

# FREE SPEECH AND SCIENTIFIC EXCHANGE: TESTING THE LIMITS OF FDA’S AUTHORITY TO REGULATE MANUFACTURER SCIENTIFIC DISCUSSIONS

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## I. INTRODUCTION

Ever since Congress enacted the Federal Food, Drug, and Cosmetic Act (“FFDCA”) in 1938, dynamic uncertainty has existed regarding the rules and restrictions on speech<sup>1</sup> made by pharmaceutical and medical device companies, their employees, and their agents, including healthcare professional consultants (collectively “manufacturers”). The U.S. Food and Drug Administration (“FDA”) has long asserted its right to restrict manufacturers’ speech promoting or discussing unapproved (i.e., off-label) uses of drugs or medical devices. However, with the introduction of field-based medical support (i.e., Medical Affairs), by the Upjohn Company in 1967, the focus began expanding beyond just promotional claims to encompass any scientific discussions or scientific exchange by manufacturers.<sup>2</sup>

The FDA’s rules and restrictions surrounding manufacturer speech were clearly outlined through the late 1990s. However, rulings by the U.S. Supreme Court and other lower courts have posited new limits on FDA’s authority to regulate the limits on speech by manufacturers. Based on these rulings, the FDA limited the rights to regulate or restrict manufacturer scientific speech. Furthermore, any permissible restrictions by the FDA are controlled by the First Amendment and not the FFDCA.

The breadth of permitted First Amendment restrictions turns on whether manufacturer scientific speech is commercial or non-commercial (so-called “pure speech”). However, without a definitive ruling by the Supreme Court on how to consider such speech, manufacturer scientific speech classifies as pure speech. Therefore, the FDA’s authority is limited to addressing false or misleading speech and imposing time limits, place, and manner restrictions that are subject to “strict

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1. As used throughout this Article, “speech” describes both oral and written materials.

2. See Sandeep K. Gupta & Roopa P. Nayak, *An Insight Into the Emerging Role of Regional Medical Advisor in the Pharmaceutical Industry*, 4 PERP. CLINICAL RSCH. 186, 187 (2013).

scrutiny” by the courts.

## II. FDA’S TRADITIONAL AUTHORITY TO REGULATE MANUFACTURER SPEECH

FDA asserts its authority to regulate the labeling, advertising, and promotion of drugs and medical devices by a complex connection of FFDCA provisions,<sup>3</sup> which predate the Second World War. The Act prohibits introducing a misbranded drug or device into interstate commerce.<sup>4</sup> A drug or device is considered misbranded if the product’s labeling: (1) is false or misleading in any way; (2) it does not contain adequate directions for use; or (3) it does not contain clear and comprehensible warnings of potential consequences resulting from its use.<sup>5</sup>

Thus, FDA’s authority to control manufacturer speech under the misbranding provision is through the products’ labeling and its intended use. However, misbranding turns on whether the manufacturer’s statements are “false or misleading.” A plain reading of the statute suggests that if the statements are truthful and not misleading, the product is not, by definition, misbranded, rendering it free from FDA enforcement.

The FFDCA defines labeling as “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.”<sup>6</sup> However, the Supreme Court expanded and refined the definition by clarifying that “accompanying” does not necessitate physical attachment, but instead, “[i]t is the textual relationship that is significant.”<sup>7</sup>

The FDA defines “intended use” as “the objective intent of the persons legally responsible for the labeling of drugs.”<sup>8</sup> To determine a product’s intended use, “the Agency may look to any relevant source of evidence,” including product advertising, which the Act does not explicitly define.<sup>9</sup> However, if the advertising is either false or misleading, the FDA can use that to support a misbranding charge.<sup>10</sup> Thus, “[t]he manufacturer’s intent will necessarily be determined on a case-by-case basis, looking at the totality of the facts and circumstances.”<sup>11</sup>

The combination of misbranding, labeling, and intended use allows the FDA to assert broad regulatory authority over product-related speech. Therefore, until

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3. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

4. 21 U.S.C. § 331(a) (misbranding applies to any FDA regulated product including food, drugs, devices, or biologics). Under the Federal Trade Commission Act, the FTC regulates unfair or deceptive acts and practices affecting interstate commerce, which includes the express authority to address false advertising made by a company. *See* 15 U.S.C. §§ 44, 45(a)(1), 52(a).

5. *See* 21 U.S.C. §§ 321(n), 352(a)(1), 352(f).

6. 21 U.S.C. § 321(m).

7. *Kordel v. United States*, 335 U.S. 345, 350 (1948).

8. *See* 21 C.F.R. §§ 201.128, 801.4 (2021).

9. 21 C.F.R. §§ 201, 801 (as amended by 86 Fed. Reg. 41383, 41388 (2021) (regulations regarding “Intended Uses”).

10. *Id.*

11. *Id.*

recently, “the FDA has categorically banned manufacturers of drugs and devices from promoting their use for unapproved purposes to the medical profession.”<sup>12</sup>

Although the FDA has broad authority to regulate promotional information pertaining to off-label uses by a manufacturer, its authority is limited in the context of scientific speech, discussions, or exchange because of the practice of medicine exception.<sup>13</sup> Furthermore, the FDA recognizes the public health benefit derived from providing “truthful and non-misleading scientific or medical publications on unapproved new uses” to healthcare professionals.<sup>14</sup> The FDA also acknowledges that “in some specific and narrow areas of medical practice, practitioners consider off-label use to constitute the standard of good medical care.”<sup>15</sup> Consequently, where investigational (i.e., unapproved) drugs are involved, the FDA explicitly allows “the full exchange of scientific information concerning the drug[,]” provided the manufacturer does not make promotional claims about the drug’s safety or effectiveness.<sup>16</sup>

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Likewise, the FDA also allows the dissemination of off-label information about an FDA-approved drug or device by a manufacturer to an HCP, pharmacy benefit manager, health insurance issuer, group health plan, or regulatory agency that meets all relevant regulatory requirements.<sup>18</sup> Chief among these requirements is that the information disseminated must be truthful, not misleading and does not

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12. See Coleen Klasmeier & Martin 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, 320 (2011).

13. The “practice of medicine” exception is well-enshrined in statute and FDA regulations. See 21 U.S.C. § 396; 21 C.F.R. § 312.3(d) (2008). The exception allows a prescriber to use a drug or device product for an unapproved indication when the best interests of the patient require it. See U.S. FOOD & DRUG ADMIN., “OFF-LABEL” AND INVESTIGATIONAL USE OF MARKETED DRUGS, BIOLOGICS, AND MEDICAL DEVICES: GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS, 6 (1998); see also U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY – RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES: DRAFT GUIDANCE, 3 (2011).

14. See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY DISTRIBUTING SCIENTIFIC AND MEDICAL PUBLICATIONS ON UNAPPROVED NEW USES — RECOMMENDED PRACTICES: REVISED DRAFT GUIDANCE, 8 (2014); U.S. FOOD & DRUG ADMIN. MEMORANDUM ON PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS RELATED TO MANUFACTURER COMMUNICATIONS REGARDING UNAPPROVED USES OF APPROVED OR CLEARED MEDICAL PRODUCTS, 17 (Jan. 2017).

15. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998).

16. See 21 C.F.R. § 312.7(a) (2009).

17. *Friedman*, 13 F. Supp. 2d at 56.

18. See 21 C.F.R. §§ 99.1(a)(2), 99.101(a), and 99.105 (1998); but see 21 C.F.R. § 99.1(b) (1998) (the regulations do not apply to manufacturer responses to unsolicited requests by HCPs).

pose a significant risk to public health.<sup>19</sup> Furthermore, in these situations, the provision of such information is not considered evidence of a manufacturer's promotion of the product for an "off-label" use.<sup>20</sup>

### III. FIRST AMENDMENT PROTECTIONS

In addition to the FDCA, manufacturer speech is subject to free speech guaranteed by the First Amendment of the U.S. Constitution. Freedom of speech states, "Congress shall make no law . . . abridging the freedom of speech, or of the press."<sup>21</sup>

As the U.S. Supreme Court articulated, "[t]he protection given speech and press was fashioned to assure unfettered interchange of ideas for the bringing about of political and social changes desired by the people."<sup>22</sup> Therefore, "[a]ll ideas having even the slightest redeeming social importance – unorthodox, controversial, and even ideas hateful to the prevailing climate of opinion – have the full protection of the guaranties, unless excludable because they encroach upon the limited area of more important interests."<sup>23</sup>

Where First Amendment protections exist, "[f]reedom of speech presupposes a willing speaker [but] where a speaker exists . . . the protection afforded is to the communication, source, and recipients."<sup>24</sup> Therefore, the First Amendment also protects the "right to 'receive information and ideas.'"<sup>25</sup>

#### *A. Free Speech Has Certain Limits*

However, not all speech is protected by the First Amendment. For example, as Justice Oliver Wendell Holmes pointed out in 1919, "there is not constitutionally protected right to yell fire in a theatre and cause panic when there is no fire."<sup>26</sup> Likewise, the First Amendment "does not embrace certain categories of speech, including defamation, incitement, obscenity, or [child] pornography."<sup>27</sup> Nor does it embrace false or misleading speech.<sup>28</sup>

There also is a nexus between speech and conduct. For example, in *Cox v. Louisiana*, involving a peaceful protest march and sit-in at segregated lunch

19. 21 C.F.R. §§ 99.101(a)(3), (4).

20. See U.S. FOOD & DRUG ADMIN., "OFF-LABEL" AND INVESTIGATIONAL USE OF MARKETED DRUGS, BIOLOGICS, AND MEDICAL DEVICES: GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS at 6 (1998); see also U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY – RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES: DRAFT GUIDANCE, 3 (2011).

21. U.S. CONST. amend. I.

22. See *Roth v. United States*, 354 U.S. 476, 484 (1957).

23. *Id.*

24. See *Va. State Bd. of Pharmacy v. Va. Consumer Council, Inc.*, 425 U.S. 748, 756 (1976).

25. See *id.* at 757 (citing *Kleindienst v. Mandel*, 408 U.S. 753, 762-63 (1972)).

26. *Schenck v. United States*, 249 U.S. 47, 52 (1919).

27. *Ashcroft v. Free Speech Coal.*, 535 U.S. 234, 246 (2002).

28. *Va. State Bd. of Pharmacy*, 425 U.S. at 771.

counters, Justice Goldberg noted that protestors have no right to cordon off a street or block entrances to buildings to require people to listen to “their exhortations.”<sup>29</sup> Therefore, “it has not been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language; either spoken, written, or printed.”<sup>30</sup>

Enshrined in the concept of free speech is the principle that “the government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable.”<sup>31</sup> Therefore, the “regulation of communication may not be affected by sympathy or hostility for the point of view being expressed by the communicator.”<sup>32</sup>

Nevertheless, the Supreme Court has determined that the First Amendment permits “reasonable regulation of speech-connected activities in carefully restricted circumstances.”<sup>33</sup> Restrictions that target speech based upon content “are presumptively unconstitutional” and are justifiable “only if the government proves that they are narrowly tailored to serve compelling state interests.”<sup>34</sup> Content restrictions also must satisfy strict scrutiny requirements because the government cannot ban speech merely because it expresses offensive ideas.<sup>35</sup> However, where there is a significant governmental interest, the government can impose time, place, and manner restrictions, “provided they are justified without reference to the content of regulated speech.”<sup>36</sup>

Furthermore, the government must ground any restrictions on more than “mere speculation about serious harms.”<sup>37</sup> However, the Supreme Court has noted that “state action to punish the publication of truthful information seldom can satisfy constitutional standards.”<sup>38</sup> Finally, even when there is a legitimate and compelling interest to restrict or criminalize speech, the context surrounding a

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29. *Cox v. State of Louisiana*, 379 U.S. 536, 554-55 (1965) (citations omitted).

30. *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)).

31. *Texas v. Johnson*, 491 U.S. 397, 414 (1989) (upholding flag burning as a permitted form of protest); *see also* *Roth v. United States*, 354 U.S. 476, 484 (1957).

32. *Young v. Am. Mini Theatres, Inc.*, 427 U.S. 50, 67 (1976) (upholding a zoning ordinance distinguishing between several types of theatres); *see also* Stewart Jay, *The Creation of the First Amendment Right to Free Expression: From the Eighteenth Century to the Mid-Twentieth Century*, 34 WM. MITCHELL L. REV. 773, 774 (2008).

33. *See Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 513 (1969) (discussing whether the school district could suspend students from wearing black armbands to protest the Vietnam War).

34. *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2014).

35. *Matal v. Tam*, 137 S. Ct. 1744, 1751 (2017).

36. *See Va. State Bd. of Pharmacy*, 425 U.S. at 771; *see also* *Bartnicki v. Vopper*, 532 U.S. 514, 526 (2001) (discussing content neutrality of the federal wiretapping statute).

37. *See Bartnicki*, 532 U.S. at 531 (quoting *United States v. Treasury Emp.’s*, 531 U.S. 454, 475 (1995)).

38. *Id.* at 527 (quoting *Smith v. Daily Mail Publ’g Co.*, 443 U.S. 97, 102 (1979)).

particular utterance may abrogate the government's restriction or punishment.<sup>39</sup>

### B. Types of Speech

Until 1942, there was no distinction between commercial and non-commercial speech; there was just speech.<sup>40</sup> However, since the mid-1970s, the Supreme Court has recognized two distinct types of speech—pure and commercial.<sup>41</sup> The distinction is essential because the extent to which the government can regulate speech turns on its classification.

Commercial speech differs from “pure speech” in three critical respects. First, unlike “pure speech,” which typically involves the communication of ideas (e.g., political viewpoints, scientific information, etc.), commercial speech is speech that connects to an individual's commercial interest (e.g., advertising) or involves something sold for profit (e.g., books).<sup>42</sup> Thus, in its purest form, commercial speech is “speech which does no more than propose a commercial transaction.”<sup>43</sup>

However, like pure speech, the Supreme Court determined that commercial speech provides an essential public benefit worthy of First Amendment protection.<sup>44</sup> Moreover, while protecting pure speech is crucial for “enlightened public democracy,” commercial speech is essential to support “intelligent and well-informed” economic decisions.<sup>45</sup> Commercial speech is not far removed from the discussion of ideas or from truth and science, unlike defamation, incitement, or obscenity, that it does not deserve protection.<sup>46</sup> Therefore, commercial speech does not lose First Amendment protection because of a commercial context or a purely economic interest.<sup>47</sup>

Second, commercial speech differs from pure speech because commercial speech relates to commercial transactions, an area traditionally subject to government regulation.<sup>48</sup> Therefore, the Supreme Court has determined that

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39. See *Watts v. United States*, 384 U.S. 705, 708 (1969) (holding that a “threat” against the President was “political hyperbole” because it was made in the context of a Vietnam War protest).

40. See *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942); see also Note, *Dissent, Corporate Cartels, and the Commercial Speech Doctrine*, 120 HARV. L. REV. 1892, 1892 (2007); Steven M. Simpson, *The Commercial Speech Doctrine: An Analysis of The Consequences of Basing First Amendment Protections on the “Public Interest”*, 39 N.Y. L. SCH. L. REV. 575, 575 (1994).

41. See *Bigelow v. Virginia*, 421 U.S. 809 (1975); *Va. State Bd. of Pharmacy*, 425 U.S. at 748.

42. See *Va. State Bd. of Pharmacy*, 425 U.S. at 762, 765.

43. See *id.* at 762.

44. See, e.g., *Pittsburgh Press Co. v. Hum. Rel. Comm'n*, 413 U.S. 376 (1973); *Bigelow*, 421 U.S. at 822; *Va. State Bd. of Pharmacy*, 425 U.S. at 748; *Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n*, 447 U.S. 557, 562-563 (1980); *Bolger v. Youngs Drug Prod.'s Corp.*, 463 U.S. 60 (1983); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1994).

45. See *Va. State Bd. of Pharmacy*, 425 U.S. at 765.

46. See *id.* at 762.

47. See *id.* at 759, 61; see also *Bigelow*, 421 U.S. at 818.

48. See *Bolger*, 421 U.S. at 64.

commercial speech is entitled to lesser protection than “pure speech.”<sup>49</sup> For example, the government may restrict commercial speech that is more likely to deceive than to inform.<sup>50</sup>

Third, unlike pure speech, the Supreme Court has outlined a four-part test to evaluate whether government restrictions of commercial speech are permissible under the First Amendment. The Court in *Central Hudson Gas & Elec. v. Pub. Serv. Comm’n* outlined the well-established 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>51</sup>

Thus, restrictions cannot stand if they provide “only ineffective or remote support for the government’s purpose.”<sup>52</sup> Nor can restrictions stand if the government’s purpose “could be served as well by a more limited restriction on commercial speech.”<sup>53</sup> Therefore, the Supreme Court has “rejected the ‘highly paternalistic’ view that government has the complete power to suppress or regulate commercial speech” because “[e]ven when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.”<sup>54</sup> This position suggests that even commercial speech that omits some crucial details (i.e., is misleading) might be worthy of some level of First Amendment protection.

Following the *Central Hudson* decision, the Supreme Court has continued to refine the boundaries of permissible government regulation of commercial speech.<sup>55</sup> Thus, the Supreme Court rejected governmental attempts to curtail commercial speech in cases involving unsolicited contraceptive advertisements (*Bolger v. Youngs Drug Products Corp.*) and beer labeling (*Rubin v. Coors Brewing Co.*).<sup>56</sup>

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49. See *Pittsburgh Press Co.*, 413 U.S. at 376; *Bigelow*, 421 U.S. at 809; *Va. State Bd. of Pharmacy*, 425 U.S. at 748; *Central Hudson*, 447 U.S. at 557; *Bolger*, 463 U.S. at 60 (1983); *Rubin*, 514 U.S. at 478.

50. See *Central Hudson*, 447 U.S. at 563 (citations omitted); *Bolger*, 421 U.S. at 65.

51. See *Central Hudson*, 447 U.S. at 566.

52. *Id.* at 564.

53. *Id.*

54. *Id.* at 562 (citations omitted).

55. See, e.g., Richard Parker, *Central Hudson Gas and Electric Corp. v. Public Service Commission (1980)*, FIRST AMEND. ENCYCLOPEDIA, <https://mtsu.edu/first-amendment/article/198/central-hudson-gas-and-electric-corp-v-public-service-commission> [<https://perma.cc/PN3K-KDP3>] (last visited Feb. 23, 2023).

56. See *Bolger*, 463 U.S. at 75 (“the justifications offered [by the government] are insufficient

The Supreme Court also rejected an attempt by the State of Vermont to restrict “data mining” activities to prevent pharmacies from selling or pharmaceutical companies from using prescriber-identifying information for marketing purposes without the prescriber’s consent.<sup>57</sup> The Court found that the law was content-based and, in practice, viewpoint discriminatory.<sup>58</sup> Therefore, the statute was not a “mere commercial regulation.”<sup>59</sup>

#### IV. TWO WORLDS COLLIDE

Following the Supreme Court’s pure and commercial speech rulings, the stage was set for a series of challenges to the FDA’s claimed authority to regulate off-label promotion (i.e., speech) by drug and device manufacturers. Like the Supreme Court in *Central Hudson*, *Bolger*, *Rubin*, and *Sorrell*, the courts in these cases rejected the FDA’s sweeping claims of authority to restrict manufacturer speech about off-label product uses.

In 1998, the Washington Legal Foundation challenged guidance documents issued by the FDA that sought to restrict “certain forms of manufacturer promotion of off-label use for FDA-approved drugs and devices.”<sup>60</sup> The FDA’s guidance documents contained restrictions on the dissemination of medical textbooks and peer-reviewed articles, as well as industry involvement in continuing medical education (“CME”) programs.<sup>61</sup>

The FDA argued that based on the need 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[,]” there was a substantial government interest.<sup>62</sup> Additionally, the Agency contended that the speech covered by the guidance documents fell outside of the First Amendment because of the FDA’s “extensive power to regulate the pharmaceutical industry.”<sup>63</sup>

The D.C. District Court rejected those propositions as being of questionable validity.<sup>64</sup> According to the District Court, the First Amendment rules must apply

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to warrant the sweeping prohibition on the mailing of unsolicited contraceptive advertisements.”); *Rubin*, 514 U.S. at 490 (finding BATF’s regulation was not sufficiently tailored to meet its goal in a direct and meaningful way).

57. See *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 574 (2011) (free speech limitations cannot stand “when the options provided by the State are too narrow to advance legitimate interests or too broad to protect speech.”).

58. *Id.* at 571.

59. *Id.* at 566.

60. See *Friedman*, 13 F. Supp. 2d at 54.

61. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (1997); Advertising and Promotion Guidance, 61 Fed. Reg. 52800-02 (1996).

62. *Friedman*, 13 F. Supp. 2d at 58.

63. See *id.* at 60.

64. *Id.*



if the speech is about a lawful activity and not misleading.<sup>65</sup> In rejecting the FDA's contention that off-label speech is about illegal activities, the Court noted:

The proper inquiry is not whether the speech violates a law or a regulation but whether the conduct that the speech promotes violates the law . . . . Therefore, only at such time as off-label prescriptions are proscribed by law could the FDA legitimately claim that the speech at issue addresses "illegal activities."<sup>66</sup>

In other words, the FDA's power may be limited to "off-label" speech that results, or may result, in an illegitimate prescription (e.g., medically unnecessary). Furthermore, Judge Lamberth, in an often-quoted passage, wrote "[i]n 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, FDA exaggerates its overall place in the universe."<sup>67</sup>

While the District Court concluded that the FDA's interests in protecting the public are substantial, the Agency's approaches were "more extensive than necessary to serve the asserted government interest and that they unduly burden important speech."<sup>68</sup> Therefore, the FDA could not prevent manufacturers from disseminating peer-reviewed journal articles or medical textbooks discussing off-label uses or suggesting content or speakers at CME programs.<sup>69</sup> However, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS-OIG") has highlighted potential kickback issues with industry-sponsored speaker and CME programs, suggesting that the government can raise other non-First Amendment concerns.<sup>70</sup>

Although *Friedman* held that speech about drug and device off-label uses was not *per se* illegal, the FDA, in 2005, proceeded to target Alfred Caronia, a pharmaceutical sales representative, for making off-label promotional statements.<sup>71</sup> Before his trial, Caronia moved to dismiss the charges.<sup>72</sup> However, the District Court for the Eastern District of New York rejected his motion, ruling that, "[i]f, as the manufacturer's representative, Caronia promoted Xyrem for off-label uses, whatever information (accurate or inaccurate) Caronia may have provided in the course of the promotion of those off-label uses is irrelevant to a

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65. *See id.* at 61 ("FDA's argument that it may freely limit [a manufacturer's free speech] because of the government's broad power to regulate the food and drug industry does not comport with current First Amendment jurisprudence, and therefore must be rejected.")

66. *See id.* at 66.

67. *Id.* at 67.

68. *Id.* at 74.

69. *Id.*

70. *See* U.S. DEP'T OF HEALTH & HUM. SERV'S, OFF. OF INSPECTOR GEN., OIG Advisory Opinion 22-14 (June 29, 2022); U.S. DEP'T OF HEALTH & HUM. SERV'S, OFF. OF INSPECTOR GEN., Special Fraud Alert: Speaker Programs (Nov. 16, 2020).

71. *See* *United States v. Caronia*, 703 F.3d 149, 149 (2d Cir. 2012).

72. *See* *United States v. Caronia*, 576 F. Supp. 2d 385, 385 (E.D.N.Y. 2008).

misbranding charge.”<sup>73</sup>

Based on the Court’s reasoning, simply making “off-label” promotional statements about a drug meant Caronia was guilty of misbranding.<sup>74</sup> Caronia was convicted at trial even though the government did not argue that Caronia’s statements were either false or misleading.<sup>75</sup> However, on appeal, the Second Circuit Court of Appeals rejected the trial court’s reasoning and noted that the FFDCA does not expressly prohibit or criminalize off-label promotion. Instead, the statute and its accompanying regulations only discuss “promotion” in terms of evidence of a drug’s intended use.<sup>76</sup> Thus, consistent with *Friedman*, the Court concluded that the promotion of a drug off-label “is not in and of itself false or misleading,” nor is the use of a drug off-label *per se* illegal, given the latitude the FDA grants to prescribers (i.e., the practice of medicine exception).<sup>77</sup>

Finally, the Court, relying on *Sorrell*,<sup>78</sup> concluded that “the government’s construction of the FFDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government’s substantial interests.”<sup>79</sup> Therefore, the Second Circuit determined the FDA can no longer support a misbranding prosecution simply because the statements were “off-label,” but rather must show that the statements were either false or misleading.

Following the *Caronia* decision, the U.S. District Court for the Southern District of New York held that Amarin could “engage in truthful and non-misleading speech promoting the off-label use of [its product, and] such speech may not form the basis of a prosecution for misbranding.”<sup>80</sup> Later in 2015, Pacira Pharmaceuticals, Inc., and the FDA settled a similar case where the FDA agreed to withdraw its Warning Letter and approve new labeling allowing Pacira to make truthful and non-misleading product claims.<sup>81</sup> Finally, in 2016, the FDA was forced to admit in a subsequent off-label prosecution involving medical devices that it “is . . . not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device.”<sup>82</sup>

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73. *See id.* at 392.

74. *See United States v. Caronia*, 703 F.3d 149, 158-59 (2d Cir. 2012).

75. *See id.* at 165 n.10.

76. *Id.* at 160.

77. *See id.* at 165-66.

78. *See id.* at 162 (speech in connection with pharmaceutical marketing is protected under the First Amendment) (citation omitted).

79. *Id.* at 167.

80. *See Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015).

81. *See Stipulation and Order, Pacira Pharm., Inc. v. U.S. Food & Drug Admin.*, 15 Civ. 7055 (LAK) (S.D. N.Y. Dec. 15, 2015).

82. Proposed Jury Instructions, *United States v. Vascular Solutions, Inc.*, No. SA:14-CR-926-RCL (W.D. Tex. Jan. 7, 2016).

## V. FDA “DOUBLES DOWN” ON ITS POSITION

The decisions in the *Friedman*, *Caronia*, *Amarin*, *Pacira*, and *Vascular Solutions* cases should have settled the limits of the FDA’s authority over manufacturer speech. Based on those cases, the FDA can only assert authority when the information is false or misleading or where a manufacturer in a commercial context actively promotes a product for off-label use. Thus, the FDA does not have regulatory authority to limit legitimate (i.e., truthful, non-misleading, and non-promotional) scientific exchanges between manufacturers and other parties.

Despite these decisions, the FDA has steadfastly maintained that the Agency has almost unlimited regulatory authority to address any off-label speech. It has done so by failing to address two Citizens Petitions and redefining the long-settled concept of intended use.

In 2011, and again in 2013, two groups of pharmaceutical companies petitioned the FDA seeking further clarity on its policies surrounding new uses of marketed drugs and devices and other regulatory terms.<sup>83</sup> For example, the petitioners wanted clarity on the scope of “scientific exchange” and labeling, advertising, and intended use through formal regulations.<sup>84</sup>

They also advocated that the FDA review its policies considering the Supreme Court’s free speech cases and the Second Circuit’s *Caronia* ruling.<sup>85</sup> Thus, they urged the FDA to ensure that any policies it developed “adequately respect statutory and constitutional limitations.”<sup>86</sup> To date, the FDA has rejected the requests in the petitions, choosing instead to focus on redefining “intended use.”<sup>87</sup>

The intended use revision was buried in a 2017 final rule clarifying how the FDA would regulate tobacco-derived products and was a surprise to the industry.<sup>88</sup> In that final rule, the FDA added a new standard. Based on the final

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83. See Citizen Pet., Alan R. Bennett & Paul E. Kalb et al., to Div. of Dockets Mgmt., U.S. Food & Drug Admin. at 1 (July 5, 2011) (submitted on behalf of Allergan, Inc.; Eli Lilly & Co.; Johnson & Johnson; Novartis Pharm. Corp.; and Novo Nordisk, Inc.) [hereinafter “CP 2011”]; see also Citizens Pet., Alan R. Bennett & Paul E. Kalb et al., to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (Sept. 3, 2013) (submitted on behalf of Allergan, Inc.; Bayer Healthcare Pharm., Inc.; Boehringer Ingelheim Pharm., Inc.; Eli Lilly & Co.; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharm. Corp.; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US) [hereinafter “CP 2013”].

84. See CP 2011, *supra* note 82, at 7, 9; CP 2013, *supra* note 82, at 13-19.

85. See CP 2013, *supra* note 82, at 2 (citing *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011); *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239 (2012); *Caronia*, 703 F.3d 149 (2d Cir. 2012)). Fox held that regulated parties should know what is required of them, and precision and guidance is necessary to prevent arbitrary or discriminatory enforcement. Although the petition was filed in 2012, FDA’s review would now include *Amarin*, *Pacira*, and *Vascular Solutions*.

86. See CP 2013, *supra* note 82, at 3.

87. See 21 C.F.R. §§ 201.128 & 801.4.

88. See Clarification of When Products Made or Derived From Tobacco Are Regulated as

rule, the FDA now defined “intended use” as follows:

If the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved (if any), he is required . . . to provide for such drug adequate labeling that accords with such other intended uses.<sup>89</sup>

From the perspective of regulating scientific speech, the “totality of the evidence” standard presented a new dimension in evaluating intended use, and as argued by the Medical Information Working Group (MIWG) in a 2017 Citizen Petition, not only is “totality of the evidence” not found in the FDCA, but it “allows the FDA to consider any evidence, including knowledge” when making an intended use determination.<sup>90</sup>

The FDA acknowledged this expansion in the rule’s preamble but refused to “narrow the scope of evidence it will consider for intended use.”<sup>91</sup> To justify its refusal, the FDA asserted that narrowing the scope of intended use would not only create a loophole for manufacturers and distributors to evade FDA oversight of the marketing of approved/cleared medical products for unapproved uses but would also open the door to the marketing of wholly unapproved medical products—all to the detriment of the public health.<sup>92</sup>

The Final Rule also reignited the First Amendment debate concerning the limits of the FDA’s authority to regulate scientific (and promotional) speech. Here, the FDA refused to limit its expansive interpretation considering the *Central Hudson* and *Caronia* cases, stating that:

We do not agree with the assertion that the current case law allows FDA to consider speech as evidence of intended use only when it is false or misleading, “because the First Amendment ‘does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.’”<sup>93</sup>

Therefore the “use of speech to infer intent, which in turn renders an otherwise

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Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193 (Jan. 9, 2017); *see also* Pet. to Stay & For Reconsideration from Paul Kalb et al., to Div. of Dockets Mgmt. at 2, U.S. Food & Drug Admin. (Feb. 8, 2017) (submitted on behalf of the MIWG, the Pharm. Res. & Mfr. of Am., and the Biotechnology Innovation Org. - asserting the revisions were not communicated to the public prior to publishing the final rule in violation of the Administrative Procedure Act (“APA”).

89. 82 Fed. Reg. at 2217 (to be codified at 21 C.F.R. § 201.128).

90. *See* Pet. to Stay, *supra* note 89, at 12.

91. 82 Fed. Reg. at 2207. The several types of evidence cited included “advertising; press statements; official or unofficial statements made by corporate officials; statements made in social media and other online arenas; and statements made in point-of-sale locations, both traditional retail and online.” *Id.*

92. *Id.*

93. *Id.* at 2209 (*quoting* *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)).

permissible act unlawful, is constitutionally valid.”<sup>94</sup>

The FDA argued that because it had a substantial interest in protecting the public health and safety delegated to it by Congress, the FDA’s regulatory policies were justified because “in other cases, the use of approved/cleared medical products for unapproved uses has also been associated with significant harm to patients, fraud, and waste of health care resources.”<sup>95</sup> Likewise, the FDA rejected the contention that heightened judicial scrutiny should apply to truthful and non-misleading speech, arguing that *Sorrell* held that sometimes content-based restrictions on protected expressions are permitted.<sup>96</sup> Going further, the FDA stated, “In *Reed v. Town of Gilbert*, the Court applied strict scrutiny to content-based restrictions on non-commercial speech in public fora. That holding has no bearing on the commercial speech at issue here.”<sup>97</sup>

In 2021, the FDA reasserted that any speech by a manufacturer is “commercial speech,” as outlined by *Central Hudson* and its progeny.<sup>98</sup> The FDA argued that:

The key issue in the intended use analysis is whether the evidence is “relevant,” which does not necessarily depend on whether there is evidence of “promotional” activity. . . Accordingly, FDA declines the suggestion to include “promotional” as a limiting principle for non-claims-based evidence that may be relevant to intended use.<sup>99</sup>

The FDA also contended that the “intended use regulations describe evidence that may be relevant to establishing intended use; they do not in themselves directly regulate speech.”<sup>100</sup>

The FDA’s assertion of almost unbridled authority to restrict truthful, non-misleading scientific speech by manufacturers contains several flaws and is inconsistent with the applicable case law. For example, based on its redefinition of “intended use,” the FDA considers all manufacturer speech commercial speech. However, the Supreme Court has not made such a determination.

Furthermore, the FDA’s claim is at odds with the Supreme Court’s holding in *Sorrell*, which concluded that “Vermont’s law [prohibiting the sale of prescriber-identifying data by data miners] does not simply have an effect on speech but is directed at certain content and is aimed at particular speakers.”<sup>101</sup> Here, the intended use determination is directed at certain content (promotional and scientific information about off-label uses) and is aimed at a particular type of speaker (manufacturers).

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94. *Id.* (quoting *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004)).

95. *Id.* at 2210.

96. *See id.* at 2211.

97. *Id.* (referencing *Reed*, 576 U.S. at 178).

98. *See* Regulations Regarding “Intended Use,” *supra* note 9. In 2021, the FDA reopened the docket in response to the MIWG’s 2017 petition, *id.* at 41385.

99. *Id.* at 41390.

100. *Id.* at 41391.

101. *See Sorrell*, 564 U.S. at 567.

## VI. FDA'S CLAIMS OF EXPANSIVE AUTHORITY ARE FLAWED

When evaluating government restrictions on speech, the Supreme Court has ruled that the distinction between pure or commercial speech is relevant for determining the level of judicial scrutiny to apply.<sup>102</sup> Unlike commercial speech, the Supreme Court has not articulated a standard approach for analyzing “pure speech” cases. However, no matter the type of speech at issue, “it is the [government’s] burden to justify its content-based law [is] consistent with the First Amendment.”<sup>103</sup> This requirement suggests the four-part test from *Central Hudson* is a proper standard for analyzing the FDA’s asserted authority to regulate manufacturer scientific discussions, whether they are deemed “pure” or commercial speech given the government’s identical burden.<sup>104</sup>

### *A. First Amendment Protections Apply to Scientific Discussions*

Based on the Supreme Court’s analysis in *Virginia Pharmacy Board*, manufacturer scientific discussions, whether commercial or pure speech, which does not involve false or misleading information, are worthy of a certain level of free speech protection. This is because scientific discussions fit squarely into the Supreme Court’s view that speech includes the exposition of ideas, including truth, science, morality, the arts, or the “diffusion of liberal sentiments on the administration of Government.”<sup>105</sup> Thus, speech casts a long shadow, and scientific discussions about commercial drugs or medical devices, even if initiated by a manufacturer, fall within that shadow.

Furthermore, scientific discussions are not *per se* illegal, even if the content involves discussions about off-label or uncleared uses.<sup>106</sup> Manufacturer scientific discussions can become illegal if they are false, misleading, or used by manufacturers to promote a product for an unapproved or uncleared use.<sup>107</sup> However, scientific exchange is permitted absent facts establishing that a manufacturer or their representatives are engaging in scientific discussions as a

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102. *Id.* at 571.

103. *See id.* at 571–72.

104. Manufacturer scientific discussions, however, do not fall under the FDA’s new rubric of “consistent with the FDA-required labeling (CFL),” because CFL is “limited to information about the approved or cleared uses of a product.” *See* U.S. FOOD & DRUG ADMIN., *Medical Product Communications That Are Consistent with the FDA-Required Labeling Questions and Answers: Guidance for Industry 1*, 1 (2018), <https://www.fda.gov/media/133619/download> [<https://perma.cc/3F85-WCGE>].

105. *See Va. Pharm. Bd.*, 425 U.S. at 759–62.

106. *See, e.g., Friedman*, 13 F. Supp. 2d at 66; *Caronia*, 703 F.3d at 165–66; 21 U.S.C. §§ 352(a)(1), (f) and 321(n); 21 C.F.R. 312.7(a).

107. *See, e.g., Friedman*, 13 F. Supp. 2d at 66; *Caronia*, 703 F.3d at 165–66; 21 U.S.C. §§ 352(a)(1), (f) and 321(n); 21 C.F.R. 312.7(a); *see also Va. Pharm. Bd.*, 425 U.S. at 748; *Cent. Hudson Gas & Elec.*, 447 U.S. at 557; *Bolger*, 463 U.S. at 60.

pretext to provide false information or unlawfully promote their products.<sup>108</sup> Even the FDA concedes this point and acknowledges a public health benefit from scientific exchange.<sup>109</sup>

### *B. Scientific Discussions Must Be Considered Pure Speech*

Unlike political speech or product advertisements, scientific discussions do not fall neatly within either pure or commercial speech like the types of speech involved in the Supreme Court's rulings. Therefore, although scientific exchange is subject to free speech protections, the lack of a clear delineation between pure and commercial speech makes it difficult to determine the extent of those protections.

For example, in the *Virginia Pharmacy Board* case, the Supreme Court defined commercial speech as “speech which does no more than propose a commercial transaction.”<sup>110</sup> Under this definition, product advertisements are the clearest examples of commercial speech. However, as in the *Bigelow* case, which involved abortion advertisements in a newspaper, the Supreme Court struggled with the pure versus commercial speech distinction.<sup>111</sup>

One can argue that there is a commercial connection surrounding scientific discussion since the discussions are about the uses of a product the manufacturer sells or plans to sell in the marketplace. However, it is disingenuous to claim that scientific discussions do no more “than propose a commercial transaction.” As the FDA concedes, these discussions are essential to provide prescribers with the evidence to make sound medical decisions for their patients.<sup>112</sup> Thus, manufacturers often have large bodies of data about their products and have the most current and accurate information essential to inform the prescriber's decisions.<sup>113</sup>

Manufacturer scientific discussions also do not fall cleanly into the “pure

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108. See, e.g., *Watts*, 394 U.S. at 708 (requiring the government to factually establish a threat existed); see also *Caronia*, 703 F.3d at 167 (admonishing the FDA for asserting that all scientific claims are “presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them.”).

109. See 21 C.F.R. §§ 99.1(a)(2), 99.101(a), 99.105, and 312.7(a) (2022); see also U.S. FOOD & DRUG ADMIN., *Guidance for Industry Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices: Revised Draft Guidance* 1, 8 (2014), <https://www.fda.gov/media/88031/download> [<https://perma.cc/3VZY-42NH>]; Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193, 2210 (Jan. 9, 2017).

110. See *Va. Pharm. Bd.*, 425 U.S. at 762.

111. See *Bigelow*, 421 U.S. at 818 (discussing *Bigelow*'s commercial interests); but cf. *id.* at 817 (noting that his claim involved pure speech).

112. See *Friedman*, 13 F. Supp. 2d at 56 (“in some specific and narrow areas of medical practice, practitioners consider off-label use to constitute the standard of good medical care.”).

113. See, e.g., FDA Unsolicited Request Guidance, *supra* note 13, at 2-3.

speech” category. While scientific discussions expound on ideas, they are not political speech like the anti-war rhetoric in *Watts*.<sup>114</sup> Nor are manufacturer scientific discussions symbolic speech like the armbands in *Tinker*.<sup>115</sup> Finally, manufacturers are not media outlets like the parties in the *Cox* and *Bartnicki*.<sup>116</sup> However, as the FDA acknowledges,<sup>117</sup> like speech by media outlets, manufacturer scientific discussions contain information that is of substantial public interest and concern.<sup>118</sup>

Since manufacturer scientific discussions do not fall cleanly within the binary classification of “pure” or commercial speech or another hybrid designation, declaring scientific discussions are pure speech, best aligns the Supreme Court’s free speech rulings with the lower court rulings in *Friedman* and *Caronia*. The FDA takes a contrary position, arguing that all manufacturer speech is commercial speech.<sup>119</sup> However, the Agency’s position ignores the Supreme Court’s decisions in *Watts* and *Bartnicki* that context matters when evaluating free speech restrictions.<sup>120</sup> It also ignores the *Friedman* ruling that not all scientific discussions are false or misleading unless approved by the FDA.<sup>121</sup>

The FDA’s belief that manufacturer scientific discussions are commercial speech also is inconsistent with the current industry practice outlined by the HHS-OIG and the U.S. Department of Justice (DOJ) to separate medical affairs responsibility for scientific discussions from a manufacturer’s commercial functions.<sup>122</sup> However, where manufacturers fail to maintain the required separation, the DOJ and HHS-OIG have asserted that manufacturer scientific discussions become *de facto* commercial speech and are subject to the FDA’s restrictions on promotional (i.e., commercial) speech.<sup>123</sup> Nonetheless, even if

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114. See *Watts*, 394 U.S. at 708.

115. See *Tinker*, 393 U.S. at 513.

116. See *Cox*, 379 U.S. at 555 (1965); *Bartnicki*, 532 U.S. at 519.

117. See, e.g., FDA Unsolicited Request Guidance, *supra* note 13, at 2-3.

118. See, e.g., *Bartnicki*, 532 U.S. at 518.

119. See, e.g., 82 Fed. Reg. 2211.

120. See *Watts*, 394 U.S. at 708 (ruling that the speech when taken in context was political hyperbole and not a threat).

121. *Friedman*, 13 F. Supp. 2d at 67. (“FDA exaggerates its overall place in the universe.”).

122. See OIG Compliance Program Guidance for Pharm. Mfr., 68 Fed. Reg., 23731, 23735-36 (May 5, 2003) (discussing the need to separate educational grants and research funding awards from marketing); Corporate Integrity Agreement Between the Off. of Inspector Gen. of the Dep’t of Health & Hum. Serv., and Allergan, Inc. 11 § 3.B.3.h (Sept. 1, 2010), <https://www.sec.gov/Archives/edgar/data/850693/000119312510202820/dex102.htm> [<https://perma.cc/LN6K-SFN7>]; Corporate Integrity Agreement Between the Off. of Inspector Gen. of the Dep’t of Health & Hum. Serv., AstraZeneca Pharmaceuticals LP, and AstraZeneca LP, 11 §§ III.B.3(g-h) (May 2011), <http://psychrights.org/2010/100427AstraZenecaCorpIntegrityAgmt.pdf> [<https://perma.cc/7LD6-EZYJ>].

123. See, e.g., Corporate Integrity Agreement Between the Off. of Inspector Gen. of the Dep’t of Health & Hum. Serv., and GlaxoSmithKline LLC, 42-43 § III.M.4 (June 2012), <https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-ex-d.pdf> [<https://perma.cc/P6Y6-KD7Y>].



scientific discussions are transformed into commercial speech by the manufacturer's actions, First Amendment commercial speech protections would still apply.<sup>124</sup>

### *C. FDA Has a Limited Government Interest*

Regardless of whether manufacturer scientific discussions are considered pure or commercial speech, the FDA must establish the existence of a substantial government interest to justify limitations or restrictions that impinge on free speech.<sup>125</sup> Over the years, the FDA has postulated a variety of justifications to support its restrictions on manufacturer speech. Although some justifications have merit, others do not.

For example, the FDA asserts that Congress enacted the FFDCA partly to protect the public from harm caused by unsafe or ineffective treatments.<sup>126</sup> Therefore, the Agency has repeatedly argued that its regulatory policies are justified because, in some cases, “the use of approved/cleared medical products for unapproved uses has also been associated with significant harm to patients, fraud, and waste of health care resources.”<sup>127</sup> While the FDA has a governmental interest in protecting the public from fraud or misrepresentations by a product's manufacturer, the free speech cases establish that such an interest does not automatically give the government unlimited authority to restrict entire categories of speech.<sup>128</sup> Nor can the government impose restrictions based on speculation or conjecture, but instead must show the harms are real and its proposed restrictions will alleviate them “to a material degree.”<sup>129</sup>

The FDA also asserts it has a substantial interest in “motivating the development of robust scientific data on safety and efficacy.”<sup>130</sup> While this is undoubtedly true, it implies that the FDA's market application process is the only way to ensure the development of that data; a presumption rejected by the *Friedman* court.<sup>131</sup>

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124. See, e.g., *Caronia*, 703 F.3d at 149; *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015).

125. See *Central Hudson Gas & Elec.*, 447 U.S. at 563 (1980); *Bolger*, 463 U.S. at 65; *Rubin*, 514 U.S. at 485-86.

126. See U.S. FOOD & DRUG ADMIN. MEM., ON PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS, *supra* note 14, at 1.

127. See 82 Fed. Reg. 2210.

128. See *Sorrell*, 564 U.S. at 572 (2011); *Bolger*, 463 U.S. at 64 (declaring that the government has no power to restrict speech because of its messages, ideas, subject matter, or content); *Rubin*, 514 U.S. at 487 (providing a limit that even where the government has a substantial interest, the regulation must advance that interest “in a direct and meaningful way”).

129. See *Rubin*, 514 U.S. at 487 (citation omitted).

130. See U.S. FOOD & DRUG ADMIN. MEMORANDUM ON PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS, *supra* note 14, at 3.

131. See *Friedman*, 13 F. Supp. 2d at 67; *Amarin Pharma, Inc.*, 119 F. Supp. 3d at 250.

Next, the FDA asserts it has an interest in protecting against bias.<sup>132</sup> Bias is inherent in developing scientific hypotheses, especially when prescribers deem using a product off-label is in their patients' best interests. Certainly, bias that tips the balance and results in false or misleading information is inappropriate. Nevertheless, under the existing statutory provisions, the FDA already has the means to address these situations.<sup>133</sup> Thus, the type of "bias" at issue here is unclear.

Finally, the FDA asserts an interest in ensuring the "integrity and reliability of promotional information regarding medical product uses."<sup>134</sup> This justification, however, only applies to promotional information and not scientific exchange. Furthermore, the FDA's position exaggerates the scope of the Agency's jurisdiction if "integrity and reliability" mean more than being truthful and non-misleading.<sup>135</sup>

#### *D. FDA Has Limited Restrictive Options*

Assuming the FDA successfully establishes a substantial government interest, the Agency's options to limit manufacturer scientific discussions beyond restricting false or misleading information are limited. When determining what options are available, it is easier to determine what the FDA cannot do.

First, the FDA cannot impose a complete ban on manufacturer scientific discussions or communications. This limitation is valid regardless of whether manufacturer scientific discussions are considered "pure" speech<sup>136</sup> or commercial speech.<sup>137</sup>

To be fair, the Agency has never considered a complete ban on manufacturer scientific discussions and has continued reaffirming the potential public health benefits of these discussions. Therefore, any attempt by the FDA to impose a complete ban is improbable. However, given the FDA's innate skepticism about manufacturers' motives, the Agency will continue to assert the right to impose restrictions on manufacturer scientific speech.

Second, the FDA may not favor one form of speech over another.<sup>138</sup> In other words, the FDA cannot allow oral representations but restrict written communications if the content is the same, but the purposes are different.<sup>139</sup>

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132. See *Friedman*, 13 F. Supp. 2d at 67; *Sorrell*, 564 U.S. at 572; *Caronia*, 703 F.3d at 167.

133. See, e.g., 21 U.S.C. § 331(a) (misbranding); 21 U.S.C. § 352(f); U.S. FOOD & DRUG ADMIN., DEMONSTRATING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS: DRAFT GUIDANCE FOR INDUSTRY (2019).

134. See U.S. FOOD & DRUG ADMIN. MEMORANDUM ON PUBLIC HEALTH INTERESTS AND FIRST AMENDMENT CONSIDERATIONS, *supra* note 14, at 3.

135. See, e.g., *Friedman*, 13 F. Supp. 2d at 67.

136. See *Tinker*, 393 U.S. at 513; and *Bartnicki*, 532 U.S. at 527.

137. See *Bigelow*, 421 U.S. at 809; *Va. Pharm. Bd.*, 425 U.S. at 748; *Central Hudson Gas & Elec.*, 447 U.S. at 557; *Bolger*, 463 U.S. at 60; *Sorrell*, 564 U.S. at 578-80.

138. *Cox*, 379 U.S. at 536; *Tinker*, 393 U.S. at 513; *Bartnicki*, 532 U.S. at 527.

139. See *Bolger*, 463 U.S. at 60 (restricting only mailers with a commercial interest).

Furthermore, the FDA may be limited in its ability to restrict speech based on different types of speakers (e.g., a manufacturer versus an independent medical professional).<sup>140</sup>

Third, any applied restrictions must consider the context surrounding the speech.<sup>141</sup> In the case of intended use, the FDA has conceded as much, noting that intended use turns on whether “the manufacturer objectively intends” the product to be used off-label.<sup>142</sup> Thus, the Agency must evaluate the “totality of the evidence” (i.e., the context) and not just the actual statements made by the manufacturer.

Because manufacturer scientific discussions are pure speech, the Supreme Court in *Bolger* was quite clear that “the First Amendment means that government has no power to restrict [the] expression because of its message, its ideas, its subject matter, or its content.”<sup>143</sup> While the FDA might be able to impose reasonable time, place, and manner restrictions, any restrictions must be minimal to avoid impinging on content.<sup>144</sup> However, it is difficult to imagine the FDA imposing time, place, or manner restrictions that would neither target particular speakers nor content.

However, if manufacturer scientific discussions are commercial speech, based on the Supreme Court’s *Central Hudson* and *Sorrell* rulings, the FDA still lacks “the complete power to suppress or regulate” these discussions.<sup>145</sup> Furthermore, based on *Caronia*, a court should view attempts by the FDA to criminalize truthful and non-misleading scientific discussions by manufacturers as more extensive than is needed to address the government’s legitimate interests.<sup>146</sup>

In addition, the *Friedman* and *Caronia* cases stand for the proposition that the FDA has limited authority to restrict truthful or non-misleading speech by manufacturers over a wide range of activities.<sup>147</sup> Therefore, while there is yet to be a definitive Supreme Court test of the FDA’s authority to regulate manufacturer scientific speech, a fair reading of the cases suggests that the FDA’s authority is limited to regulating only false or misleading discussions. As the Supreme Court concluded in *Virginia Pharmacy Board* and *Sorrell*, the government may not simply ban speech it does not like or is fearful about its

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140. *Caronia*, 703 F.3d at 167 (sales representative versus independent HCP).

141. *See Watts*, 394 U.S. at 708 (finding the speech to be political hyperbole in the situation); *Bartnicki*, 532 U.S. at 528 (right of the press to publish information of great public concern regardless of how it was obtained); *Friedman*, 13 F. Supp. 2d at 67 (rejecting the FDA’s contention that all scientific claims not reviewed by the Agency are presumptively false or misleading).

142. 82 Fed. Reg. 2217 (2017).

143. *See Bolger*, 463 U.S. at 65 (citation omitted); *Sorrell*, 564 U.S. at 572 (content-based or viewpoint discriminatory restrictions are not permitted) (citation omitted).

144. *See Va. Pharm. Bd.*, 425 U.S. at 771; *Cox*, 379 U.S. at 554-55.

145. *See Central Hudson*, 447 U.S. at 562, 63; *Sorrell*, 564 U.S. at 570.

146. *See Caronia*, 703 F.3d at 149.

147. *See Friedman*, 13 F. Supp. 2d at 74 (peer-reviewed journal articles, medical textbooks, CME programs); *Caronia*, 703 F.3d at 165-66 (sale representative statements).

effect on recipients.<sup>148</sup>

## VII. DIVINING THE FUTURE

The future of the FDA's attempt to limit manufacturer scientific discussions is by no means certain. The only clear pathway to determine the boundaries of the FDA's authority will require a Supreme Court decision on whether manufacturer scientific discussions are "pure" speech, commercial speech, or some new, yet undefined, hybrid. From a timing perspective, such a case will take years to work its way through the federal judicial system.

In the meantime, the FDA will persist in asserting that all manufacturer speech, promotional and scientific, is commercial speech. In addition, the Agency will continue using "intended use" to limit those discussions. Thus, it is unlikely that the FDA will address the concerns raised by the 2011 and 2013 Citizens Petitions.

In doing so, we expect the FDA will continue arguing that "intended use" is not a restriction on speech but an evidentiary standard even though, in practice, it amounts to a free speech restriction. Furthermore, using the new expansive "totality of evidence" standard, the Agency could attempt to characterize legitimate scientific discussions as objective evidence of the manufacturer's intent about the product.<sup>149</sup>

However, other non-free speech developments could potentially challenge the FDA's continued broad interpretation of its authority. For example, in 2019, the Supreme Court in *Kisor v. Wilkie* noted that deference to an agency's interpretation of its own rules is not absolute but must be reasonable and fall within the bounds of reasonable interpretation.<sup>150</sup>

The Supreme Court also recently determined that an agency's regulations must have a "textual basis" in the statute.<sup>151</sup> The *American Hospital Association v. Becerra* case suggests that the FDA's interpretations and creation of new concepts, such as its Consistent with the FDA-Required Labeling (CFL),<sup>152</sup> must be grounded on the Congressional grant of authority in the FFDCRA.<sup>153</sup>

Furthermore, the FDA's steadfast refusal to clarify its positions as outlined by the Citizens Petitions casts doubt on the Agency's regulatory policies concerning scientific discussions and intended use. In *Safeco Insurance Co. of America v. Burr* and *Federal Communications Commission v. Fox Television Stations*, the Supreme Court determined that a defendant's reasonable statutory

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148. See *Va. Pharm. Bd.*, 425 U.S. at 773; *Sorrell*, 564 U.S. at 578-80.

149. See, e.g., 82 Fed. Reg. 2217 (2017).

150. See *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019).

151. See *Am. Hosp. Ass'n v. Becerra*, No. 20-1114, 8 (June 15, 2022) (rejecting HHS's 340B reimbursement changes for participating hospitals).

152. See 83 Fed. Reg. 27602 (June 13, 2018).

153. See *Becerra*, *supra* note 152, at 11-12 (discussing the interplay between statutory language and an agency's interpretation of its authority under the statute).

interpretations are not actionable without authoritative guidance to the contrary.<sup>154</sup> Various Circuit Courts of Appeals have adopted this standard and applied it to federal False Claims Act cases.<sup>155</sup> Although *Safeco* and *Fox* have yet to be used in the context of the FDA's regulatory policies, we believe the Supreme Court would take a similar tack if confronted with this question.

#### VIII. DEALING WITH AMBIGUITY

Absent the resolution of whether manufacturer scientific discussions are commercial or "pure" speech, we believe that manufacturers should treat scientific discussions as commercial speech. Doing so mitigates the risk that the courts grant the FDA discretion to impose restrictions under the commercial speech doctrine or attempts by the FDA to use scientific discussions as evidence of "intended use" applying the new "totality of the evidence" standard.

Therefore, manufacturers should continue to separate scientific from commercial discussions and restrict commercial personnel from engaging in scientific discussions. It is safer to let clinical or medical affairs personnel in the R&D function handle scientific discussions.

Manufacturers also should institute internal controls (e.g., legal, medical, and regulatory ("LMR") review) to ensure that scientific discussions involve only truthful and non-misleading information. For example, manufacturers should avoid materials that lack fair balance (i.e., only report favorable information that discounts product risks or negative clinical trial results).

Manufacturers also should avoid discussions of poorly designed or conducted studies. Although using unabridged, peer-reviewed medical or scientific journal articles reduces the risk, it does not absolve manufacturers from needing to review the materials' quality before disseminating them.

Finally, since the FDA may consider scientific information misleading in some contexts, manufacturers should distribute this information, primarily if it discusses "off-label" uses, with appropriate disclaimers. For example, the information should highlight that the FDA does not approve the "off-label" uses and that it may not be "consistent with the FDA-required labeling." Manufacturers should also clarify that the information is being disseminated for scientific discussion, not product promotion.

#### IX. CONCLUSION

With the rapid pace of healthcare innovations and new therapies, the need for

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154. See *Safeco Insurance Co. v. Burr*, 551 U.S. 47, 69-70 (2007); *Federal Comm'n v. Fox Television Stations*, 567 U.S. 239, 253-254 (2012).

155. See, e.g., *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 472 (7th Cir. 2021)); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873, 874 (4th Cir. 2022); see also Laura McLane et al., *When a Law is Ambiguous and a Defendant's Interpretation Makes Sense: Fourth Circuit Rejects FCA "Liability Through Ambush,"* Vol. XIII, No. 95 NAT'L L. REV. (2022), available at <https://www.natlawreview.com/article/when-law-ambiguous-and-defendant-s-interpretation-makes-sense-fourth-circuit-rejects> [<https://perma.cc/4XC9-2AQ3>].

wide-ranging and transparent manufacturer scientific discussions has never been greater. However, the FDA's continued regulation of these discussions is not aligned with current free speech protections. Furthermore, it remains an open question whether manufacturer scientific discussions constitute "pure" or commercial speech and the extent to which the FDA can regulate them. In the absence of a definitive Supreme Court ruling on the topic, it is left to manufacturers to determine the limits and the degree of risk a company wishes to assume. However, as discussed, manufacturer scientific discussions are best classified as "pure speech," thus limiting the FDA's regulatory authority to addressing only false or misleading scientific information.