that the state statute in question would be “unconstitutional even under the lesser intermediate standard set forth in *Central Hudson*.”<sup>86</sup> Though the Supreme Court appeared to indicate that its abridged analysis could supplant the four-prong test developed in *Central Hudson*, the *Caronia* court offered an ordinal and merged interpretation of the doctrinal frameworks, beginning with *Sorrell*’s two-step inquiry to determine whether a constitutional violation based on viewpoint-discrimination exists and ending with *Central Hudson*’s

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80. 21 C.F.R. § 201.128 (2016).

81. See *Caronia*, 703 F.3d at 160 (“[We] construe the FDCA as not criminalizing the simple promotion of a drug’s off-label use because such a construction would raise First Amendment concerns.”).

82. See, e.g., *Skilling v. United States*, 561 U.S. 358, 406 (2010) (instructing courts to “avoid constitutional difficulties by adopting a limiting interpretation if such a construction is fairly possible” (brackets omitted)); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (“Another rule of statutory construction, however, is pertinent here: where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.”); *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.”).

83. *Caronia*, 703 F.3d at 168.

84. *Id.* at 163.

85. *Id.* at 163–64.

86. *Id.* at 164.

less rigorous examination to consider whether the government can justify its criminal proscription of off-label promotion.<sup>87</sup>

A determination of content-based discrimination turns on whether the FDCA “distinguishes between ‘favored speech’ and ‘disfavored speech on the basis of the ideas or views expressed.’”<sup>88</sup> Under the government’s proffered construction, speech about government-approved uses of drugs would be permissible while speech about off-label uses would necessarily remain prohibited, even if off-label use was not prohibited per se. This interpretation would have the express purpose of diminishing “the effectiveness of [off-label drug] marketing by manufacturers,” strongly suggesting that the FDCA’s regulation of commercial speech was content-based and therefore presumptively unconstitutional.<sup>89</sup> That this construction would effect speaker-based discrimination was facially manifest — as the court noted, “it targets one kind of speaker — pharmaceutical manufacturers — while allowing others to speak without restriction.”<sup>90</sup> The court leveraged the *Sorrell* analysis to repudiate the government’s construction of the FDCA, and, after rejecting this reading of the statute, it turned to *Central Hudson* to determine whether the government could nevertheless pursue criminal sanctions under an alternative reading of the FDCA. Insofar as the government’s position advocated the criminalization of off-label promotion, it could not be squared with its curious acquiescence in the dissemination of information regarding off-label use when requested by physicians;<sup>91</sup> accordingly, the court concluded that the government’s “criminal ban on off-label promotion by pharmaceutical manufacturers [was] more

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87. *Id.* at 164 (“We review the government’s theory of prosecution under the *Sorrell* Court’s two-step analysis to determine whether [the FDCA] runs afoul of the First Amendment. . . . Second, we conclude the government cannot justify a criminal prohibition of off-label promotion even under *Central Hudson*’s less rigorous intermediate test.”).

88. *Id.* at 165 (citing *Turner Broad. System, Inc. v. F.C.C.*, 512 U.S. 622, 643 (1994)).

89. *Id.* at 165 (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011)).

90. *Id.* at 165.

91. Although the court in *Caronia* does not substantively explore the consequences of the FDA’s embrace of significantly conflicting policies, the Supreme Court has stated clearly that, “if conflicting or inconsistent government policies exist regarding restrictions on commercial speech, the First Amendment mandates that pro-speech policies trump censorship.” Hall & Sobotka, *supra* note 42, at 23 (citing *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 194–95 (1999)). In *Greater New Orleans*, the Court addressed the constitutional permissibility of certain government regulations regarding casino gambling, and, upon review of the statutory regime in question, the Court held that “the operation of [the statute] and its attendant regulatory regimen is so pierced by exemptions and inconsistencies” that it could not survive First Amendment scrutiny. *Greater New Orleans*, 527 U.S. at 190.

extensive than necessary to achieve [its] substantial interests.”<sup>92</sup> The court ultimately construed the FDCA’s misbranding provisions “as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved drugs.”<sup>93</sup>

A year prior to the decision in *Caronia*, Amarin Corporation (Amarin), a biopharmaceutical company, sought FDA approval for a single use of Vascepa, a drug it had developed to address cardiovascular health issues.<sup>94</sup> Subsequent to the FDA’s authorization of Vascepa’s intended use, Amarin sought in 2013 an additional approval for Vascepa to treat a derivatively related cardiovascular condition; the FDA, however, denied Amarin’s application, stating that the clinical trials Amarin conducted failed to yield sufficient data to support the medical benefits of this second usage.<sup>95</sup> In response, Amarin stated that it wished at minimum to include the results of those clinical trials on Vascepa’s label to better ensure that physicians were aware of the drug’s positive indication for multiple cardiovascular conditions.<sup>96</sup> In 2015, the FDA issued a letter refusing Amarin’s request and further stated that, should the company market Vascepa for any usage other than the one approved by the agency, the company would expose itself to criminal liability for “misbrand[ing] under the FDCA.”<sup>97</sup> Ten days after FDA’s implicit threat of prosecution, Amarin filed a civil suit in the Southern District of New York, claiming that “FDA’s threat of a misbranding action [was] chilling it from engaging in constitutionally protected truthful speech”<sup>98</sup> and seeking “an injunction that would prohibit the FDA from bringing a misbranding action against [the company] for its truthful and non-misleading statements to doctors regarding Vascepa . . . .”<sup>99</sup>

In granting Amarin’s application for preliminary injunctive relief, the district court rooted its analysis squarely in the prece-

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92. *Caronia*, 703 F.3d at 167.

93. *Id.* at 168.

94. *See* Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp.3d 196, 209 (S.D.N.Y. 2015) (“Vascepa was developed by Amarin to improve cardiovascular health.”).

95. *See id.* at 212 (“However, the FDA refused to approve Amarin’s proposed new use for Vascepa,” stating that “the clinical trials failed to demonstrate any additional benefit of [Vascepa], and although some later analyses had suggested that patients . . . may benefit from [such use], this remains to be confirmed.” (quotation marks and citations omitted)).

96. *See id.* (“The FDA also refused to approve Amarin’s request to include the [clinical trial] results in the Vascepa label.”).

97. *Id.* (brackets omitted).

98. *Id.* at 198.

99. *Id.* at 215.

dent set by *Caronia*. In order to establish the intent (*mens rea*) and act (*actus reus*) elements of a misbranding action, the FDA argued at trial that it could “use Amarin’s statements regarding Vascepa’s [second usage] as objective evidence of Amarin’s intent to promote [Vascepa] for [an] off-label purpose” and cite any “truthful and non-misleading statements about that use” made by Amarin as evidence of the act of misbranding itself.<sup>100</sup> However, the court noted that, “under *Caronia*, the FDA may *not* bring such an action based on truthful promotional speech alone, consistent with the First Amendment.”<sup>101</sup> The *Caronia* majority presented the issue as “whether a misbranding prosecution that identified a defendant’s speech alone as the proscribed conduct [could be] constitutionally permissible,” and the ensuing analysis held categorically that the FDCA’s misbranding provisions were not to be construed as reaching truthful speech promoting off-label use.<sup>102</sup> *Caronia* is thus to be understood as a case of statutory construction that turned not on the *mens rea* requirement of the misbranding provision but rather on the *actus reus* requirement of that provision, and, because the court read the FDCA did not reach truthful, non-misleading speech promoting off-label uses, the FDA could not constitutionally pursue its threatened prosecution.<sup>103</sup>

#### IV. CONTESTING TRUVADA — CONSIDERING PHARMACEUTICAL SPEECH POST-CARONIA AND THE FDA’S NEW REGULATORY CALCULUS

##### A. A “BRAZEN NEW AD CAMPAIGN” — DETAILING THE CONTENT OF THE GILEAD-SUPPORTED VIDEO ADVERTISEMENTS

The AHF’s letter to the FDA regarding Gilead’s putative misbranding of Truvada, now written just over one year ago, has not yet incited a legal response from the agency. Although the president of AHF, Michael Weinstein, addressed the letter to Stephen Ostroff, the then-Acting Commissioner of the FDA, there is no

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100. *Id.* at 223.

101. *Id.* at 224 (emphasis in original).

102. *Id.* at 225 (quotation marks and brackets omitted).

103. *Id.* at 227 (“But *Caronia* did not turn on the intent element of misbranding. It turned on the *actus reus* requirement. And *Caronia*’s holding was that the FDCA’s misbranding provisions cannot constitutionally criminalize, and therefore do not reach, the act of truthful and non-misleading speech promoting off-label use.”).

evidence the document was routed to the FDA's Office of Prescription Drug Promotion (OPDP), the branch of the FDA charged with the review and surveillance of drug advertisement materials and thus the proper addressee.<sup>104</sup> The FDA marshals the OPDP to run its "Bad Ad Program," the purpose of which is "to increase the effectiveness of OPDP's surveillance . . . especially with regard to curtailing inappropriate promotional activities" by allowing any individual to report misleading prescription-drug promotion.<sup>105</sup> Assuming, arguendo, the AHF's letter to the FDA can be taken as a form of reporting to the Program, the central investigative inquiry facing an OPDP reviewing officer would be whether the speech cited by AHF — three online videos, the production of which was financially supported by Gilead — encourage a use of Truvada inconsistent with the FDA's approved usage. A review of the videos produced for the advertising campaign is therefore useful in proceeding with the below analyses.

In total, Gilead appears to have sponsored the production of three videos by Public Health Solutions, a nonprofit organization based in New York City,<sup>106</sup> all of which addressed the question of whether Truvada was the right choice for an individual or a couple. In the first video, an actor is seen collecting condoms and a small plastic bag of unidentifiable pills before heading out to a bar.<sup>107</sup> The actor states that he "like[s] to party" while dancing at the bar. In the following scene, he is seated at home, looking at his cellphone, which provides him with a reminder to take his daily dosage of Truvada.<sup>108</sup> As the reminder appears on the

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104. See *The Office of Prescription Drug Promotion (OPDP)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm> [https://perma.cc/YU2G-62DP] (last updated Jan. 19, 2017) ("OPDP reviewers have responsibility for reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these promotional materials is not false or misleading.").

105. *Key Points of the Bad Ad Program*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm211498.htm> [https://perma.cc/5UH7-S7TA] (last updated Oct. 10, 2014).

106. See *Overview*, PUB. HEALTH SOLS.: MERGING RESEARCH AND ACTION, <http://www.healthsolutions.org/?event=page.Overview> [https://perma.cc/RN74-RB89] (last visited Oct. 21, 2016) (describing Public Health Solutions as a "a nonprofit organization that develops, implements and advocates dynamic solutions to prevent disease and improve community health").

107. Pub. Health Sols., *I Like To Party*, YOUTUBE (Nov. 4, 2015), <https://www.youtube.com/watch?v=FXZcoBsoGBY> (video on file with author).

108. *Id.*

screen, the actor states that he also “like[s] to be safe.”<sup>109</sup> In the second video, a man is seen on his cellphone, facilitating a casual sexual encounter with another user of a cellphone application.<sup>110</sup> After the two enter the man’s bedroom, he states to his paramour: “Hey . . . I’m on PrEP.”<sup>111</sup> When his partner admits to complete ignorance regarding Truvada, the man is shocked.<sup>112</sup> The screen then cuts to a slide that offers a hyperlink for viewers to learn more about the medication.<sup>113</sup> The third video is a series of crosscut interviews among several couples, all of whom are serodiscordant in HIV status.<sup>114</sup> Each couple speaks about the multiple reasons why one might use Truvada or instead depend on condoms as the means of prophylaxis.<sup>115</sup> One couple discusses the side effects of Truvada, after which an individual describes the three-month testing regimen for HIV status, as well as testing for kidney and liver health, that is medically necessary when taking Truvada.<sup>116</sup> Perhaps most notable is when one member of a couple plainly states that he does not believe that Truvada is for everyone, as it requires an individual to have educated herself about HIV/AIDS and make the personal choice about what role she expects the medication to play in a serodiscordant relationship.<sup>117</sup>

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109. *Id.*

110. Pub. Health Sols., *Mario and Lamar (Edited)*, YOUTUBE (Nov. 5, 2015), <https://www.youtube.com/watch?v=qvbilrBA9oI> (video on file with author). The title of this video notes that the video has been edited. In its original form, when the actors use expletives in their discussion with one another, the expletives are not censored. In the form of the video cited here, the expletives are “bleeped out.”

111. *Id.*

112. *Id.*

113. *Id.*

114. Pub. Health Sols., *PrEP and Love*, YOUTUBE (Nov. 4, 2015), [https://www.youtube.com/watch?v=\\_yGqspOEL\\_o](https://www.youtube.com/watch?v=_yGqspOEL_o) (video on file with author).

115. *Id.*

116. *Id.*

117. *Id.*

B. THE VIABILITY OF AHF'S ALLEGATIONS AFTER *CARONIA* AND  
*AMARIN*

A determination of misbranding turns on a drug's labeling; as mentioned, the FDCA defines "labeling" as "all labels and other written, printed, or graphic matter . . . accompanying [a drug]."<sup>118</sup> At the outset, then, AHF's linkage of the videos to Truvada's labeling is legally sound. Nevertheless, the primary allegation in AHF's letter — that Gilead engaged in the purposeful misbranding of Truvada through Public Health Solutions' video campaign — seems unsustainable upon a plain review of the three videos' content. In the letter's concluding paragraph, AHF President Michael Weinstein characterizes the video campaign as misleading viewers into believing that Truvada "is safe and effective for use on a situational basis," a point the letter earlier supports by reference to the content of the first video.<sup>119</sup> The letter suggests that the small plastic bag the actor takes as he leaves his home contains recreational drugs, and, because the use of recreational drugs is assumed to be metonymic with a "cavalier attitude toward complying with the established PrEP regimen, consistent condom use, and regular testing," the video necessarily "undermines the effectiveness of Truvada and expressly contradicts the approved usage of the drug."<sup>120</sup> While the suggestion that recreational drug use is integrated into certain sites of queer male culture is not without merit,<sup>121</sup> the chain of inferential reasoning the letter proposes is incoherent. First, the conclusory statement that recreational drug use bears a relationship to an individual's ability to adhere to a specific medical regimen is without support; second, the statement is intentionally written in bombastic fashion to veil the weaknesses of AHF's legal arguments, which re-

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118. 21 U.S.C. § 321(m) (2012) (defining labeling to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"); *see also supra* note 41 and accompanying text.

119. AHF Letter, *supra* note 2, at 3.

120. *Id.* at 2.

121. *See generally* KANE RACE, PLEASURE CONSUMING MEDICINE: THE QUEER POLITICS OF DRUGS 185 (Duke Univ. Press 2009) (demonstrating the value of an approach to drug cultures that "is grounded in given formations of drug use and which involves queer practices of self-relation"); Mathew Rodriguez, *After Party*, POZ (Apr. 4, 2016), <https://www.poz.com/article/party> [<https://perma.cc/TB8D-8SER>] (providing a clarifying discussion on the complex relationship between drug usage and queer male sexual and social cultures).

quire the presence of misleading speech within the video and thus cannot be sustained.

As explained in *Amarin*, *Caronia* held that “the FDCA’s misbranding provisions cannot constitutionally criminalize, and therefore do not reach, the act of truthful and non-misleading speech promoting off-label use.”<sup>122</sup> This conclusion necessarily followed from the Supreme Court’s prior observation that “[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment” and thus cannot be restricted absent a failure to satisfy the four parts of the *Central Hudson* analysis.<sup>123</sup> AHF’s claim that Gilead promotes the situational use of Truvada as medically effective would, if before a court, likely be addressed under *Central Hudson*’s first prong, which queries whether the commercial speech under scrutiny is “more likely to deceive the public than inform it . . . .”<sup>124</sup> The court in *Caronia* reiterated the axiom that “the First Amendment does not protect false or misleading commercial speech,” and the court’s construction of the FDCA affords no protection to the manufacturer who employs misleading communications in the promotion of an off-label use.<sup>125</sup>

The content of the first promotional video, though potentially referencing illegal substance use, certainly does not bind this provocative possibility to its representations of how Truvada is properly used. The actor states that his enjoyment of socializing does not compromise his commitment to sexual safety, a message that the ringing of his cellphone’s daily reminder to take Truvada daily reiterates, a schedule clearly aligned with the medication’s prescription regimen. Indeed, it may be that “partying” and “safety” are placed in such purposeful juxtaposition to demonstrate that the two are not irreconcilable — an individual can pursue autonomous sexual choices while remaining committed to bodily health and integrity. Of equal consequence is that, in the context of the other two videos that constitute the advertising campaign, the messages presented in this first video appear in-

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122. *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp.3d 196, 227 (S.D.N.Y. 2015).

123. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011).

124. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563 (1980) (citations omitted).

125. *Amarin*, 119 F. Supp.3d at 228 (referencing *U.S. v. Caronia*, 703 F.3d 149 (2d Cir. 2012)).

tended to acknowledge the frank reality both of HIV/AIDS and of a strong desire to pursue enjoyment without sacrificing one's sense of bodily care.

The crystallization of *Caronia*'s jurisprudential legacy as articulated in *Amarin* may have suffered partial erosion in mid-2016, when the Second Circuit Court of Appeals issued its decision in *U.S. ex rel. Polansky v. Pfizer*.<sup>126</sup> The court there asserted in a footnote that its holding in *Caronia*, though having avoided the constitutional question presented by the FDCA's potential implication of the First Amendment, had nevertheless "left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label."<sup>127</sup> A textual examination of *Caronia*, however, suggests that the court's misrepresents the *Caronia* dicta. The court in *Caronia* did not decide but rather *assumed* that a drug manufacturer's promotional speech could be marshaled as evidence to prove that manufacturer's intended use of a drug, a determination that would then support a criminal prosecution for mislabeling or misbranding.<sup>128</sup> Although this difference in language is ostensibly minute, it effectively circumscribes the reach of *Caronia*'s holding. *Caronia* is characterized as a case about simple promotional speech that does not seek to furtively supplant the particular use of a drug that the FDA specifically approved; this retrospective gloss once again opens the possibility of pharmaceutical marketing and speech to function as evidence of a criminal act.<sup>129</sup>

The essentially unanswered question of whether promotional speech may serve as the basis of a criminal prosecution or as partial evidence supporting a criminal prosecution leaves Gilead and, by necessary implication, Truvada in a precarious position.

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126. See *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613 (2d Cir. 2016).

127. *Id.* at 615 n.2 (citing *Caronia*, 703 F.3d at 162).

128. See *Caronia*, 703 F.3d at 162 n.9 ("Although we assume, *without deciding*, that such use of evidence of speech is permissible under [related Supreme Court precedent], we observe that it still remains unclear how the government would identify criminal misbranding from communications between drug manufacturers and physicians authorized to prescribe drugs for off-label use.").

129. *But see Amarin*, 119 F. Supp.3d at 227 ("But *Caronia* did not turn on the intent element of misbranding. It turned on the *actus reus* requirement. And *Caronia*'s holding was that the FDCA's misbranding provisions cannot constitutionally criminalize, and therefore do not reach, the act of truthful and non-misleading speech promoting off-label use."); see also *id.* at 226 ("Where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, cannot be the act upon which an action for misbranding is based.").

Should AHF's allegations be taken seriously, the nuanced rereading of *Caronia* in *Polansky* could allow the FDA to marshal the video campaign as a piece of criminalizing evidence — one of many that AHF has worked to compile and provide.<sup>130</sup> Unsurprisingly, the FDA has taken notice of the jurisprudential ripples effected by *Caronia*. In September 2015, the FDA issued a proposed rule that included amendments to the agency's regulations regarding "intended uses."<sup>131</sup> In January 2017, the agency promulgated the rule in its final version, and the commentary accompanying the rule in the Federal Register offers useful insight into how the FDA will pursue misbranding allegations in the wake of *Caronia*.

### C. POTENTIAL EFFECTS OF RECENT FDA RULEMAKING PROCEEDINGS AND THE JANUARY 2017 "INTENDED USES" FINAL RULE

In September 2015, the FDA initiated a rulemaking proceeding that had as one of its objectives the amendment of the agency's "Intended Use" regulations.<sup>132</sup> To better elucidate its position on the types of evidence that are permissibly considered in an intended-use determination, the agency then recommended the deletion of the final sentence of 21 C.F.R. § 201.128,<sup>133</sup> which stated:

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130. See generally *PrEP Update: The Facts Speak for Themselves*, Notes AHF, BusinessWire (July 21, 2016, 7:32 AM), <http://www.businesswire.com/news/home/20160721005613/en/PrEP-Update-Facts-Speak-Notes-AHF> [<https://perma.cc/C5P3-DGVX>] (describing the rollout of AHF's national campaign, entitled "Open Letter to the CDC on PrEP," which argues that Gilead's promotion of Truvada has played a significant role in skyrocketing numbers of individuals contracting sexually-transmitted infections).

131. Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193, 2195 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts. 201, 801, 1100).

132. See Amendments to Regulations Regarding "Intended Uses," 80 Fed. Reg. 57,756 (proposed Sept. 25, 2015).

133. In its proposed rule and in its final rule, the FDA addressed both 21 C.F.R. § 201.128 (2016), which regulates the intended use of drugs, and 21 C.F.R. § 801.4 (2016), which regulates the intended use of medical devices. Because consideration in this text is given exclusively to pharmaceutical promotion of drugs, i.e., Gilead's promotional advertising for Truvada, the text will not reference the medical-device regulation.

But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.<sup>134</sup>

When first promulgated, the regulation sparked significant criticism from pharmaceutical companies because the final sentence, when literally read, appeared to hold that “a manufacturer’s mere knowledge of an unapproved use of its approved drug automatically triggers requirements for new labeling that in turn render distribution of that approved product unlawful . . . .”<sup>135</sup> The FDA’s proposed deletion of that sentence intended to clarify that a manufacturer’s knowledge of physicians’ off-label use of a drug it had manufactured would not, by itself, trigger the FDCA’s labeling provisions.<sup>136</sup> After reviewing the comments submitted in response to the proposed rule, the FDA ultimately decided to forego deletion of the sentence in favor of a detailed re-articulation that would “better reflect” how the agency has consistently applied its intended-use regulation.<sup>137</sup> The final rule excised the former’s focus on manufacturer knowledge and articulated instead that an evaluation of “the totality of the evidence [can] establish[] that a manufacturer objectively intends that a drug . . . be used for conditions, purposes, or uses other than ones for which it is approved . . . .”<sup>138</sup>

Several comments to the proposed rule asserted that the FDA was constitutionally required to contract its proposed definition of “intended use” because of recent court rulings, including *Caronia* and *Amarin*. The FDA’s response to these comments emphasized the agency’s express disagreement with “the assertion that the current case allow allows FDA to consider speech as evidence of intended use only when it is false or misleading,”<sup>139</sup> as articulated in *Caronia*. The agency buttressed its claim with a citation to *Polansky*, quoting the language of the very same footnote that

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134. 21 C.F.R. § 201.128 (2016).

135. Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. at 2206.

136. *See id.* (“FDA does not consider a firm’s knowledge that a health care provider has used or prescribed its approved/cleared medical product for an unapproved use, by itself, as sufficient to establish the intended use element of a prohibited act . . .”).

137. *Id.* at 2205.

138. *Id.* at 2206.

139. *Id.* at 2209.

undermined the scope of the *Caronia* decision.<sup>140</sup> Interestingly, after the *Polansky* court stated that *Caronia* left intact the government's ability to prove misbranding through reliance on promotional speech as evidence, the court then cited the final sentence of 21 C.F.R. § 201.128, the FDA's intended-use regulation, as analogous support for its argument.

The FDA's citation to the *Polansky* footnote in its final rule curiously omitted any reference to court's inclusion of the intended-use regulation — a somewhat glaring excision insofar as the agency altered the text of that very sentence. The effect of *Polansky's* subtle circumscription of *Caronia* here becomes manifest, as the FDA was implicitly able to cite itself as judicial authority through its purposeful tailoring of the *Polansky* court's footnoted text. This reassertion of the evidentiary value of pharmaceutical speech further corrodes the protection afforded by *Caronia*. Despite clearly addressing the constitutional complexities of off-label promotion throughout the text of the final rule, the FDA described the legal issues as sufficiently complex to merit a separate examination,<sup>141</sup> which the FDA initiated in September 2016.<sup>142</sup>

The newly altered version of 21 C.F.R. § 201.128 ostensibly provides some legal protection for drug manufacturers against discretionary enforcement actions for off-label promotion, but the FDA's continuous equivocation in responses to comments on the rule's proposed form suggests that the agency will not easily abandon its use of speech as prosecutorial evidence. AHF's assault on Truvada, though amenable to being categorized as politically reactionary, may function as an unexpected symbol of the entropic policy adjustments now characteristic of the current fed-

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140. See *id.* (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613 n.2 (2d Cir. 2016)) (noting the Second Circuit had recently confirmed that *Caronia* did not preclude the government from proving misbranding on a theory using promotional speech as evidence).

141. Despite stating that review of the "broader policy questions [and] related First Amendment issues," *id.*, implicated by the FDCA's misbranding provisions would be the exclusive focus of a separate proceeding, the FDA nonetheless devoted several pages of its final rule to a trenchant critique of the *Caronia* majority opinion. See *id.* at 2208–11 (stating the legal analysis conducted in *Caronia* failed to consider the multiple facets of the FDA's responsibilities for public health and demonstrated only a limited understanding of the public-health interests at stake that, if understood, would have resulted in an alternative conclusion pursuant to the *Central Hudson* analysis).

142. See *Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments*, 81 Fed. Reg. 60,299 (proposed Sept. 1, 2016) (to be codified at 21 C.F.R. pt. 15).

eral political climate. Although the FDA took pains to describe its alteration of the intended-use regulation's last sentence as a simple clarification of longstanding policy, a totality-of-the-evidence standard may, by virtue of the subjectivity involved in such an assessment, promote greater arbitrariness in the enforcement of FDCA prohibitions. AHF is a powerful advocacy organization whose capacity to ignite unexpected sociopolitical change cannot be discredited,<sup>143</sup> and thus its sustained criticism of Truvada as the potential site of a second AIDS epidemic may tap into an internalized reservoir of AIDS-phobia potent enough to exploit the plasticity of the FDA's purportedly "consistent" regulatory position.

#### V. OSSIFYING REGULATIONS OF OFF-LABEL SPEECH — CONCLUDING THOUGHTS ON THE IMPERILING OF TRUVADA AND COMMERCIAL SPEECH

On January 18, 2017, two days before the Trump administration took office and the regulatory ethos of the executive branch would begin to undergo substantive change, the FDA released an official agency document (entitled a "memorandum," thereby reducing the scope of its regulatory significance to possibly nil) wherein it staked out its position on the First Amendment questions pertaining to off-label commercial speech.<sup>144</sup> This document, which breaks years of agency silence on the specific question of the scope of First Amendment protection to which biopharmaceutical companies are entitled in the off-label marketing of approved drugs, suggests an attempt by the agency to place its views "on the record" before the change in administration results

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143. See *AHF: Measure B Condom Requirement is Now ". . . Settled Law," after L.A. County, Porn Industry Reach Legal Settlement*, BUS. WIRE (Mar. 29, 2016), <http://www.businesswire.com/news/home/20160329006649/en/AHF-Measure-Condom-Requirement-%E2%80%9C%E2%80%A6Settled-Law%E2%80%9D-L.A.> [<https://perma.cc/59MR-QBMY>] (noting AHF had been the proponent and principal funder of a public measure that enacted an enormous change in the protocols of the pornography industry in Los Angeles by requiring "actors in pornographic films to wear condoms").

144. See Press Release, U.S. Food and Drug Admin., Statement from FDA Commissioner Robert Califf, M.D., Announcing New Draft Guidances on Medical Product Communications (Jan. 18, 2017), *available at* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537371.htm> [<https://perma.cc/2W55-F2S2>] (stating that memorandum "provides additional background on the issues the FDA is considering as part of our comprehensive review of our rules and policies relating to firm communications regarding unapproved uses of approved or cleared medical products, including a discussion of First Amendment considerations").

in an alternative approach; indeed, the memorandum may function to undercut the viability of any substantive change in the FDA's position on off-label marketing, as significant changes in agency policy adversely affect the scope of deference afforded such changes.

The position the FDA articulates in its memorandum reflects the longstanding, implicit stance it has taken on off-label promotion: that the "government's multi-faceted interests in the public health are substantial and . . . the relevant FDA Authorities directly advance many of those interests."<sup>145</sup> While it is certainly worthwhile to retain the rigorous standards of examination to which new medical drugs are subjected prior to their approval for placement within the national market, the FDA's cursory dismissal of the legal questions addressed by the courts in *Caronia* and *Amarin* cast doubt on the FDA's attempt at a reasonable, evidence-based analysis of the public-health concerns those cases raised. The concern of heavily politicized bias within the domain of the FDA's health policy determinations, augmented by the publication of the aforementioned Memorandum, led an organization of pharmaceutical companies and biotechnology corporations to file a petition to stay the implementation of the FDA's Final Rule on intended use.<sup>146</sup> According to the industry groups' petition, the new standard the FDA will employ in its determination of a drug's intended use, completed under a "totality of the evidence standard," would allow anything to "be considered to establish a product's intended use,"<sup>147</sup> thereby allowing the FDA "to rely even on non-promotional scientific exchange as evidence of intended use."<sup>148</sup> The chilling effect of such a standard is difficult to comprehensively imagine, as any kind of speech a pharmaceutical corporation engages in could be marshaled as evidence that the firm intended to misrepresent the manner in which the drug is approved to be used.

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145. U.S. FOOD & DRUG ADMIN., MEMORANDUM: PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS RELATED TO MANUFACTURER COMMUNICATIONS REGARDING UNAPPROVED USES OF APPROVED OR CLEARED MEDICAL PRODUCTS 23 (2017) [hereinafter FDA, FIRST AMENDMENT MEMORANDUM] (footnote omitted), available at <https://www.regulations.gov/document?D=FDA-2016-N-1149-0040> [<https://perma.cc/YQY3-KMRD>].

146. MED. INFO. WORKING GRP. ET AL., PETITION TO STAY AND FOR RECONSIDERATION (2017), available at <https://www.regulations.gov/document?D=FDA-2016-N-1149-0048> [<https://perma.cc/U223-XYDP>].

147. *Id.* at 21.

148. *Id.*

This new standard and the recalcitrance of the FDA to offer a more nuanced position on the relationship between the rights the First Amendment protects and the effects of those rights on commercial speech must be considered in contexts beyond those to which the FDA blithely alludes, such as those in which biopharmaceutical corporations seek the First Amendment as a shield to veil their exploitative efforts.<sup>149</sup> A medication such as Truvada, which serves communities subject to multiple forms of social disqualification, is particularly vulnerable to the kind of attacks the FDA's policy would allow — a concern that is undoubtedly aggravated in the new political context portended by the Trump administration. The question here is thus not whether the FDA should or should not relax its standards regarding the proliferation of off-label speech; rather, it is whether the broad stroke the current policy effects may prove hazardous to continued access to drugs capable of changing the destruction experienced by communities that remain vulnerable to systemic exposure to illness and disease. Further, this question must consider whether the FDA's position may offer the new administration a sword against which to assault those biopharmaceutical companies not engaged in off-label speech, as conventionally envisioned, but engaged in providing medication and information to communities otherwise imperiled by lack of access to medical information and drug availability.

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149. Policy organizations, legal entities, and governmental agencies such as the FDA that favor an expansive regulatory regime of commercial speech vis-à-vis biopharmaceutical companies often reference the unintended lethal consequences of Tambocor and Enkaid's unapproved uses. Originally approved in 1985 and 1986, respectively, by the FDA to treat ventricular arrhythmias, the two drugs became increasingly associated with the treatment of *asymptomatic* ventricular arrhythmias, common in heart-attack patients who were suffering from irregular heartbeats. See Declaration of Rachel E. Sherman, MD, Par Pharm., Inc. v. United States, No. 1:11-cv-1820 (D.D.C. Jan. 11, 2012), available at <http://www.hpm.com/pdf/blog/ParShermanDec.pdf> [<https://perma.cc/84UX-EJYZ>]. This unapproved use was so widespread by 1987 that the National Institutes of Health launched a study to investigate the efficacy of the medications in treating asymptomatic ventricular arrhythmias; the study was discontinued after two years when the findings revealed that patients prescribed the medications during heart-attack recovery demonstrated a risk of death that was 2.5 times greater than patients who did not receive the medications during heart-attack recovery. Debra S. Echt et al., *Mortality and Morbidity in Patients Receiving Encainide, Flecainide, or Placebo: The Cardiac Arrhythmia Suppression Trial*, 324 NEW ENG. J. MED. 781 (1991) (concluding same). The FDA takes this situation as an exemplar of a situation where the unapproved use of a medication has led to significant patient harm. See FDA, FIRST AMENDMENT MEMORANDUM, *supra* note 144, at 51–52.