

No Longer Business as Usual: FDA Exceptionalism, Commercial Speech, and the First Amendment

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ABSTRACT

FDA's crucial mission of protecting the safety and integrity of our nation's food and drug supply has led to several areas of "FDA exceptionalism"—a tendency to apply available exceptions to general legal norms. Until the late 1990s, the First Amendment seemed another of these areas, and FDA was free to regulate the labeling and advertisement of products within its jurisdiction. But in the last two decades, FDA has lost case after case with respect to challenges under the First Amendment. Its response has been to strategically avoid appealing these decisions, to construe these decisions as narrowly as possible, and to attempt to continue on business as usual. This article covers the evolution of the Supreme Court's First Amendment jurisprudence as relates to FDA. It argues that commercial speech restrictions are currently subject to a de facto strict scrutiny applied under the *Central Hudson* name. It also covers the areas of compelled speech, compelled access, compelled subsidies, government speech, and compelled commercial disclosure, all of which will prove relevant to FDA in designing future regulatory approaches. It discusses three areas of current FDA First Amendment difficulty—health claims for dietary supplements, off-label pharmaceutical promotion, and graphic cigarette warning labels—and argues that FDA's current approach to addressing First Amendment concerns is unsustainable. It uses First Amendment caselaw to offer guidance on possible future approaches that would proactively address these issues and balance the First Amendment rights of regulated entities with FDA's crucial public health goals.

I. INTRODUCTION

It is no coincidence that governments have played a role in maintaining the integrity of their countries' food supply for thousands of years, from Roman statutes targeting the adulteration of food through the English assizes of 1266 prohibiting the sale of food and drink "not wholesome for Man's body."¹ What mission could be more

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¹ See generally Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REV. OF NUTRITION 1 (1984).

fundamental to a government than protecting its citizens' access to the substances necessary to maintain public health—foods and medicines?² In the United States, FDA has been in charge of this fundamental objective since 1906.³ Its mission is to protect and promote the public health by regulating the supply of food, human and veterinary drugs, biological products, medical devices, cosmetics, and products that emit radiation.⁴ To accomplish this mission, FDA regulates a diverse group of industries that represent between one fifth and one quarter of all consumer spending in the United States, and it does so on the equivalent of a shoestring budget.⁵ And unlike many other agencies, which can afford to respond to crises after-the-fact, FDA is expected to stop problems before they happen.⁶

As a result of these special factors, FDA has tended to receive what this article terms “FDA exceptionalism”—a tendency to apply available exceptions relaxing the general rules that apply across government more broadly. This is seen in the application of the “pervasively regulated” exception to the usual Fourth Amendment ban on warrantless searches, which courts have held applies to the food and drug manufacturing industries.⁷ It is also seen in the *Park* doctrine, which has upheld the Food, Drug, and Cosmetic Act’s (FDCA) imposition of strict criminal liability—a crime based not on any *mens rea* but only on a finding that the defendant bears a “responsible relation” to the violation.⁸ Similarly, the Court has historically demonstrated a willingness to endorse FDA’s statutory interpretations even pre-*Chevron*.⁹ Thus, FDA was

² The line between the two is less than clear, with much overlap between the two categories. See Lewis A. Grossman, *Food, Drugs, and Droids: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091 (2008).

³ See Lauffer Hayes & Frank Ruff, *The Administration of the Federal Food and Drugs Act*, 1 LAW & CONTEMPORARY PROBLEMS 16 (1933).

⁴ *What We Do*, U.S. FOOD & DRUG ADMINISTRATION (last visited Mar. 25, 2018), <https://www.fda.gov/AboutFDA/WhatWeDo/> [<https://perma.cc/J8C6-T9TR>]; see also 21 U.S.C. § 393(b) (2011).

⁵ See PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 24 (Foundation Press 2014) (1980).

⁶ Cf. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950) (“The purpose of the [enforcement provision at issue] . . . is to arrest the distribution of an article that is dangerous[.] . . . The public therefore has a stake in the jurisdictional issue [and should not] . . . be denied the speedy protection which Congress provided.”); Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 901–02 (2008) (“What started as a fairly simple regime of after-the-fact policing aimed at substandard foods and drugs has morphed into a complex set of product licensing requirements.”).

⁷ See, e.g., *United States v. Jamieson-McKames Pharm., Inc.*, 651 F.2d 532, 538–39 (8th Cir. 1981); *United States v. Argent Chem. Labs., Inc.*, 93 F.3d 572, 577 (9th Cir. 1996); *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230, 238–39 (D. Mass. 1980).

⁸ See *United States v. Dotterweich*, 320 U.S. 277, 281 (1943); *United States v. Park*, 421 U.S. 658, 683 (1975).

⁹ See *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 799 (1969) (agreeing with FDA that what would traditionally be termed a “device” could be regulated as a drug under the FDCA); Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. ONLINE 124, 132–33 (2016) (describing the success of FDA’s position starting in 1938 that it had jurisdiction over advertising as well as labelling of drugs, despite the fact that “Congress had chosen to vest authority over advertising for FDA-regulated products with the Federal Trade Commission rather than FDA, over FDA’s bitter opposition.”); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 983–84 (1986) (using *Chevron* deference to uphold FDA’s position that the FDCA’s “shall” permitted FDA to establish informal tolerances with respect to poisonous or deleterious residues in food); Noah, *supra* note 6, at 903. *But see* *FDA v. Brown &*

reasonable to assume that as commercial speech rose to the level of being protected by the First Amendment, the agency's crucial mission would once again result in application of available exemptions from the usual constitutional standards.

This was not to be the case. From the 1990s onwards, as commercial speech protections emerged from the doctrine with their present-day strength, FDA has lost a series of court battles over the constitutionality of its regulatory approaches. Speech is at the center of many of FDA's regulations—regulation of labeling, regulation of marketing, even regulation of what to call a food item.¹⁰ Possibly because regulation of speech is so central to so much of FDA's regulatory scheme, FDA's response to these series of losses was not to reevaluate its approach. Instead, its response was to limit the damage by construing cases narrowly, presenting the approaches it was forced to take as "enforcement discretion" rather than constitutional mandates, strategically choosing not to appeal losses, and generally attempting to carry on business as usual.¹¹

This article argues that the approach of carrying on business as usual is not sustainable. Sooner or later, FDA will have to contend with the protections that commercial speech has gained over the past four decades. Designing new systems that respect the speech rights of regulated entities will be much more effective *before* a Supreme Court loss forces FDA's hand, and precedent says that loss will come. Additionally, these new approaches should be designed not only with an eye to the technicalities of commercial speech jurisprudence, but also to its spirit.

To assist with designing new approaches, this article begins in Part II by documenting the historical development of the areas of First Amendment commercial speech jurisprudence. It covers the development of protections for commercial speech, discussing the rise or fall of various arguments and the solidification of policy considerations into constitutional rules. It shows that restrictions on commercial speech are currently subject to what is essentially a *de facto* strict scrutiny applied under the *Central Hudson* name. It also covers other areas which will prove important to FDA's future regulatory approaches—compelled speech, compelled access, compelled subsidies, government speech, and compelled commercial disclosure. Next, in Part III this article examines several examples of FDA's past approaches to addressing First Amendment concerns. In each of these examples—regulation of health claims for dietary supplements, regulation of the advertisement of drugs for off-label use, and the short-lived graphic warning labels for cigarette packages—FDA's approach was to attempt to carry on business as usual. The approach has not proved successful. Finally, this article will finish in Part IV by suggesting several new approaches that FDA might try that would fit with the letter and spirit of Supreme Court speech precedent and conclude by briefly discussing possible applications to the issues presented throughout the article.

As a word of limitation, this article does not purport to "solve" FDA's problem with the First Amendment. This issue is best solved by FDA with its scientific and regulatory expertise. Instead, it argues that FDA must proactively work to address the intersection of public health and commercial speech, and it hopes to show that the

Williamson Tobacco Corp., 529 U.S. 120, 156 (2000) (holding invalid FDA's position that cigarettes are drug delivery devices, in a case that was later effectively overturned via statute).

¹⁰ See generally HUTT, *supra* note 5, at 379, 332, 925.

¹¹ See section III, *infra*.

future for FDA is not at all bleak by documenting the contours of the caselaw and presenting some solutions for FDA to consider as it works to update its regulatory practices.

II. THE FIRST AMENDMENT AND COMMERCIAL SPEECH

This section will proceed in three parts. It will begin with a quick summary of the current First Amendment rules relevant to FDA. Next, it will discuss the historical development of rules concerning restrictions on commercial speech. Finally, it will cover cases considering the many forms of compelled speech as well as the government speech doctrine.

II.A. Summary of Commercial Speech Rules

Since 1975, commercial speech has been protected under the First and Fourteenth Amendments against federal or state interference.¹² The protection for commercial speech results from three intersecting interests: the interest of the advertiser in the speech (even if purely economic), the interest of the individual consumer as recipient of the information conveyed by the speech, and the interest of society that economic decisions in the aggregate be intelligent and well-informed.¹³ Commercial speech paradigmatically is speech that proposes a transaction;¹⁴ speech is likely to be found commercial if (1) it is an advertisement; (2) it refers to specific products; or (3) the speaker has an economic motive—though none of these factors are dispositive.¹⁵ Though it is sometimes difficult to classify speech as commercial or noncommercial,¹⁶ the distinction comes under much less pressure in recent years as commercial speech, while ostensibly still subject to intermediate scrutiny,¹⁷ has tended to draw *de facto* strict scrutiny.¹⁸

¹² *Bigelow v. Virginia*, 421 U.S. 809, 825 (1975). First Amendment speech protections with respect to the federal government similarly apply against state and municipal governments via the Fourteenth Amendment. *E.g.*, *Schneider v. New Jersey*, 308 U.S. 147, 160 (1939).

¹³ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–65 (1976) [hereinafter “*Virginia Board*”].

¹⁴ *Id.* at 761.

¹⁵ *Bolger v. Youngs Drug Products*, 463 U.S. 60, 66–67 (1983).

¹⁶ *See, e.g.*, *Riley v. Nat’l Fed’n for the Blind*, 487 U.S. 781, 796 (1988) (applying strict scrutiny to a disclosure requirement where the commercial aspects of the speech were “inextricably intertwined with otherwise fully protected speech”); *Bolger*, 463 U.S. at 81 (stating that “advertisements may be complex mixtures of commercial and noncommercial elements”) (Stevens, J., concurring); *but see* *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474 (1989) (applying commercial speech analysis to mixed speech where commercial aspects dominated) [hereinafter “*SUNY v. Fox*”].

¹⁷ Commercial speech has traditionally been subject to less than strict scrutiny due to its “greater objectivity and hardness”—that is, it can be more easily regulated for truth than ideological speech, and the speaker’s profit motive means it will be less easily chilled by regulation. *Virginia Board*, 425 U.S. at 780–81 n.24 (Stewart, J., concurring).

¹⁸ *See Sorrell v. IMS Health*, 564 U.S. 552, 563–66, 71 (2011) (declining, in an opinion by Justice Kennedy, to decide whether the speech at issue was commercial or noncommercial, and instead applying traditional First Amendment content-based restriction analysis and an amorphous “heightened judicial scrutiny”); *id.* at 584–85 (faulting the majority opinion for “apply[ing] a strict First Amendment standard virtually as a matter of course when a court reviews ordinary economic regulatory programs”) (Breyer, J., dissenting); section II.B.3., *infra*.

Restrictions on commercial speech are subject to intermediate scrutiny in the form of the four-prong *Central Hudson* test.¹⁹ The first prong of the *Central Hudson* test states that commercial speech is not protected by the First Amendment if it concerns unlawful activity or is misleading. The second prong requires that governmental regulations on commercial speech be motivated by a substantial governmental interest to be upheld. The third and fourth prongs of *Central Hudson* are designed to ensure that the regulation is proportional to the governmental interest; the third prong requires that the regulation advance the interest in a direct and material way, while the fourth prong requires that the regulation be no more extensive than necessary to serve the interest.

Throughout the 1990s, the Court considered abandoning the *Central Hudson* test but never summoned a majority to adopt a new standard.²⁰ Instead, it finally settled upon a new form of *Central Hudson* that was heightened from the original intermediate scrutiny and had several distinct features. First, a state interest in restricting advertisements out of fear of its effect on disseminators or recipients—*i.e.*, paternalism—will paradigmatically fail *Central Hudson*'s second prong.²¹ Second, a regulatory scheme that is inconsistent will be held to fail *Central Hudson*'s third prong.²² Finally, and most important to the new *Central Hudson*, is the interpretation of the fourth prong. While initial cases had suggested that the regulation's fit need only be reasonable²³—and this ostensibly holds true today—later cases held that fit is not reasonable if other methods which restrict less or no speech remain available (*i.e.*, speech restrictions must be of last resort—akin to a least restrictive means requirement).²⁴ Further, as with fully protected speech, regulations that are overbroad lack reasonable fit.²⁵ When applying *Central Hudson*, the Court has been reluctant to provide any sort of deference to legislative determinations as to justifications, fit, or necessity.²⁶ The one prong of *Central Hudson* that has held steady is the first; false or

¹⁹ *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980) [hereinafter "*Central Hudson*"].

²⁰ *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484 (1996) (failing to draw a majority as to what test to apply); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001) ("several Members of the Court have expressed doubts about the *Central Hudson* analysis").

²¹ This particular requirement was not new in the 1990s, and had been expressed since before, and even in, *Central Hudson* itself. *E.g.*, *Virginia Board*, 425 U.S. at 771–72; *Linmark Assoc. v. Twp. of Willingboro*, 431 U.S. 85, 96 (1977); *Central Hudson*, 447 U.S. at 561–62; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 497 (1995) (Stevens, J., concurring); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002); *Sorrell*, 564 U.S. at 577.

²² *Rubin*, 514 U.S. at 487–88; *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 185–88 (1999) [hereinafter "*New Orleans Broad.*"].

²³ *SUNY v. Fox*, 492 U.S. at 480.

²⁴ *See, e.g., Rubin*, 514 U.S. at 491; *44 Liquormart*, 517 U.S. at 507; *New Orleans Broad.*, 527 U.S. at 185–87; *Thompson*, 535 U.S. at 371. Justice Thomas in his *44 Liquormart* concurrence stated the effect of this rule most clearly: "[I]t would seem that directly banning a product (or rationing it, taxing it, controlling its price, or otherwise restricting its sale in specific ways) would virtually always be at least as effective in discouraging consumption as merely restricting advertising regarding the product would be, and thus virtually all restrictions [designed to reduce consumption by regulating speech] would fail the fourth prong of the *Central Hudson* test." *44 Liquormart*, 517 U.S. at 524–26 (Thomas, J., concurring).

²⁵ *Lorillard*, 533 U.S. at 561–63.

²⁶ Compare the early position of *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341–42 (1986) (finding a legislature's reasonable belief that a speech restriction would advance the governmental interest sufficient to pass *Central Hudson* prong three) with the prevailing position of *44*

misleading commercial speech, or commercial speech advocating for the consumption of an unlawful product or service, may still be banned.²⁷

The First Amendment also protects against compelled speech, including compelled commercial speech. The paradigmatic example of this is compelled ideological or political speech.²⁸ But the prohibition also extends to compelled subsidies; absent a compelling governmental interest a party cannot be forced to subsidize another party's speech.²⁹ However, a party can be forced to subsidize the government, and the government can use its general funds to speak whatever messages it desires in its own name. The First Amendment cannot be used by private parties to control the government's own speech or to refuse to support general governmental programs.³⁰ Private speech is distinguished from government speech by examining three factors: speech is generally government speech if (1) the message has historically been communicated from the state, (2) the public associates the message with the state, and (3) the state maintains direct control over the message.³¹ And last, in the commercial speech context the government may compel commercial speech in the form of disclosure requirements for uncontroversial factual information, if the government is furthering the interest of preventing consumer deception, the harm to be prevented is at least potentially real, and the disclosures are no broader than reasonably necessary.³²

II.B. Restrictions on Commercial Speech

This section will cover the evolution of the Supreme Court's jurisprudence with respect to restrictions on commercial speech, subdivided into four areas. First, it will discuss the evolution of the doctrine until commercial speech was declared as protected in *Virginia Board of Pharmacy*. Second, it will consider the *Central Hudson* form of intermediate scrutiny applicable to commercial speech and subsequent developments lowering this form of scrutiny. Third, this section will explain the shift that began in the 1990s toward raising the level of scrutiny applied under the *Central Hudson* name. And last, it will cover the Court's parallel and related line of commercial speech caselaw governing the regulation of lawyer advertising.

Liquormart, 517 U.S. at 508–14 (rejecting arguments for deference to the legislature's judgment) (plurality); see also *Thompson*, 535 U.S. at 373; cf. *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S.Ct. 2361, 2377 (2018).

²⁷ *Freidman v. Rogers*, 440 U.S. 1, 3–7 (1979); *Rubin*, 514 U.S. at 494–96 (Stevens, J., concurring); cf. *Virginia Board*, 425 U.S. at 771–72 (extending commercial speech protection to only truthful information about lawful activities).

²⁸ *West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943); *Wooley v. Maynard*, 430 U.S. 705, 715 (1977).

²⁹ *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 256 (1974); *Pacific Gas & Elec. Co. v. Pub. Util. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality); *Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 235 (1977); *United States v. United Foods, Inc.*, 533 U.S. 405, 411 (2001); *Janus v. American Fed'n of State, Cty., and Mun. Emps., Council 31*, 138 S. Ct. 2448, 2460 (2018).

³⁰ *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 135 S.Ct. 2239, 2253 (2015); *Bd. of Regents of the Univ. of Wisconsin v. Southworth*, 529 U.S. 217, 229 (2000); *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 477 (1997); *Johanns v. Livestock Mktg Ass'n*, 544 U.S. 550, 553–54 (2005).

³¹ *Walker*, 135 S.Ct. at 2248.

³² *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); *Becerra*, 138 S.Ct. at 2377.

II.B.1. Early Development to Virginia Board of Pharmacy

Any exposition of the development of the commercial speech doctrine must begin with the fact that for the first 184 years of the First Amendment—from 1791 until 1975—the Amendment provided no protection for commercial speech.³³ Commercial speech was simply not mentioned until the 1942 case of *Valentine v. Chrestensen*, which established that commercial speech had no protection and upheld a provision of New York City’s Sanitary Code that forbade street distribution of commercial advertising.³⁴ The facts are as follows: F. J. Chrestensen owned a decommissioned navy submarine, of which he gave tours for profit.³⁵ He brought it to New York City and there attempted to pass out handbills advertising tours of the submarine.³⁶ However, police informed him that this violated a prohibition on street distribution of commercial advertising.³⁷ Chrestensen was not deterred for long: he simply prepared identical handbills but affixed to the back a protest against the City Dock Department.³⁸ He was then advised that the protest handbills by themselves would be allowed, but the dual-purpose handbills were still prohibited.³⁹

In rejecting Chrestensen’s challenge, Justice Roberts held that although “streets are proper places for the exercise of the freedom of communicating information and disseminating opinion[,] . . . the Constitution imposes no such restraint on government as respects purely commercial advertising,” restrictions on which are simply “matters for legislative judgement.”⁴⁰ Chrestensen’s trick of adding protest material to his advertisements did not save his pamphlets, because it was done with the intent to evade the ordinance, and because every merchant would use this loophole if it were held valid.⁴¹

But just as with many other categories of unprotected speech, commercial speech would not stay exempted from the First Amendment’s reach. The next step in the development of the doctrine came, in a roundabout way, with the Court’s 1973 decision in *Roe v. Wade* that a woman’s right to choose an abortion was constitutionally protected.⁴²

³³ See *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942); *Breard v. City of Alexandria*, 341 U.S. 622, 644–45 (1951) (upholding an ordinance prohibiting door-to-door solicitation of magazine subscriptions). Even so, there remains an argument that commercial speech was implicitly afforded some early protection, at least when commercial speech was mixed with the Free Exercise Clause of the First Amendment. See *Murdock v. Pennsylvania*, 319 U.S. 105, 111 (1943) (“the mere fact that . . . religious literature is “sold” . . . rather than “donated” does not transform evangelism into a commercial enterprise.”); see generally Jeremy Kessler, *The Early Years of First Amendment Lochnerism*, 116 COLUM. L. REV. 1915 (2016).

³⁴ *Valentine*, 316 U.S. at 53.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.* at 53–54.

⁴¹ *Id.* at 55. See also *Bolger*, 463 U.S. at 67–68; *SUNY v. Fox*, 492 U.S. at 474.

⁴² *Roe v. Wade*, 410 U.S. 113 (1973); see also *Griswold v. Connecticut*, 381 U.S. 479 (1965).

In the aftermath of *Roe*, states sought to end-run its holding in a variety of ways.⁴³ One method states used was to limit advertisement of contraceptive options.⁴⁴ For example, a Virginia statute prohibited circulation of publications encouraging or promoting the procurement of an abortion.⁴⁵ Jeffrey Bigelow, the managing editor of a newspaper called the Virginia Weekly, published and circulated an issue that contained an advertisement stating, “UNWANTED PREGNANCY LET US HELP YOU,” and advertising the availability of abortions in New York.⁴⁶ Virginia tried, convicted, and fined Bigelow, and the Supreme Court of Virginia rejected his First Amendment claim, stating that his speech was unprotected commercial advertisement and the statute was a valid exercise of the state’s police power because it was furthering the goal of protecting pregnant women facing a crucial decision from “commercial advertising pressure.”⁴⁷

Justice Blackmun, who had also authored the majority in *Roe*, did not see it the same way. Virginia Courts were wrong, he held in *Bigelow v. Virginia*, to assume that advertising had no First Amendment protection.⁴⁸ The “relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas.”⁴⁹ The advertisement did not just propose a commercial transaction. Instead, it contained “factual material of clear public interest.”⁵⁰ Virginia could not legitimately regulate or prohibit the underlying service—abortion—and thus it could not regulate the speech giving information about the service.⁵¹

Commercial speech’s initial shift from unprotected to protected category blossomed one year later in *Virginia State Board of Pharmacy*.⁵² As part of its thorough regulation of the pharmacy profession, Virginia effectively banned price advertisement of prescription drugs by licensed pharmacists.⁵³ Justice Blackmun saw this as a chance to squarely address pure commercial speech. Pharmacists did not wish to editorialize on an idea, but simply communicate information: “I will sell you the X prescription drug at the Y price.”⁵⁴ As Blackmun explained, speech does not lose First Amendment

⁴³ See generally *An Overview of Abortion Laws: State Laws and Policies*, GUTTMACHER INSTITUTE, <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws> [<https://perma.cc/9P49-EWMA>]; cf. *Harris v. McRae*, 448 U.S. 297 (1980) (upholding the constitutionality of the Hyde Amendment, which limited funding for abortions at the federal level).

⁴⁴ *Bigelow*, 421 U.S. 809; *Carey v. Population Servs. Int’l*, 431 U.S. 678, 700–01 (1977) (invalidating a prohibition on advertising of contraceptives); *Bolger*, 463 U.S. at 69 (holding the same, and stating that advertising for contraceptives “relates to activity which is protected from unwarranted state interference”).

⁴⁵ *Bigelow*, 421 U.S. at 811.

⁴⁶ *Id.* at 811–12.

⁴⁷ *Id.* at 813–15.

⁴⁸ *Id.* at 825.

⁴⁹ *Id.* at 826.

⁵⁰ *Id.* at 822.

⁵¹ *Id.* at 825. See also *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376 (1973) (upholding a statute which operated to forbid sex-designated job classified advertising on grounds that an advertiser who wished to segregate its job ads would be likely to unlawfully discriminate in its hiring practices). This idea was eventually folded into prong one of the *Central Hudson* test.

⁵² See generally *Virginia Board*, 425 U.S. 748.

⁵³ *Id.* at 752.

⁵⁴ *Id.* at 761.

protection because money is spent to project it,⁵⁵ nor does it lose protection because it is sold,⁵⁶ and speech proposing a commercial transaction is not of such low societal value as to otherwise justify it remaining an unprotected category.⁵⁷

Three separate interests acted to protect the speech in *Virginia Board*. First, the Court held that the advertiser herself has an interest in the speech, which warrants its protection—even though the interest may be purely economic.⁵⁸ Second, the Court determined that the individual consumer has an interest as a recipient of the information.⁵⁹ And third, the Court stated that society has an interest in ensuring that economic decisions in the aggregate be intelligent and well-informed.⁶⁰

Ultimately, though the protection results from various interests, the information is protected.⁶¹ The state was of course free to regulate the pharmaceutical profession for safety and professionalism.⁶² But *Virginia Board* established that the state was not free to suppress the dissemination of truthful information about lawful activity based on fears regarding the effect on disseminators or recipients.⁶³ Justice Blackmun thoroughly rejected such a paternalistic approach: “[I]nformation is not in itself harmful[.] . . . [P]eople will perceive their own best interests if only they are well enough informed[.] . . . [T]he best means to that end is to open the channels of communication rather than to close them.”⁶⁴

⁵⁵ *Id.* (citing *Buckley v. Valeo*, 424 U.S. 1, 35–36 (1976)).

⁵⁶ *Id.* (citing *Smith v. California*, 361 U.S. 147, 150 (1959) (books)); *Murdock*, 319 U.S. at 111 (religious literature).

⁵⁷ *Virginia Board*, 425 U.S. at 762 (stating that speech solely proposing a commercial transaction is not “so removed from exposition of ideas . . . that it lacks all protection”).

⁵⁸ *Id.* (citing *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 617–18 (1969) (protecting labor dispute communications, which involve primarily economic interests, even when the parties do not address “the merits of unionism in general”)); *id.* at 764–65 (stating that distinctions would be needlessly formal because the pharmacist could just recast herself “as a commentator on store-to-store disparities in drug prices”).

⁵⁹ *Id.* This was implicit in the fact that the Virginia Citizens Consumer Council, which represented consumers of prescriptions drugs, was able to assert First Amendment protection as recipients of the communication. *Id.* at 753, 757 (“the protection afforded is to the communication, to its source and to its recipients both”); *id.* at 763–64 (stating that the consumer needs protection because “the poor, the sick, and particularly the aged” spend so much of their income on drugs that “information as to who is charging what becomes more than a convenience”).

⁶⁰ *Id.* at 765 (“So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.”).

⁶¹ *Cf.* *Red Lion Broadcasting v. FCC*, 395 U.S. 367, 390 (1969) (stating that the public has a right “to receive suitable access to social, political, [and] aesthetic” ideas); *Time, Inc. v. Hill*, 385 U.S. 374, 389 (1967) (suggesting a right to publish newsworthy information “for the benefit of all of us”); *Pacific Gas & Elec. Co. v. Pub. Util. Comm’n of Cal.*, 475 U.S. 1, 8 (1986) (plurality) (“The identity of the speaker is not decisive in determining whether speech is protected. Corporations and other associations, like individuals, contribute to the discussion, debate, and the dissemination of information and ideas that the First Amendment seeks to foster.”) (quoting *First Nat’l Bank of Boston v. Belotti*, 435 U.S. 765, 783 (1978)).

⁶² *Virginia Board*, 425 U.S. at 769–70.

⁶³ *Id.* at 771–72. *See also* *Linmark Associates*, 431 U.S. at 96 (“the constitutional defect . . . [in an ordinance that prohibited display of “for sale” signs in order to combat “white flight,” is that that township] has sought to restrict the free flow of these data because it fears that otherwise homeowners will make decisions inimical to what the [council] views as the homeowners’ self-interest.”).

⁶⁴ *Virginia Board*, 425 U.S. at 770.

Justice Stewart's *Virginia Board* concurrence offered an important qualification: in his view, the protection for commercial speech does not extend to "false or deceptive advertising."⁶⁵ He wrote separately to clarify the "important differences" between ideological communications and commercial price and product advertising. Ideological expression is constitutionally protected, "whether or not it contains factual representations and even if it includes inaccurate assertions of fact," while commercial speech "may be tested empirically and corrected to reflect the truth without in any manner jeopardizing the free dissemination of thought."⁶⁶ Since commercial speech's protection derives from its "information of potential interest and value," it can be comfortably regulated for truth—false commercial speech does not have the same value.⁶⁷

Justice Rehnquist in dissent levelled what has become a common critique of modern First Amendment jurisprudence at the *Virginia Board* majority: that they were reviving the anticanon staple *Lochner v. New York*.⁶⁸ In fact, in an earlier due process challenge after the statute was originally amended in 1968, a district court had upheld the statute.⁶⁹ That the Court was now striking it under the Free Speech Clause looked to Justice Rehnquist like the Court was substituting its policy views for the Virginia legislature's. Justice Rehnquist also faulted the court for simply abandoning the line between commercial and noncommercial speech in favor of the line between truthful and false or misleading commercial speech. Both lines are difficult to define.⁷⁰ And finally, his prediction that pharmacists would "energetically promote" the sale of drugs with advertisements such as, "Pain getting you down? Insist that your physician prescribe Demerol," has proved more than prescient.⁷¹

Justice Rehnquist's views on the similarity between commercial speech protections and *Lochner*'s freedom of contract has come back into focus in recent years, with the

⁶⁵ *Id.* at 776 (Stewart, J., concurring).

⁶⁶ *Id.* at 780–81 (Stewart, J., concurring). *See also id.* at n.24 ("The truth of commercial speech, for example, may be more easily verifiable by its disseminator[.] . . . Also, commercial speech may be more durable than other kinds. [Because of its profit motive] there is little likelihood of its being chilled by proper regulation and forgone entirely. Attributes such as these, the greater objectivity and hardness of commercial speech, may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker.").

⁶⁷ *Id.* Demonstrably false speech does have protection in the ideological context, but not the same amount as clearly verifiable statements. *See New York Times Co. v. Sullivan*, 376 U.S. 254, 279 (1964) (holding that since errors are inevitable in free debate, the freedom of expression needs "breathing room" to survive); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 342–47 (1974) (holding that demonstrable falsehoods are not protected in the same manner as truthful statements); *United States v. Alvarez*, 567 U.S. 709 (2012) (agreeing that false statements are entitled to at least some protection, but failing to draw a majority on whether the protection is the same level as for true statements).

⁶⁸ *Virginia Board*, 425 U.S. at 784 (Rehnquist, J., dissenting) ("Courts [should] not substitute their social and economic beliefs for the judgment of legislative bodies who are elected to pass laws."); *Lochner v. New York*, 198 U.S. 45 (1905).

⁶⁹ *Patterson Drug Co. v. Kingery*, 305 F. Supp. 821 (W.D. Va. 1969).

⁷⁰ *Virginia Board*, 425 U.S. at 787 (Rehnquist, J., dissenting).

⁷¹ *Id.* at 788 (Rehnquist, J., dissenting). For examples of the extensive advertising this doctrine has ended up protecting, turn on any television set or see, *e.g.*, *Do not get sold on drug advertising*, HARVARD HEALTH PUBLISHING: HARVARD MEDICAL SCHOOL (Feb. 2017), <https://www.health.harvard.edu/drugs-and-medications/do-not-get-sold-on-drug-advertising> [http://perma.cc/Y35Z-HYZT].

liberal justices on the court often agreeing with him while writing in dissent.⁷² Recent scholarship, too, has criticized “[t]he new *Lochner*’s absolutist ‘speech is speech’ argument” “both for its lack of limiting principle and for its failure to reflect social reality,” noting that its advocates “seek to remake the American administrative state,” “pit[ting] the Constitution against democracy itself.”⁷³ Other scholarship argues that such “information libertarianism” supports traditional First Amendment theories while also being “limited enough to permit the modern regulatory state to function largely unimpeded.”⁷⁴ This article does not seek to add to this debate but instead merely to present (and argue that FDA must contend with) the law as it currently is.

II.B.2. *The Central Hudson Era*

Bigelow determined that commercial speech on matters of public interest had First Amendment protection, while *Virginia Board* established that all commercial speech concerns matters of public interest. But the precise test for commercial speech protections did not solidify until the 1980 case of *Central Hudson Gas & Electric*.⁷⁵ *Central Hudson* concerned a challenge to the New York Public Service Commission’s complete ban on advertising by electrical companies.⁷⁶ The Court held that advertising was protected despite the service holding a monopoly because “[e]ven in monopoly markets, the suppression of advertising reduces the information available for consumer decisions and thereby defeats the purpose of the First Amendment.”⁷⁷ Although the state had a substantial interest in energy conservation, the ban was more extensive than necessary to further that interest, and although the state had a substantial interest in preventing inequities in rates, the means-ends connection was, at best, tenuous.⁷⁸

The *Central Hudson* case established that commercial speech is subject to a version of intermediate scrutiny, and its inquiry provided the framework for evaluating commercial speech challenges that has held, in name at least, to the present day. The *Central Hudson* intermediate scrutiny test comes in four parts, as follows.⁷⁹ First, the threshold inquiry is whether the expression is protected by the First Amendment, *i.e.*, whether it concerns lawful activity and is not misleading. Second, for the regulation to be upheld, the asserted governmental interest must be substantial. Further, the regulatory technique must be in proportion to the interest, which is shown by third, directly advancing the interest, and fourth, being no more extensive than necessary to serve the interest.

The Court’s next commercial speech case concerned another effort to limit access to contraceptives by limiting the advertisement of such—this time, by the federal

⁷² *Sorrell*, 564 U.S. at 585 (Breyer, J., dissenting); *Becerra*, 138 S.Ct. at 2381–83 (Breyer, J., dissenting); *Janus*, 138 S. Ct. at 2464 (“[T]he majority’s road runs long. And at every stop are black-robed rulers overriding citizens’ choices.”) (Kagan, J., dissenting).

⁷³ Amanda Shanor, *The New Lochner*, WIS. L. REV. 133, 205–06 (2016); see also Thomas Colby & Peter Smith, *The Return of Lochner*, 100 CORNELL L. REV. 527 (2015).

⁷⁴ Jane R. Bambauer & Derek E. Bambauer, *Information Libertarianism*, 105 CALIF. L. REV. 335, 394 (2017).

⁷⁵ *Central Hudson*, 447 U.S. 557.

⁷⁶ *Id.* at 559.

⁷⁷ *Id.* at 567.

⁷⁸ *Id.* at 566–72.

⁷⁹ *Id.* at 566.

government.⁸⁰ 39 U.S.C. §3001(e)(2) prohibited unsolicited mailing of advertisements for contraceptives; when Youngs Drug Products sought to mail unsolicited advertisements containing a combination of information on venereal diseases and advertisements for its contraceptive products, the Postal Service informed them that doing so would violate the statute.⁸¹ In *Bolger*, the Court struggled with how to classify the speech: was it commercial speech that did no more than propose a commercial transaction, or did the discussions of important public issues such as venereal disease and family planning give it the usual protection afforded to speech against content-based restrictions?⁸² Justice Marshall determined that three relevant factors were present: (1) they were advertisements; (2) they referred to a specific product; and (3) Youngs had an economic motivation for the mailing.⁸³ Although none of these factors by itself would justify characterization as commercial speech, in combination they “provide[d] strong support” for such a characterization.⁸⁴ Despite the decision that Youngs Drugs’ speech was commercial and the ensuing application of *Central Hudson* intermediate scrutiny, the Court still struck the prohibition.⁸⁵ The governmental interest in shielding recipients from offensive materials was “classically” not a justification for suppression, and while the governmental interest in aiding parents’ efforts to control when and how their children were informed about birth control was substantial, the means were too broad.⁸⁶

The *Bolger* Court’s classification of the speech as commercial or noncommercial thus was irrelevant to the outcome. Had the speech been noncommercial, the law would have received strict scrutiny due to its content-based restriction, which it would have necessarily failed given it failed intermediate scrutiny. A better explanation for the outcome in *Bolger*—one that is more satisfying than the mechanics of the *Central Hudson* inquiry—is that Justice Marshall was troubled by the same issue that troubled Justice Blackmun in *Bigelow*. That is, the government here was attempting to manipulate consumer behavior by restricting consumers’ access to information. This is troubling in most cases,⁸⁷ but when it comes to cases where the underlying product or service is not only legal, but constitutionally protected, it is especially troubling—enough that the law will likely be struck regardless of the level of scrutiny applied.⁸⁸

Justice Stevens in his concurrence to *Bolger* did not think the classification question quite as easily settled. The idea that commercial speech is “a fairly definite category of communication . . . may not be wholly warranted,” he stated, because

⁸⁰ *Bolger*, 463 U.S. at 62.

⁸¹ *Id.* at 62–63.

⁸² *Id.* at 62–68; see also *Virginia Board*, 425 U.S. at 762.

⁸³ *Bolger*, 432 U.S. at 66–67.

⁸⁴ *Id.*

⁸⁵ *Id.* at 74.

⁸⁶ *Id.* at 71–74.

⁸⁷ *E.g.*, *Virginia Board*, 425 U.S. at 770–72.

⁸⁸ Justice Marshall’s majority opinion alluded to this by stating that advertising for contraceptives is clearly protected under prong one of *Central Hudson* because, contrary to being illegal, it actually “relates to activity which is protected from unwarranted state interference.” *Bolger*, 462 U.S. at 69 (emphasis added). Justice Stevens in concurrence would have found it relevant “whether a law regulates communications for their ideas or for their style,” because form or context regulations are less suspect and statutes that “censor ideas” are more suspect. This law was in the latter, idea-censoring, category. *Id.* at 84 (Stevens, J., concurring).

“advertisements may be complex mixtures of commercial and noncommercial elements.”⁸⁹ “[T]he noncommercial message does not obviate the need for appropriate commercial regulation; conversely, the commercial element does not necessarily provide a valid basis for noncommercial censorship.”⁹⁰ *Valentine v. Chrestensen* would appear to provide an answer to Justice Stevens’ dilemma: perhaps the determination turns on whether the noncommercial aspect was added with intent to evade a commercial classification.⁹¹ But this only holds inasmuch as the protection is for the speaker, and *Virginia Board* stated that the protection is for the speech—the speaker, the listener, and society.⁹² Additionally, cases rarely present such a neat demonstration of motive as Chrestensen’s dual-sided pamphlets offered.⁹³

After *Bolger*, the Court returned to considering commercial speech restrictions where the underlying product or service was legal, but not constitutionally protected. The two final decisions of the *Central Hudson* era upheld Puerto Rico’s prohibition on the advertisement of gambling and the State University of New York’s refusal to permit Tupperware parties in campus dormitories.⁹⁴ Along the way, the Court either—depending on one’s views—illuminated or weakened *Central Hudson*’s requirements.

1986 brought a challenge to Puerto Rico’s gambling laws in *Posadas de Puerto Rico Associates v. Tourism Company of Puerto Rico*.⁹⁵ Puerto Rico legalized gambling in order to promote development of tourism, but banned advertisement of gambling rooms to the Puerto Rican public (advertisement to tourists remained lawful).⁹⁶ Justice Rehnquist upheld the ban using the *Central Hudson* test:⁹⁷ (1) gambling was a lawful activity; (2) the governmental interest in reducing its residents’ demand for casino gambling was a substantial interest as an extension of its police powers; (3) the restrictions directly advanced the interest because the legislature’s belief that it would advance the interest was reasonable (and the under-inclusivity was not an issue); and (4) the restrictions were no more extensive than necessary, because the Puerto Rican courts had interpreted them to prohibit only advertising directly addressed to residents. Further, the Court distinguished *Carey* and *Bigelow* on the nature of the underlying product or service. Unlike the product or service in those cases, here “the Puerto Rican government surely could have prohibited casino gambling by the residents of Puerto Rico altogether. In our view, the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling.”⁹⁸ When

⁸⁹ *Bolger*, 462 U.S. at 81 (Stevens, J., concurring).

⁹⁰ *Id.*

⁹¹ *Valentine*, 316 U.S. at 55.

⁹² *Virginia Board*, 425 U.S. at 757.

⁹³ The commercial speech may also be not as easily separated from the noncommercial speech. *See, e.g., Riley*, 487 U.S. at 796 (applying strict scrutiny to compelled disclosure to potential donors, before an appeal for funds, of the percentage of a fundraiser’s collections that were actually turned over to charity, despite its commercial aspects, because the speech was “inextricably intertwined with otherwise fully protected speech” and thus the proper level of scrutiny was determined by “the nature of the speech taken as a whole”).

⁹⁴ *Posadas*, 478 U.S. 328; *SUNY v. Fox*, 492 U.S. 469.

⁹⁵ *Posadas*, 478 U.S. 328.

⁹⁶ *Id.* at 331–32.

⁹⁷ *Id.* at 341–42.

⁹⁸ *Id.* at 345–46.

the underlying conduct is not constitutionally protected and the product or service is deemed harmful, *Posadas* held, advertising prohibitions are simply another tool in the legislature's chest.⁹⁹

Justice Brennan in dissent took issue with the majority's application of *Central Hudson*, essentially accusing it of applying mere rational basis review. While "tipping its hat" to the *Central Hudson* test, Justice Brennan wrote, the majority did "little more than defer" to the Puerto Rican legislature.¹⁰⁰ On this view, the majority's application of *Central Hudson* prong three is particularly weak. The restrictions were held to directly advance the interest because the legislature held a reasonable belief that they would, and because "the fact that appellant has chosen to litigate this case all the way to [the Supreme] Court" showed that the Tourism Company, too, believed that it would advance the interest.¹⁰¹ Under this reasoning nearly every challenge that reached the Supreme Court would automatically satisfy *Central Hudson* prong three. Justice Brennan also had a different view on whether *Carey* and *Bigelow* were distinguishable. There the ultimate sin was not that the legislature could not ban the underlying behavior, but that the government sought "to manipulate private behavior by depriving citizens of truthful information concerning lawful activities."¹⁰² Of this sin, the Puerto Rican government was guilty.

Justice Stevens dissented on a separate (but related) point, namely, the majority's conclusion that the greater always includes the lesser in the commercial speech area. It was inappropriate for the majority to address the issue, he wrote, because Puerto Rico's "bizarre restraints on speech" (*i.e.*, "blatantly discriminat[ing] . . . depending upon the publication, audience, and words employed") meant that the law was "plainly forbidden by the First Amendment."¹⁰³ To compare the two concurrences, Justices Brennan and Stevens both faulted the majority for implicitly lowering the *Central Hudson* standard. Justice Brennan would have incorporated (or kept) the strict scrutiny staple of not deferring to the legislature,¹⁰⁴ while Justice Stevens would have applied to the commercial speech at issue the First Amendment rule for fully-protected speech that regulatory schemes riddled with exceptions, or regulatory schemes that are speaker- or listener-specific as a proxy for content-specificity, are viewed more suspiciously.¹⁰⁵

⁹⁹ *Id.* at 346–47 ("Legislative regulation of products or activities deemed harmful . . . has varied from outright prohibition . . . to legalization . . . with restrictions To rule out the latter, intermediate kind of response would require more than we find in the First Amendment."). This view has not held up over time. See section II.B.3., *infra*.

¹⁰⁰ *Id.* at 352 (Brennan, J., dissenting).

¹⁰¹ *Id.* at 341–42.

¹⁰² *Id.* at 351 (citing *Central Hudson*, 447 U.S. at 574–75 ("[This restriction] is a covert attempt by the State to manipulate the choices of its citizens . . . by depriving the public of the information needed to make a free choice.")) (Blackmun, J., concurring)).

¹⁰³ *Id.* at 359.

¹⁰⁴ Compare *Fitzgerald v. Racing Ass'n of Central Iowa*, 539 U.S. 103, 108 (2003) (upholding a statute under minimum rationality review because the legislature "might [have a] general objective") with *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 501 (1989) (holding that in the strict scrutiny realm of race classifications, courts should not defer to a governmental body's conclusions).

¹⁰⁵ On the first point, see *Metromedia v. San Diego*, 453 U.S. 490 (1981) (striking an ostensibly content-neutral ordinance because it was riddled with content-based exceptions) (plurality); *Reed v. Town of Gilbert*, 135 S.Ct. 2218 (2015) (striking a content-based sign ordinance as hopelessly underinclusive of the city's interests in aesthetics and traffic safety, because the exceptions allowed proliferation of other

The final case¹⁰⁶ of what this article has termed the *Central Hudson* era took a similar approach to *Posadas*. In *Board of Trustees of State University of New York v. Fox*, the Court considered a challenge to the state university's refusal to permit American Future Systems, Inc., a company that sold housewares to college students, to conduct Tupperware parties in campus dormitory rooms.¹⁰⁷ As a threshold matter, Justice Scalia summarily dismissed the argument that the fact that the commercial presentations also touched on noncommercial subjects such as how to be financially responsible and how to run an efficient home meant it had the full protection of noncommercial speech.¹⁰⁸ The commercial speech here was not "inextricably intertwined with otherwise fully protected speech," and thus the commercial aspect—that the students seek to "propose a commercial transaction"—was the relevant portion.¹⁰⁹

Justice Scalia framed the ultimate question in *SUNY v. Fox* as "whether governmental restrictions upon commercial speech are invalid if they go beyond the least restrictive means to achieve the desired end."¹¹⁰ This question he answered in the negative: the fit must only be reasonable and proportional, not perfect.¹¹¹ The case was then remanded to consider an as applied challenge in light of the new guidance.¹¹²

II.B.3. *The Modern Era*

This article places a dividing line between "the *Central Hudson* era" and "the modern era" because of the Court's fundamental shift in approach. While *Posadas* and *SUNY v. Fox* relaxed *Central Hudson*, cases after this era considered rejecting the *Central Hudson* test altogether in favor of a heightened standard of review. However, the Court never achieved enough votes to officially overturn *Central Hudson*, and

signs). In the commercial speech context, see *Rubin*, 514 U.S. at 488 (holding that a commercial speech regulation could not pass scrutiny, even given a substantial governmental interest, if "other provisions of the same Act directly undermine and counteract its effects"); *New Orleans Broad.*, 527 U.S. at 188 (striking a speech-restricting regulatory regime due to too many exemptions and inconsistencies).

On the second point, see *Leathers v. Medlock*, 499 U.S. 439 (1991) (holding that tax schemes with speaker-specificity implicate the First Amendment if the specificity functions as idea discrimination); *Turner Broadcasting v. FCC*, 512 U.S. 622 (1994) [hereinafter *Turner I*] (stating that regulations discriminating between speakers within a medium present First Amendment concerns unless the differential treatment is justified by some special characteristic of the particular medium being regulated). In the commercial speech context, see *City of Cincinnati v. Discovery Network*, 507 U.S. 410 (1993) (holding it constitutionally invalid to treat commercial and noncommercial speech differently, except if aiming at a particular harm generated by the commercial speech).

¹⁰⁶ The Court considered other cases in the meanwhile, but the approach taken in these was largely the same as that set forth in *Posadas* and *SUNY v. Fox*. See section II.B.4., *infra*; see also *United States v. Edge Broadcasting*, 509 U.S. 418 (1993) (upholding prohibition on advertisement of a state's lottery by a radio station in another state in which the lottery was not legal).

¹⁰⁷ *SUNY v. Fox*, 492 U.S. at 472.

¹⁰⁸ *Id.* at 474–75.

¹⁰⁹ *Id.* at 473–75. The rule that compelled commercial speech gets full protection when "inextricably intertwined with otherwise fully protected speech" comes from *Riley*, 487 U.S. at 796. The rule that commercial speech "propose[s] a commercial transaction" comes from *Virginia Board*, 425 U.S. at 762.

¹¹⁰ *SUNY v. Fox*, 492 U.S. at 471.

¹¹¹ *Id.* at 480. This view has not held up over time. See section II.B.3, *infra*.

¹¹² *SUNY v. Fox*, 492 U.S. at 485–86.

eventually has settled on applying a version of *Central Hudson* which is much-strengthened from its original form.

The first clear evidence of the Court's shift in approach came in the early 1990s with *Rubin v. Coors*.¹¹³ *Rubin* involved the Federal Alcohol Administration's regulations implementing the FAAA (27 U.S.C. § 205(e)(2)), which operated to prohibit beer labels from displaying the beer's alcohol content.¹¹⁴ Justice Thomas' majority purported to use a straightforward application of *Central Hudson*—but unlike past precedent, he struck the policy both because it did not advance the interest in a “direct and material way”¹¹⁵ and because there were more speech-friendly alternatives available.¹¹⁶ The first point is at least in tension with *Posadas*' point on deferring to a legislature's reasonable determination that the regulation will advance the interest,¹¹⁷ while the second point runs counter to *SUNY v. Fox*'s determination that the least restrictive means are not required under *Central Hudson*.¹¹⁸

As to the mechanics, the majority held that the government did have a substantial interest in avoiding “strength wars” among brewers as an extension of its interest in protecting the health, safety, and welfare of its citizens via avoiding alcoholism.¹¹⁹ But the regulations did not advance the interest in a direct and material way because the scheme was irrational given that other provisions of the same Act (*e.g.*, allowing wine and distilled spirits to display alcohol content and labeling of high alcohol content beers differently) counteracted the interest.¹²⁰ Additionally, there were several available alternatives that would advance the goal in a less speech-restrictive manner, such as directly regulating alcohol content or targeting only advertising emphasizing high alcohol strength.¹²¹

Curiously enough, despite its implicit repudiation of the lowered standard of the 1980s, the *Rubin v. Coors* case was unanimous in judgment, with only Justice Stevens concurring and all others—including Justice Rehnquist, author of *Posadas*, and Justice Scalia, author of *SUNY v. Fox*—joining the majority.

Justice Stevens' concurrence bears further detailing, as its theories will soon come into prominent view: specifically, his theory on the “artificiality of a rigid commercial/noncommercial [speech] distinction” first laid forth in his *Bolger* concurrence.¹²² First, he rejected several options for defining speech as “commercial”: (1) the commercial content of the speech; (2) the economic motivation of the speaker; and (3) the effect of inducing purchase. As to the first, this does not suffice, he argued, because a nonprofit could publish the same information—“an unadorned, accurate statement” of the alcoholic content of certain beers—and it would clearly be fully

¹¹³ *Rubin v. Coors*, 514 U.S. 476 (1995).

¹¹⁴ *Id.* at 480–81.

¹¹⁵ *Id.* at 486–88; *see also* *Edenfield v. Fane*, 507 U.S. 761, 767, 770–71 (1993).

¹¹⁶ *Rubin*, 514 U.S. at 490–91.

¹¹⁷ *Posadas*, 478 U.S. at 341–42.

¹¹⁸ *SUNY v. Fox*, 492 U.S. 469, 480 (1989).

¹¹⁹ *Rubin*, 514 U.S. at 483–85.

¹²⁰ *Id.* at 488–89.

¹²¹ *Id.* at 490–91.

¹²² *Id.* at 494 (Stevens, J., concurring).

protected.¹²³ He rejected the second and third as well, since past precedent (including *Bolger*) had established that neither by itself could establish speech as commercial, and because the work of authors or artists does not lose protection if they choose to sell it.¹²⁴

Instead, Justice Stevens offered a coherent theory for why commercial speech has less protection than other types of speech, a theory drawn from Justice Stewart's *Virginia Board* concurrence: "commercial speech's potential to mislead."¹²⁵ "The evils of false commercial speech, which may have an immediate harmful impact on commercial transactions, together with the ability of purveyors of commercial speech to control falsehoods, explain why we tolerate more governmental regulation of this speech than of most other speech."¹²⁶ Because this was not targeted at preventing misleading speech or protecting consumers from the dangers of incomplete information, Justice Stevens would have found the commercial speech doctrine inapplicable to this case.¹²⁷ As *Virginia Board* and *Central Hudson* had stated, paternalism in the sense of "keep[ing] people in the dark for what the government believes to be their own good" cannot possibly justify regulations on speech.¹²⁸ Congress could directly limit the alcoholic content, but "Congress may not seek to accomplish the same purpose through a policy of consumer ignorance."¹²⁹ The government can protect its citizens, but it should not aim (however well-intentioned) to protect its citizens from themselves.

At this point it is appropriate to pause and take stock of how far commercial speech had come. It had moved from fully outside of the First Amendment's scope—*Valentine v. Chrestensen*—to being ambiguously protected in *Virginia Board*, with false and misleading commercial speech remaining unprotected. *Central Hudson* officially applied intermediate scrutiny but left the ambiguity. (Intermediate scrutiny is inherently ambiguous: strict scrutiny is the equivalent of a presumption against legislation; rational basis review the equivalent of a presumption for legislation; while intermediate scrutiny is left in the middle.) But as of *Rubin v. Coors*, Justice Stevens was credibly proposing commercial speech get full strict scrutiny, with false and misleading commercial speech being the only segment left in the realm of lowered review.

The following year *Central Hudson* looked doomed. *44 Liquormart* produced a remarkable splintering of opinions, with only two areas of agreement.¹³⁰ At issue in the case was a Rhode Island ban on liquor price advertisement except at the place of sale.¹³¹ The state proposed that §2 of the 21st Amendment, which delegated to the States the power to prohibit commerce in, or the use of, alcoholic beverages, qualifies

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.* at 496.

¹²⁷ *Id.* at 491–92.

¹²⁸ *Id.* at 497.

¹²⁹ *Id.* at 498.

¹³⁰ See *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484 (1996).

¹³¹ *Id.* at 489–90.

the First Amendment in the state's favor.¹³² That is, regulation of speech pertaining to alcoholic beverages was the converse of the situation in *Bigelow* and *Bolger* and like *Posadas*, but even stronger: here, contrary to being constitutionally protected against state interference (*Bigelow*), or even lacking constitutional protection (*Posadas*), the commerce to be regulated was explicitly constitutionally *unprotected* against state interference. The Court rejected this argument, however, holding that “the Twenty-first Amendment does not qualify the constitutional prohibition against laws abridging the freedom of speech.”¹³³ The other area of agreement in *44 Liquormart* was the outcome: Rhode Island's ban was constitutionally invalid.¹³⁴

The other portions of Justice Stevens' opinion failed to draw a majority, instead attracting (at various points along the way) Justices Kennedy, Souter, Ginsburg, and Thomas. Justice Stevens' approach was that of his concurrence in *Rubin*: he would have held that state regulation of commercial messages “to protect consumers from misleading, deceptive, or aggressive sales practices, or requir[ing] the disclosure of beneficial consumer information” would be “subject to less than strict review.”¹³⁵ But on the other end of the spectrum were blanket prohibitions on “the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process” (usually for fear of consumers' reactions to the information), which would be subject to “the rigorous review that the First Amendment generally demands.”¹³⁶

Despite laying out this approach, and deciding that the regulation at issue was in the paternalistic blanket ban category, Justice Stevens went on to decide that the ban didn't even survive *Central Hudson* analysis because it did not materially advance the state goal of promoting temperance and because there were alternative options that would have restricted less speech.¹³⁷ In the sole section of his in which Justice Thomas joined, Justice Stevens also rejected the state's arguments for deference to their legislative judgment.¹³⁸

Justice O'Connor (joined by Justices Rehnquist, Souter, and Breyer) concurred in the judgment, but would have simply applied *Central Hudson* to strike the legislation.¹³⁹ She would have purported to keep *Central Hudson* intact, quoting *SUNY v. Fox*'s definition of prong four: the fit must be “not necessarily perfect, but reasonable.”¹⁴⁰ But Rhode Island's ban would fail prong four, she wrote, because

¹³² *Id.* at 514–15.

¹³³ *Id.* at 516.

¹³⁴ *Id.*

¹³⁵ *Id.* at 501–504 (Stevens, J. plurality).

¹³⁶ *Id.*

¹³⁷ *Id.* Specifically, the state lacked evidence that the ban would reduce alcohol consumption “to a material degree,” meaning the regulation did not advance the state's goal. And the state could have also discouraged consumption by raising prices of alcohol or engaging in an educational campaign. *See id.* at 504–08. (Stevens, J. plurality).

¹³⁸ *Id.* The state had argued for deference because (1) experts were not in agreement on the regulation's affect; (2) the state could have banned the sale of the product; and (3) they believed a “vice” exception applied (all three arguments draw strongly from *Posadas*). *Id.* at 508–14. (Stevens, J. plurality).

¹³⁹ *Id.* at 528 (O'Connor, J., concurring).

¹⁴⁰ *Id.* at 529 (O'Connor, J., concurring) (quoting *SUNY v. Fox*, 492 U.S. at 480).

other, less-speech-restrictive, means were available to lower consumption of alcohol: for example, establishing a minimum price or increasing sales taxes.¹⁴¹

Justice Thomas, in a lone concurrence, set forth the view to which he would consistently adhere in future decisions—and a view which is helpful to consider because it is one goalpost (the other being *Chrestensen*) and knowing its location helps one appreciate the current view from the 20-yard-line. Whenever “the government’s asserted interest is to keep legal users of a product or service ignorant in order to manipulate their choices in the marketplace,” Justice Thomas wrote, *Central Hudson* should not be applied at all. “Rather, such an interest is *per se* illegitimate.”¹⁴² He went on to characterize the *Central Hudson* test as “accept[ing] the legitimacy of laws that suppress information in order to manipulate the choice of consumers—so long as the government could show that the manipulation was in fact successful.”¹⁴³ Since prong three of *Central Hudson* requires a showing that the regulation will directly advance the interest, the characterization in that sense holds. But Justice Thomas did not disapprove of Justices Stevens’ and O’Connor’s application of a heightened *Central Hudson* prong four, one that appears to require adoption of the least speech-restricting alternative.¹⁴⁴ Such an outcome—requiring speech restrictions as a last resort—would “go a long way” towards his position of speech restrictions being illegitimate.¹⁴⁵

If 44 *Liquormart* seemed to signal a Cold War of sorts on the fate of *Central Hudson*, *Greater New Orleans Broadcasting Association* was the fall of the Berlin Wall and a *de facto* end to the war, though not an explicit peace treaty. The case concerned a federal law prohibiting “any advertisement of or information concerning any lottery”; as applied to broadcast advertisements subsequent enactments and implementing FCC regulation narrowed its scope to prohibit only advertisements from stations licensed in States that did not conduct their own lotteries (while exempting gaming conducted by Native American tribes or not-for-profit organizations).¹⁴⁶

The Court had previously considered and upheld the constitutionality of the same provision as applied to advertising of Virginia’s lottery in North Carolina, who had no such lottery.¹⁴⁷ But six years had passed, and this time, the challenge was as applied to broadcasts in Louisiana, where lotteries *were* legal.¹⁴⁸

Justice Stevens, who had advocated in the two alcohol cases for abandoning the *Central Hudson* standard, wrote the majority opinion. And what test did he apply? Begrudgingly, *Central Hudson*. *Central Hudson* had been applied “[i]n a number of

¹⁴¹ 44 *Liquormart*, 517 U.S. at 530 (O’Connor, J., concurring).

¹⁴² *Id.* at 518 (Thomas, J., concurring).

¹⁴³ *Id.* at 521 (Thomas, J., concurring).

¹⁴⁴ *Id.* at 524–26 (“[I]t would seem that directly banning a product (or rationing it, taxing it, controlling its price, or otherwise restricting its sale in specific ways) would virtually always be at least as effective in discouraging consumption as merely restricting advertising regarding the product would be, and thus virtually all restrictions with such a purpose would fail the fourth prong of the *Central Hudson* test . . . [B]ut, rather than “applying” the fourth prong of *Central Hudson* to reach the inevitable result[.] . . . I would adhere to the doctrine adopted in *Virginia Board of Pharmacy* and in Justice Blackmun’s *Central Hudson* concurrence, that all attempts to dissuade legal choices by citizens by keeping them ignorant are impermissible.”) (Thomas, J., concurring).

¹⁴⁵ *Id.* at 524 (Thomas, J., concurring).

¹⁴⁶ *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173, 177–79 (1999).

¹⁴⁷ *United States v. Edge Broad. Co.*, 509 U.S. 418, 423, 436 (1993).

¹⁴⁸ *New Orleans Broad.*, 527 U.S. at 176.

[commercial speech] cases,” he admitted, and while “petitioners as well as certain judges, scholars, and *amici curiae* have advocated repudiation of the *Central Hudson* standard and implementation of a more straightforward and stringent test,” the standard “as applied in our more recent commercial speech cases, provides an adequate basis for decision.”¹⁴⁹ The reader’s emphasis should be on *as applied in recent cases*—it is the heightened *Central Hudson* of the alcohol duo that finally allowed seven justices to agree on applying one standard.

The speech was not misleading and concerned lawful activities (Louisiana had authorized the lottery), and the government’s interests in reducing the social costs associated with gambling and assisting States that restricted or prohibited gambling were both substantial.¹⁵⁰ But the regime failed to pass the rest of the test: it did not directly advance the interests, because the scheme was “pierced by exemptions and inconsistencies,” and it was more extensive than necessary, because there were non-speech-restricting forms of regulation that remained untried.¹⁵¹

Justice Thomas, concurring only in the judgment, adhered to his view in *44 Liquormart*: a governmental interest in keeping law-abiding consumers ignorant to manipulate their marketplace choices should be *per se* illegitimate.¹⁵²

By this point it was clear that there was no “vice” product exception to the First Amendment.¹⁵³ The Court had considered multiple restrictions on advertising related to alcohol and gambling. Why did this pattern arise? Vice products are the products that draw the type of regulation that the First Amendment abhors: instead of targeting the product or service itself, which would potentially draw the ire of citizens who (perhaps surreptitiously) possess the vice, legislatures are tempted to target the advertising to reduce demand for the vice. There are two issues with this approach. First, it does not logically follow that targeting advertising will reduce demand; instead, advertising may simply channel citizens between competing providers.¹⁵⁴ This fails *Central Hudson* prong three in that such an approach does not show it directly

¹⁴⁹ *Id.* at 183–84.

¹⁵⁰ *Id.* at 184–87. But it was not a full-throated endorsement of these interests: “when we consider both [the interests’ lack of] quality and the information sought to be suppressed, the crosscurrents in the scope and application of [the policy] become more difficult for the Government to defend.” *Id.* at 187. Interestingly, a similar argument to the second interest—here, assisting States that restricted or prohibited gambling; there, facilitating state efforts to regulate alcohol—was rejected in *Rubin v. Coors*, which held that “the Government’s interest in preserving state authority is not sufficiently substantial to meet the requirements of *Central Hudson*.” *Rubin*, 514 U.S. at 485–86.

¹⁵¹ *New Orleans Broad.*, 527 U.S. at 188–95. There is arguably inconsistency with the following two propositions, both stated by Justice Stevens, and the conclusion that leaving non-speech-restricting regulatory possibilities on the table dooms regulation under *Central Hudson*: (1) “[t]he Government is not required to employ the least restrictive means conceivable;” but instead (2) “the regulation should indicate that its proponent carefully calculated the costs and benefits associated with the burden on speech.” *Id.* at 188. The inconsistency can be alleviated by leaning more heavily on (2) than on (1). More practically, the inconsistency can be viewed as a transition towards the hardline approach stated clearly in *Thompson*: “if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.” *Thompson v. Western States Medical Center*, 535 U.S. 357, 371 (2002).

¹⁵² *New Orleans Broad.*, 527 U.S. at 197 (Thomas, J., concurring).

¹⁵³ *E.g.*, *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484, 513–14 (1996) (Stevens, J. plurality).

¹⁵⁴ *See New Orleans Broad.*, 527 U.S. at 189 (“While it is no doubt fair to assume that more advertising would have some impact on overall demand for gambling, it is also reasonable to assume that much of that advertising would merely channel gamblers to one casino rather than another.”).

advances the government's interest (hence Justice Thomas' formulation of *Central Hudson*: it allows the government to suppress speech, but only if it can demonstrate such suppression is effective). And second, more broadly, this approach runs counter to the thread running throughout commercial speech jurisprudence, namely, that the state cannot suppress truthful information regarding lawful activities for fear of citizens' reaction to such speech.¹⁵⁵

Restrictions on another vice product—this time tobacco—came next in *Lorillard Tobacco Co. v. Reilly*. The state of Massachusetts, in an effort to cut down on tobacco use, extensively regulated the advertising and sale of tobacco products.¹⁵⁶ The regulations pertaining to cigarette advertising were preempted by federal law,¹⁵⁷ and of the remaining regulations (pertaining to smokeless tobacco products and cigars), Justice O'Connor held that all were barred by the First Amendment except for the provision banning self-service displays.

The petitioners in *Lorillard* once again urged the Court to abandon *Central Hudson* in favor of strict scrutiny, and Justice O'Connor stated that "[a]dmittedly, several Members of the Court have expressed doubts about the *Central Hudson* analysis."¹⁵⁸ But, just as Justice Stevens did in *New Orleans Broadcasting*, after giving the less-than-ringing endorsement that the modernized *Central Hudson* "provides an adequate basis for decision," Justice O'Connor went on to engage in the analysis.¹⁵⁹

The state did have an interest in reducing underage use of smokeless tobacco and cigars, she held, relying in part on evidence gathered by FDA in its effort to restrict tobacco advertising to children and adolescents nationwide (an effort that was later deemed beyond its statutory authority in *FDA v. Brown & Williamson Tobacco*).¹⁶⁰ First, she found that the regulations prohibiting outdoor advertising within 1,000 feet of schools and playgrounds violated the First Amendment because they were overbroad and lacked reasonable fit: such a ban would prevent advertising in 87–91 percent of cities such as Boston, and included even advertising within a store, but visible outside of the store.¹⁶¹ Second, she determined that the regulations prohibiting indoor advertising within 1,000 feet of schools and playgrounds, if lower than 5 feet from the floor of a retail establishment, did not advance the government's interest: "[n]ot all children are less than 5 feet tall, and those who are certainly have the ability to look up."¹⁶² But last, Justice O'Connor upheld the regulations banning self-service displays and requiring retailers to place tobacco products behind counters and out of direct reach of consumers.¹⁶³ For these regulations, she applied the *O'Brien* form of intermediate scrutiny applicable to conduct that has a communicative impact, and held the regulations appropriately tailored to the state's substantial interest in preventing

¹⁵⁵ *E.g.*, *Linmark Associates, Inc. v. Willingboro Tp.*, 431 U.S. 85, 97 (1977).

¹⁵⁶ *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 533–36 (2001).

¹⁵⁷ *Id.* at 540–53.

¹⁵⁸ *Id.* at 554.

¹⁵⁹ *Id.* at 555 (quoting *New Orleans Broad.*, 527 U.S. at 184).

¹⁶⁰ *Id.* at 557–61; *Food and Drug Admin. v. Brown and Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

¹⁶¹ *Lorillard*, 533 U.S. at 561–63.

¹⁶² *Id.* at 566.

¹⁶³ *Id.* at 567–70.

minors from gaining access to tobacco products, an interest that was unrelated to the suppression of speech.¹⁶⁴

Justice Thomas concurred that the regulations failed *Central Hudson*, but continued to adhere to the view that “when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech in question may be characterized as ‘commercial.’”¹⁶⁵ “[T]here is no philosophical or historical basis for asserting that ‘commercial’ speech is of ‘lower value’ than ‘noncommercial’ speech,” he wrote, continuing on to say that “I doubt whether it is even possible to draw a coherent distinction between [the two].”¹⁶⁶

The last two major cases bring the story full-circle. Three decades earlier, Virginia was worried about the over-prescription and overconsumption of pharmaceutical drugs. Such a practice has two harms: first, patients pay high prices for drugs that may not confer a corresponding benefit, and second, patients take drugs for which the risk of side effects (to the individual patient) may outweigh the potential benefit (to the individual patient).¹⁶⁷ Virginia targeted this consumption by targeting advertising of prescription drugs, which led to the Court granting protection to such speech in *Virginia Board*.¹⁶⁸ Throughout the intervening years Virginia’s concerns did not fade away but indeed became even more relevant. Even at present such concerns are once again cropping up with debates about the over-prescription of drugs such as ADD medications,¹⁶⁹ and most saliently with the opioid crisis.¹⁷⁰ Thus, it is no surprise that the next two commercial speech cases both concerned the pharmaceutical industry: the first analyzed a federal regulation of the advertisement of drug compounding services,¹⁷¹ while the second struck a state intervention designed to prevent advertisers from obtaining information necessary to target their advertising at physicians.¹⁷²

Among the provisions of the Food and Drug Modernization Act of 1997 (FDAMA) were sections which codified and strengthened FDA’s previous guidance on the

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 572 (Thomas, J., concurring).

¹⁶⁶ *Id.* at 575 (Thomas, J., concurring).

¹⁶⁷ The first was discussed in *Virginia Board*, 425 U.S. at 763–64; see also Gina Kolata, *Why Drugs Cost More in U.S.*, THE N.Y. TIMES (May 24, 1991), <http://www.nytimes.com/1991/05/24/business/why-drugs-cost-more-in-us.html?https://perma.cc/7758-CSMU>. The second was highlighted by Justice Breyer’s dissent in *Thompson v. Western States Medical Center*, 535 U.S. 357, 380 (2002) (Breyer, J., dissenting).

¹⁶⁸ *Virginia Board*, 425 U.S. 748.

¹⁶⁹ *Are ADHD Medications Overprescribed?*, THE WALL STREET JOURNAL (Feb. 14, 2013), <https://www.wsj.com/articles/SB10000872396390444301704577631591596516110https://perma.cc/HPC7-S7NP>; Sandra Boodman, *The other big drug problem: Older people taking too many pills*, THE WASHINGTON POST (Dec. 9, 2017), https://www.washingtonpost.com/national/health-science/the-other-big-drug-problem-older-people-taking-too-many-pills/2017/12/08/3cea5ca2-c30a-11e7-afe9-4f60b5a6c4a0_story.html?utm_term=.b60d977902e3https://perma.cc/JK7Q-L77Q.

¹⁷⁰ *Prescription drugs: The epidemic of addiction in the U.S.*, STANFORD NEUROSCIENCES INSTITUTE (Jan. 18, 2017), <https://neuroscience.stanford.edu/news/prescription-drugs-epidemic-addiction-ushttps://perma.cc/YGL5-VFNK>; Julie Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, THE NEW YORK TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.htmlhttps://perma.cc/Q35T-NCGS>.

¹⁷¹ *Thompson*, 535 U.S. 357.

¹⁷² *Sorrell*, 564 U.S. 552.

regulation of compounded drugs.¹⁷³ Compounded drugs are drugs for which a pharmacist combines, mixes, or alters ingredients in non-compounded drugs in order to create a new, individually-tailored drug.¹⁷⁴ Compounded drugs are exempted from FDA's New Drug Application (NDA) process.¹⁷⁵ This leaves the concern that the industry will conduct the equivalent of manufacturing a new drug, without approval, under the guise of drug compounding.¹⁷⁶ The FDAMA addressed these concerns by requiring, as a condition for the drug compounding exception from the NDA process, a number of conditions.¹⁷⁷ Among these restrictions was the requirement that prescriptions for compounded drugs be "unsolicited" and that the compounding pharmacy must "not advertise or promote the compounding of any particular drug, class of drug, or type of drug," although they remained free to "advertise and promote the [general] compounding service."¹⁷⁸

A group of licensed pharmacies that specialized in drug compounding challenged this restriction in *Thompson v. Western States Medical Center*.¹⁷⁹ This time, the parties did not challenge the appropriateness of applying *Central Hudson*, and as in *Lorillard* and *New Orleans Broadcasting*, the test was deemed "adequate."¹⁸⁰ The government argued three interests: (1) preserving the effectiveness and integrity of the FDCA's NDA process and protection of public health; (2) preserving the availability of compounded drugs; and (3) achieving a proper balance between the first two interests.¹⁸¹ Justice O'Connor admitted these were all important interests, because the government needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing. But even assuming that the advertising ban did directly advance the government's interests, Justice O'Connor found the speech restrictions to be more extensive than necessary. She characterized the modern *Central Hudson* approach to the tailoring requirement as, "if the Government [can] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."¹⁸² This, of course, is borrowed directly from general (*i.e.*, fully protected) First Amendment jurisprudence: "regulating speech must be a last—not first—resort."¹⁸³ But here, Justice O'Connor went on, "it seems to have been the first strategy the Government thought to try."¹⁸⁴

Justice Breyer, in dissent, responded to Justice O'Connor's characterization of the governmental interests. Of course, the government had to distinguish between large-

¹⁷³ *Thompson*, 353 U.S. at 364.

¹⁷⁴ *Id.* at 360–61.

¹⁷⁵ HUTT, *supra* note 5, at 793–94.

¹⁷⁶ *Thompson*, 353 U.S. at 362.

¹⁷⁷ *Id.* at 364–65.

¹⁷⁸ *Id.* at 365.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* at 367–68.

¹⁸¹ *Id.* at 368.

¹⁸² *Id.* at 371; *see also* *Rubin v. Coors*, 514 U.S. 476, 491 (1995); *44 Liquormart v. R.I.*, 517 U.S. 484, 507 (1996). Compare to the Court's earlier approach in *SUNY v. Fox*, 492 U.S. 469, 480 (1989).

¹⁸³ *Thompson*, 353 U.S. at 373. This axiom was laid out in Justice Black's dissent to the "hostile audiences" case of *Feiner v. New York*, 340 U.S. 315 (1951), and has since become the *de facto* approach to that category. *See Cox v. State of Louisiana*, 379 U.S. 536 (1965).

¹⁸⁴ *Thompson*, 353 U.S. at 373.

and small-scale manufacturers, he said, but they had another interest as well: to distinguish the sales of compounded drugs to those who clearly need them from sales of compounded drugs to those for whom a specially tailored but untested drug is a convenience but not a medical necessity.¹⁸⁵ The compounding exception created risks by giving consumers untested drugs, risks that the government needed to minimize. “Where an individual has a specific medical need for a specially tailored drug those risks are likely offset. But where an untested drug is a convenience, not a necessity, that offset is unlikely to be present.”¹⁸⁶

Justice O’Connor responded by saying that such an interest was foreclosed by precedent such as *Virginia Board* and *44 Liquormart*, because it amounted to the fear that people “would make bad decisions if given truthful information.”¹⁸⁷ The patients and doctors themselves can balance the risks against the benefit and decide if one offsets the other. Indeed, this individualized assessment (rather than the generalized assessment of risks and benefits of the NDA process) was at least partially why FDA had consistently taken the position that compounding was exempted from the FDCA.¹⁸⁸ Justice O’Connor’s other response faulted the dissent for providing a hypothetical justification for the statute.¹⁸⁹ Such a justification is appropriate for minimum rationality review, she said, but *Central Hudson* is “significantly stricter.”¹⁹⁰

After *Thompson*, it took almost a decade for another challenge to arise, this one to Vermont’s Prescription Confidentiality Law.¹⁹¹ The law restricted the sale, disclosure, and use of pharmacy records (which reveal the prescribing practices of individual doctors) to “detailers,” marketers for pharmaceutical manufacturers who would visit physicians to convince them of the advantages of the manufacturer’s (usually only brand-name) drugs.¹⁹²

Justice Kennedy in *Sorrell v. IMS Health* began with general First Amendment analysis: Vermont’s law, he held, was a content- and speaker-based restriction.¹⁹³ It disfavored marketing—speech with a particular content—and disfavored pharmaceutical detailers—particular speakers.¹⁹⁴ By targeting the message of promotion of brand-name drugs, the statute was even viewpoint-discriminatory—the paradigmatic case of a First Amendment violation.¹⁹⁵ That the law was a burden rather

¹⁸⁵ *Id.* at 380 (Breyer, J., dissenting).

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 374; see also *Linmark Associates, Inc. v. Willingboro Twp.*, 431 U.S. 85, 97 (1977).

¹⁸⁸ HUTT, *supra* note 5, at 793–94. Traditionally, regulation of “compounding”—as separated out from “manufacturing”—had been the domain of states to regulate as part of the states’ direct regulation of the pharmaceutical profession. *Id.*

¹⁸⁹ *Thompson*, 535 U.S. at 373.

¹⁹⁰ *Id.*

¹⁹¹ *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011).

¹⁹² *Id.* at 557–60.

¹⁹³ *Id.* at 563–64.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 565. See also *R.A.V. v. City of St. Paul*, 505 U.S. 377 (1992); *Kingsley International Pictures Corp. v. Regents of the University of the State of New York*, 360 U.S. 684 (1959).

than a ban on speech did not change the analysis.¹⁹⁶ Thus, Justice Kennedy held, the law is subject to “heightened judicial scrutiny.”¹⁹⁷ Whether that form of scrutiny was *Central Hudson* or strict scrutiny was irrelevant to the outcome, and thus he found no need to even determine whether the speech at issue was “commercial” in nature.¹⁹⁸

The law was not justified under the state’s first interest of enforcing physicians’ reasonable expectation that their information would not be used for purposes other than filling and processing prescriptions, because the law did not coherently advance the interest.¹⁹⁹ It only targeted sharing the information for marketing; the information could be legally shared for any other purpose.²⁰⁰ The law was also not justified under the state’s other interest, *i.e.*, lowering the cost of medical services by ensuring that brand-name drugs are not promoted more than generic alternatives, because such an interest amounted to the paternalism rationale that had been rejected many times over.²⁰¹

Justice Breyer dissented, faulting Justice Kennedy’s majority for further blurring the line between *Central Hudson* and strict scrutiny. He would have reviewed the law as ordinary economic legislation, not under a heightened First Amendment standard.²⁰² The same heightened standard would hypothetically (and problematically) apply to FDA, he noted, including its ban on the marketing of drugs until testing has completed, its “regulation of the content of drug labels and the manner in which drugs can be advertised and sold,” the marketing of drugs for off-label use, and FDA’s goal of ensuring a “fair balance” of information on marketed drugs.²⁰³ “Regulatory programs necessarily draw distinctions on the basis of content,” but “[n]o one has yet suggested that substantial portions of federal drug regulation are unconstitutional.”²⁰⁴ Scholarship has noted that under modern interpretations “the First Amendment possesses near total deregulatory potential.”²⁰⁵ The key word in Justice Breyer’s statement, then, is *yet*.

Finally, there is an epilogue of sorts in the 2017 case *Expressions Hair Design v. Schneiderman*.²⁰⁶ This concerned an as-applied challenge to a New York statute that regulated credit card surcharges.²⁰⁷ Throughout the litigation, New York courts and the government had been inconsistent about how exactly the statute should be

¹⁹⁶ *Sorrell*, 564 U.S. at 565–66 (“[T]he distinction between laws burdening and laws banning speech is but a matter of degree.”) (citing *United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 812 (2000)).

¹⁹⁷ *Id.* at 566.

¹⁹⁸ *Id.* at 571. For more on the issue, compare *SUNY v. Fox*, 492 U.S. 469, 474 (1989) (pure speech and commercial speech not intertwined) with *Riley v. National Fed’n of the Blind of North Carolina*, 487 U.S. 781, 796 (1988) (pure speech and commercial speech intertwined).

¹⁹⁹ *Sorrell*, 564 U.S. at 572–73.

²⁰⁰ *Id.*

²⁰¹ *Id.* at 577.

²⁰² *Id.* at 585 (Breyer, J., dissenting); accord *Johanns v. Livestock Mktg. Ass’n*, 544 U.S. 550, 569 (2005) (Breyer, J., concurring).

²⁰³ *Sorrell*, 564 U.S. at 586, 590, 596 (Breyer, J., dissenting). See also section III.B., *infra*.

²⁰⁴ *Sorrell*, 564 U.S. at 589, 598 (Breyer, J., dissenting).

²⁰⁵ Shanor, *supra* note 73, at 135.

²⁰⁶ *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144 (2017).

²⁰⁷ *Id.* at 1147.

interpreted, but it imposed one of: (1) banning the charging of higher prices to credit card customers; (2) a disclosure requirement for the price difference between cash and credit card customers; or (3) forbidding framing the price difference as a surcharge.²⁰⁸

Justice Roberts held that while price regulations usually control conduct (with only incidental effects on speech due to the need to communicate the new price), and thus do not implicate the First Amendment, this regulation was not a typical price regulation.²⁰⁹ Instead, it regulated “how sellers may communicate their prices.”²¹⁰ He then remanded to the Court of Appeals to decide whether the law could be upheld as “a valid commercial speech regulation under *Central Hudson*” or “a valid disclosure requirement under *Zauderer*.”²¹¹

And so there we are at present. Commercial speech still gets the *Central Hudson* four-part scrutiny, and the test seems here to stay—in name, at least. But to borrow a famous axiom, the modern *Central Hudson* test seems “intermediate in theory, but strict in fact.”²¹² Richard Fallon gives the traditional elements of strict scrutiny as consisting of a compelling interest requirement plus a narrow tailoring element, the latter of which consists of inquiries into whether it is necessary to infringe upon the right and whether the chosen means of regulation is underinclusive or overinclusive.²¹³ Another frequent principle of strict scrutiny is a lack of deference to the legislature, for one of strict scrutiny’s purposes is to uncover potentially illicit governmental motives.²¹⁴

The only one of these requirements that is not applied under *Central Hudson* is the compelling interest requirement. But the difference between a “compelling” interest or merely a “substantial” interest is easily overdrawn. At base, the only differing factor is whether the interest has received a stamp of approval in a Supreme Court decision,

²⁰⁸ *Id.* at 1153 (Breyer, J., concurring). Because of the ambiguity, while concurring with the judgment, Justices Sotomayor and Alito would have remanded to the New York courts for a definitive interpretation without deciding more. *Id.* at 1153 (Sotomayor, J., concurring). Justice Breyer would have provided further guidance: if the statute imposed interpretation (1), it would receive rational basis review as commercial legislation. If interpretation (2) controlled, it would receive a form of rational basis review as a disclosure requirement. If interpretation (3) was correct, presumably *Central Hudson* would have applied. *Id.* at 1152–53 (Breyer, J., concurring). Justice Robert’s majority made it clear that the regulation did not implement interpretation (1), since it regulated speech, but instead implemented either (2) or (3), as reflected in the two options the majority gave the Court of Appeals. *Id.* at 1150, 1152.

²⁰⁹ *Id.* at 1150–51.

²¹⁰ *Id.* at 1151.

²¹¹ *Id.* at 1151. For more on disclosure requirements, see section II.C.3., *infra*.

²¹² The original axiom is that strict scrutiny is (or is not) “strict in theory, but fatal in fact.” *E.g.*, *Grutter v. Bollinger*, 539 U.S. 306, 326 (2003) (quoting *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 237 (1995)). Others have also noted that *Central Hudson* scrutiny has been raised over the last two decades. Samantha Rauer, *When the First Amendment and Public Health Collide: The Court’s Increasingly Strict Constitutional Scrutiny of Health Regulations that Restrict Commercial Speech*, 38 AM. J.L. & MED. 690, 702 (2012); Oleg Shik, *The Central Hudson Zombie: For Better or Worse, Intermediate Tier Review Survives Sorrell v. IMS Health*, 25 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 561, 585 (2015).

²¹³ Richard Fallon, *Strict Judicial Scrutiny*, 54 U.C.L.A. LAW REV. 1267, 1321–32 (2007). He also states that strict scrutiny involves an implicit proportionality inquiry. Such an implicit inquiry would apply regardless of whether the scrutiny received by commercial speech restrictions is termed strict or intermediate because either version requires at least some tailoring at thus at least some proportionality. *Central Hudson*, 447 U.S. 557, 566 (1980).

²¹⁴ *E.g.*, *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 501 (1989) (citing *Korematsu v. United States*, 323 U.S. 214, 235–40); *R.A.V.*, 505 U.S. at 386.

and the Court “has frequently adopted an astonishingly casual approach to identifying compelling interests.”²¹⁵ Additionally, an increase in the modern trend of “even in the alternative” decisions has further blended the line between interests that would be considered compelling, substantial, or legitimate.²¹⁶

Narrow tailoring is applied under *Central Hudson*. The inquiry into whether it is necessary to infringe upon the right is shown through a “least restrictive alternative” requirement; the Court has stated that restrictions on commercial speech must be of last resort.²¹⁷ A regulatory scheme is underinclusive if it is inconsistent, and such a scheme fails *Central Hudson*.²¹⁸ A regulation is overinclusive if it is overbroad (or if the least restrictive alternative requirement is not met; this requirement is redundant). This applies under *Central Hudson*.²¹⁹ And legislatures have not received deference from the Court while applying *Central Hudson* since the 1990s.²²⁰

Thus, the only true difference between traditional strict scrutiny and today’s *Central Hudson* intermediate scrutiny is that false or misleading commercial speech is not protected. But this principle was always an awkward fit; despite being called “prong 1,” it was never a full-fledged chapter of *Central Hudson* so much as it was a prologue. For false or misleading commercial speech, there is no *Central Hudson* inquiry. Like many other categories of speech exempted from the First Amendment, there is simply no First Amendment protection at all. As an example, take obscenity and sexually explicit speech. Obscenity is a category of speech unprotected by the First Amendment, yet it is a subcategory of sexually explicit speech, restrictions on which presumptively draw strict scrutiny.²²¹ Similarly, false or misleading commercial speech is a category of speech unprotected by the First Amendment, yet it is a subcategory of commercial speech, restrictions on which presumptively draw *de facto* strict scrutiny.²²² Therefore *Central Hudson* as applied today is indistinguishable from an alternate regime that exempts the category of false or misleading commercial speech from the First Amendment but subjects commercial speech more generally to strict scrutiny.

II.B.4. The Lawyer Advertising Cases

In 1977, the year after *Virginia Board*, the Court considered what seemed like just another commercial speech case, this one concerning a lawyer’s advertising of prices for routine legal services.²²³ But this decision—*Bates*—inspired so many other challenges over the years that a whole separate line of caselaw developed concerning lawyer advertising. Because these cases generally tracked the *Virginia Board* line of cases—and because where they do not, the Court most times was likely motivated by

²¹⁵ Fallon, *supra* note 213, at 1321.

²¹⁶ *E.g.*, *Sorrell*, 564 U.S. at 571; *Becerra*, 138 S.Ct. at 2377.

²¹⁷ Fallon, *supra* note 213, at 1326; *see supra* note 24.

²¹⁸ *See supra* note 22.

²¹⁹ *See supra* notes 24, 25,

²²⁰ *See supra* note 26.

²²¹ *E.g.*, *Sable Communs. of Cal. v. F.C.C.*, 492 U.S. 115, 125–26 (1989).

²²² This is essentially the position of Justice Stevens in *Rubin v. Coors*, though he would have given a lower standard of review to false or misleading commercial speech rather than no First Amendment protection. *Rubin*, 514 U.S. at 491–92 (Stevens, J., concurring).

²²³ *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).

how the topic of the regulation of the legal profession is so close to home²²⁴—they will be presented in less detail.

Bates v. State Bar of Arizona was authored by Justice Blackmun (also the author of *Bigelow* and *Virginia Board*) and concerned a small law office’s advertisement of its legal fees for certain services, in violation of a state bar disciplinary rule.²²⁵ The majority held that such advertising was protected.²²⁶ The opinion stated that although “the bar retains the power to correct omissions that have the effect of presenting an inaccurate picture, the preferred remedy is more disclosure, rather than less. If the naiveté of the public will cause advertising by attorneys to be misleading, then it is the bar’s role to assure that the populace is sufficiently informed as to enable it to place advertising in its proper perspective.”²²⁷

The following year, the Court held that a state bar *could* constitutionally discipline a lawyer for violating anti-solicitation rules, so long as those rules were designed to prophylactically guard against solicitation in situations that may involve “fraud, undue influence, intimidation, overreaching, or other forms of vexatious conduct.”²²⁸ *Ohralik*’s conclusion was next-to-inevitable given the facts of the case, which involved a plaintiff injury lawyer who solicited agreements from two 18-year-old women who were in an auto accident.²²⁹ For one, the lawyer solicited the agreement while she was still in the hospital; for the other, the lawyer solicited oral agreement (in a conversation which he secretly taped).²³⁰ When the women received a run-of-the-mill recovery from their driver’s insurance, they had to pay one-third to settle with the lawyer, who had brought a breach of contract claim against them.²³¹ Justice Powell found that the state had a “special responsibility” to maintain the professional standards of the legal profession and an “interest in protecting the lay public.”²³²

Zauderer in 1985²³³ concerned two newspaper ads run by an attorney in Ohio.²³⁴ The first stated the attorney would represent defendants in drunk driving cases, and their “full legal fee [would be] refunded if [they were] convicted of DRUNK DRIVING.”²³⁵ The second ad was designed to advertise his ability to represent women

²²⁴ For another example of this phenomenon, compare *United States v. Grace*, 461 U.S. 171 (1983) (finding that sidewalks outside the Supreme Court building are traditional public forums) with *United States v. Kokinda*, 497 U.S. 720 (1990) (finding that sidewalks outside a postal office are not traditional public forums) (plurality). The Court has noted that “professional speech” (including professional speech by lawyers) is not a separate category of speech. However, it has not entirely foreclosed such a possibility. *Becerra*, 138 S.Ct. at 2375.

²²⁵ *Bates*, 433 U.S. at 354.

²²⁶ *Id.* at 384.

²²⁷ *Id.* at 375.

²²⁸ *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 462 (1978).

²²⁹ *Id.* at 450–52.

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.* at 460, 468.

²³³ The court also considered constitutional challenges to lawyer advertising and solicitation restraints in between *Ohralik* and *Zauderer* in *In re Primus*, 436 U.S. 412 (1978) and *In re R.M.J.*, 455 U.S. 191 (1982).

²³⁴ *Zauderer*, 471 U.S. 626.

²³⁵ *Id.* at 629–30.

who had been injured as a result of use of the Dalkon Shield Intrauterine Device, and stated that such cases would be handled on a contingent-fee basis and “[i]f there is no recovery, no legal fees are owed by our clients.”²³⁶ The lawyer was reprimanded for two aspects of the ads: (1) failing to distinguish between legal “costs” (which would not be refunded) and legal “fees” (which, as advertised, would be); and (2) use of an illustration and inclusion of certain information in the Dalkon Shield ad.²³⁷ Justice White held that as to the first, the attorney could be reprimanded, because omitting the information would make the ad misleading.²³⁸ But as to the second—the Dalkon Shield advertisement—the attorney could not be constitutionally punished, because the illustration and information were accurate representations.²³⁹

In 1988, the Court considered the constitutionality of Kentucky’s flat ban on targeted direct-mail solicitation by lawyers and struck the rule in *Shapero*.²⁴⁰ Justice Brennan rejected Kentucky’s interest in preventing victims from becoming overwhelmed, restricting *Ohralik*’s authorization for prophylactic rules to only situations that involve the “unique features of in-person solicitation by lawyers.”²⁴¹ Face-to-face solicitation involves “the coercive force of the personal presence of a trained advocate,” but targeted mail advertisements can simply be thrown away.²⁴²

Edenfield v. Fane in 1993 clarified that *Ohralik* would not be extended to other professions.²⁴³ Scott Fane, a licensed CPA in Florida, challenged Florida’s ban on direct, personal solicitation by CPAs.²⁴⁴ Justice Kennedy held that the ban was not justified under *Central Hudson*, even when informed by *Ohralik*.²⁴⁵ *Ohralik*’s authorization for prophylactic rules “was justified only in situations inherently conducive to overreaching and other forms of misconduct.”²⁴⁶ Two critical differences separated *Edenfield* from *Ohralik*: first, lawyers are “trained in the art of persuasion,” while CPAs are not; second, a lawyer’s client may usually be injured or under time pressure, while a CPA’s client is usually a sophisticated business executive.²⁴⁷

Ohralik had been decided on its facts, and seemed now limited to its facts. But in 1995, in a surprising about-face, the Court upheld a 30-day ban on targeted direct-mail solicitation in *Florida Bar v. Went For It, Inc.*²⁴⁸ Justice O’Connor used *Central Hudson* to hold that such a ban was “reasonably well tailored” to the state’s substantial interest in protecting the privacy and tranquility of personal injury victims and

²³⁶*Id.* at 631.

²³⁷*Id.* at 631–36.

²³⁸*Id.* at 650–52. *See also* section II.C.3, *infra*.

²³⁹*Id.* at 646–47, 649.

²⁴⁰*Shapero v. Kentucky Bar Ass’n*, 486 U.S. 466 (1988).

²⁴¹*Id.* at 472 (quoting *Zauderer*, 417 U.S. at 641–42).

²⁴²*Id.* at 475. *Cf.* *Cohen v. California*, 403 U.S. 15, 21 (1971) (stating that a person seeing an offensive message may simply “avert[] their eyes.”); *Bolger*, 463 U.S. at 72 (stating that recipients of offensive mail can make the “short, though regular, journey from mail box to trash can”).

²⁴³*Edenfield v. Fane*, 507 U.S. 761 (1993).

²⁴⁴*Id.* at 763.

²⁴⁵*Id.* at 767.

²⁴⁶*Id.* at 774 (quoting *Ohralik*, 436 U.S. at 646).

²⁴⁷*Id.* at 775.

²⁴⁸*Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995).

preventing erosion of confidence in the legal profession.²⁴⁹ She distinguished *Shapero* (which had invalidated a flat ban on direct-mail solicitation) with the privacy rationale: here, the targeted mailings involved “willful or knowing . . . invasion of the tranquility of bereaved or injured individuals.”²⁵⁰ That the regulation at issue was time-limited to 30 days, rather than a flat ban, was not relied upon (other than to boost the argument for narrow tailoring) but no doubt did no harm to Florida’s defense.²⁵¹

II.C. Compelled Speech

This section will cover Supreme Court jurisprudence with respect to compelled speech. The journey requires examining first, cases on compelled ideology and compelled access to a private forum; second, cases on compelled subsidies, including compelled commercial subsidies; and third, a short detour into the realm of government speech before finally reaching discussion of compelled commercial disclosure. These last two categories especially will likely prove of immense importance in designing future FDA regulatory approaches.

II.C.1. Compelled Ideological Speech and Compelled Access

The First Amendment protects the right to speak freely; this implies a corollary right to refrain from speaking.²⁵² This right was first laid out in *West Virginia State Board of Education v. Barnette*.²⁵³ But *Barnette*’s story begins three years earlier with the 1940 case of *Minersville School District v. Gobitis*.²⁵⁴ Lillian and William Gobitis, aged 12 and 10 respectively, were expelled from their local school district because they refused to salute the national flag due to their beliefs as Jehovah’s Witnesses.²⁵⁵ Justice Frankfurter held that the children were not granted any exemption from the law by the Free Exercise clause of the First Amendment.²⁵⁶ “[T]he enjoyment of all freedom,” he held, “presuppose[s] the kind of ordered society which is summarized by our flag,” and it was not the Court’s position to question the judgment of the government in its process of educating children.²⁵⁷ Justice Stone in dissent would have

²⁴⁹*Id.* at 624–25, 633.

²⁵⁰*Id.* at 630.

²⁵¹*Id.* at 633. In general, total bans on a particular medium of communication, even if content-neutral, are treated more suspiciously for purposes of First Amendment analysis. *See, e.g.*, *Martin v. City of Struthers, Ohio*, 319 U.S. 141 (1943); *Kovacs v. Cooper*, 336 U.S. 77 (1949) (Reed, J. plurality); *Watchtower Bible & Tract Soc’y of N.Y., Inc. v. Village of Stratton*, 536 U.S. 150 (2002).

²⁵²*See, e.g.*, *Barnette*, 319 U.S. at 624. In 2018, Justice Thomas appeared to fold analysis of compelled speech into general speech restriction analysis, describing a notice requirement as simple “content-based regulation of speech” because “[b]y compelling individuals to speak a particular message, such notices alter the content of [the speaker’s] speech.” *Institute Nat’l Inst. of Fam. and Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018). However, as a general rule both content-based speech restrictions and compulsion of ideological speech receive strict scrutiny or an equivalent, so whether this analysis takes hold is of little practical importance. *Cf. id.* at 2373 (describing exceptions to this general rule). For more discussion of any differences, *see infra* note 285.

²⁵³*Barnette*, 319 U.S. at 624.

²⁵⁴*Minersville School District v. Gobitis*, 310 U.S. 586 (1940).

²⁵⁵*Id.* at 591–92.

²⁵⁶*Id.* at 600.

²⁵⁷*Id.* at 598, 600. *See also* *Reynolds v. United States*, 98 U.S. 145, 166–67 (1878) (“Can a man excuse his practices [contrary to the law] because of his religious belief? To permit this would be to make the professed doctrines of religious belief superior to the law of the land, and in effect to permit every citizen

tried to find a “reasonable accommodation” between the “competing demands of the interest of government and of liberty.”²⁵⁸

Three years later, in 1943, the Court reconsidered the question, this time with two significant differences. First, the country was now in the midst of World War II. And second, the challenge was no longer based on Free Exercise, but now on Free Speech. After *Minersville v. Gobitis*, the West Virginia legislature required schools to conduct courses in history, civics, and the Constitution.²⁵⁹ The Board of Education, in turn, required a flag salute as “a regular part” of the school day, with failure to comply resulting in expulsion.²⁶⁰ The Board of Education did modify the required salute upon complaints that it was “too much like Hitler’s,” but did not exempt Jehovah’s Witnesses from the salute.²⁶¹

Justice Jackson, no doubt influenced by the international struggle against Nazism and other forms of Fascism, held that this was not education.²⁶² Instead, it was “a compulsion of students to declare a belief” and conform to an “attitude of mind.”²⁶³ The flag salute, he declared, was “a form of utterance” within the scope of the Free Speech Clause.²⁶⁴ As such, “the action of the local authorities in compelling the flag salute and pledge transcends constitutional limitations on their power and invades the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control.”²⁶⁵

Justice Frankfurter, in (lengthy) dissent, argued for judicial restraint. He was personally sympathetic because he was Jewish, he stated, but as a judge he was “not justified in writing [his] private notions of policy into the Constitution.”²⁶⁶ The tool of judicial review is a blunt one, and undemocratic, calling for “greatest caution in its use.”²⁶⁷ To strike the statute is to strike the use of symbols by the government, and “[s]ymbolism is inescapable.”²⁶⁸ Use of this symbol, he argued, was harmless, for the

to become a law unto himself.”). This “self-defense” reasoning is also present in the free speech context in the form of the incitement exception to free speech, *see, e.g.*, *Brandenburg v. Ohio*, 395 U.S. 444 (1969), and has been acknowledged in the freedom to petition context as well, *see United States v. Harris*, 347 U.S. 612 (1954). It is also implicitly present in the fact that the Court almost always upholds taxation (*i.e.*, compelled support of government). *See, e.g.*, *United States v. Lee*, 455 U.S. 252 (1982).

²⁵⁸*Minersville*, 310 U.S. at 603 (Stone, J., dissenting).

²⁵⁹*Barnette*, 319 U.S. at 625.

²⁶⁰*Id.* at 626-28.

²⁶¹*Id.* at 627-28.

²⁶²*Id.* at 631. Justice Jackson would later go on to become Chief U.S. Prosecutor in the Nuremberg Trials. John Barrett, *The Nuremberg Roles of Justice Robert H. Jackson*, 6 WASH. U. GLOBAL STUD. L. REV. 511 (2007).

²⁶³*Barnette*, 319 U.S. at 631-33.

²⁶⁴*Id.* at 633.

²⁶⁵*Id.* at 642.

²⁶⁶*Id.* at 646-47 (Frankfurter, J., dissenting).

²⁶⁷*Id.* at 650-51 (Frankfurter, J., dissenting).

²⁶⁸*Id.* at 662-63 (Frankfurter, J., dissenting). This foreshadows the later reasoning in the flag desecration cases, which held that a flag’s role as a symbol for an idea meant the expressive act of rejecting that idea was protected. *See United States v. Eichman*, 496 U.S. 310 (1990).

children and parents were free to publicly disavow the meaning attached to the symbol by others and privately avow and practice whatever belief they chose.²⁶⁹

Thus, both sides would have agreed with the proposition that the First Amendment protects against government compulsion of belief or ideology. But to Justice Jackson, the compelled salute *was* compelled belief and thus an offense to autonomy, while to Justice Frankfurter the salute was merely compelled action,²⁷⁰ since the students remained free to privately believe anything they wished.²⁷¹

Three decades later, the grand protection against compelled ideology would be applied in a much more mundane context: license plates.²⁷² Again the plaintiffs were members of the Jehovah's Witnesses faith.²⁷³ This time it was George and Maxine Maynard, who had covered up New Hampshire's motto, "Live Free or Die," on their license plates due to its repugnance to their religious beliefs, in violation of a state statute.²⁷⁴ Chief Justice Burger in *Wooley v. Maynard* held this unconstitutional as a direct result of *Barnette*, finding that the state was attempting to coerce an individual to participate in the dissemination of an ideological message by requiring its display on private property.²⁷⁵ "The First Amendment protects the right of individuals to hold a point of view different from the majority and to refuse to foster . . . an idea they find morally objectionable."²⁷⁶

Justice Rehnquist in dissent, like Justice Frankfurter in *Barnette*, held the view that this was simply compelled action: here, carrying the license plate.²⁷⁷ New Hampshire could have compelled a tax, he argued, and used it to erect billboards proclaiming "Live Free or Die," and such a message would be "fostered" by citizens just like the license plate message.²⁷⁸ But such a tax would clearly be constitutional, even under *Barnette*, because *Barnette* only prohibited the State from compelling an individual to apparently or actually assert the message to be believed.²⁷⁹

An illuminating comparison with *Wooley v. Maynard* is the 2015 case of *Walker v. Sons of Confederate Veterans*.²⁸⁰ In *Walker*, the Sons of Confederate Veterans organization challenged the Texas Department of Motor Vehicle Board's denial of their petition to sponsor a specialty license plate featuring a Confederate battle flag.²⁸¹

²⁶⁹*Barnette*, 319 U.S. at 664 (Frankfurter, J., dissenting).

²⁷⁰*See id.* *See also* Reynolds v. United States, 98 U.S. 145, 166 (1878) ("Laws are made for the government of actions, and while they cannot interfere with mere religious belief and opinions, they may with practices."); Emp. Div., Dep't of Hum. Resources of Or. v. Smith, 494 U.S. 872 (1990).

²⁷¹*See also* Stanley v. Georgia, 394 U.S. 557 (protecting possession of obscene materials within the privacy of one's home); Rumsfeld v. Forum for Acad. & Institutional Rts, Inc., 547 U.S. 47 (2006) (holding that requiring schools to allow access to military recruiters did not regulate speech because the schools remained free to say whatever they liked).

²⁷²*Wooley v. Maynard*, 430 U.S. 705, 707 (1977).

²⁷³*Id.*

²⁷⁴*Id.* at 707–08.

²⁷⁵*Id.* at 713.

²⁷⁶*Id.* at 715.

²⁷⁷*Id.* at 720 (Rehnquist, J., dissenting).

²⁷⁸*Id.* at 721 (Rehnquist, J., dissenting).

²⁷⁹*Id.*

²⁸⁰*Walker v. Tex. Dep't of Motor Vehicles Bd.*, 135 S. Ct. 2239, 2252–53 (2015).

²⁸¹*Id.* at 2245.

Justice Breyer held that the license plates conveyed government speech, using a three-part analysis: (1) license plates had historically communicated messages from the State; (2) the public associated license plate designs with the State; and (3) the State maintained direct control over the messages on its license plates.²⁸² As such, it was constitutional for Texas to refuse to display a design with a Confederate flag.²⁸³

What distinctions can be found between *Wooley* and *Walker*? Three come to mind. First, in the time between the two cases, the now-liberalized Government Speech area of jurisprudence matured.²⁸⁴ Second, the plaintiff-side framing was different between the two cases. In *Wooley*, the First Amendment was presented as a shield, granting protections against compelled individual speech. In *Walker*, the First Amendment was presented as a sword, granting the right to compel government speech.²⁸⁵ And third, *Wooley* was simply poorly argued by the government. The two state interests advanced to justify the prohibition were (1) facilitating the identification of passenger vehicles; and (2) promoting appreciation of history, individualism, and state pride.²⁸⁶ The first was clearly unnecessary, as there are numerous, better alternative ways of identifying passenger vehicles.²⁸⁷ And the second was exactly what *Barnette* prohibited: requiring people to disseminate an ideology, here of “state pride.”²⁸⁸ Further, New Hampshire failed to see the irony in requiring all citizens to uniformly project an appreciation of individualism.

Another area close to compelled ideology bears discussion here. Halfway between the compelled ideology cases and the compelled subsidies cases lie cases that consider compelled access to a private forum.²⁸⁹ The most notable of these cases is *Miami Herald v. Tornillo*, although we will also briefly discuss *Pacific Gas & Electric* and *Turner Broadcasting I*.²⁹⁰

²⁸²*Id.* at 2248–50.

²⁸³*Id.* at 2253.

²⁸⁴See discussion *infra* Section II.C.2..

²⁸⁵Granted, the argument was framed by the plaintiff as a right against government restrictions on private speech, and only reframed on the Government Speech theory. The distinction between *Wooley* and *Walker* could thus also be viewed as support for the idea that compelled speech (*Wooley*) is a greater affront to the First Amendment than restraints on speech (*Walker*); this would follow from the idea that the First Amendment guarantees the freedom of thought and belief. See, e.g., *Palko v. Connecticut*, 302 U.S. 319, 326 (1937) (“Freedom of thought . . . is the matrix, the indispensable condition, of nearly every other form of freedom.”); *Barnette*, 319 U.S. at 637 (speaking of the “individual freedom of mind.”) (Murphy, J., concurring); see also *Janus*, 138 S. Ct. at 2464 (stating that compelling speech does “additional damage” beyond restricting speech because “[f]orcing free and independent individuals to endorse ideas they find objectionable is always demeaning”); *Becerra*, 138 S. Ct. at 2379 (“Freedom of speech secures freedom of thought and belief.”) (Kennedy, J., concurring).

²⁸⁶*Wooley v. Maynard*, 430 U.S. 705, 716 (1977).

²⁸⁷*Id.*

²⁸⁸*Id.* at 717.

²⁸⁹The compelled access here is to non-physical mediums of information dissemination (e.g., media). This is in contrast to compelled access to physical property, for which there is also no general federal right, and for which rights if granted by states would be governed by the Fifth Amendment, if extensive enough to amount to a taking, or the First Amendment, if extensive enough to limit the owner’s speech. See *Pruneyard Shopping Ctr. v. Robins*, 447 U.S. 74 (1980); *Hudgens v. NLRB*, 424 U.S. 507 (1976).

²⁹⁰*Miami Herald v. Tornillo*, 418 U.S. 241, 256–57 (1974); *Pacific Gas & Elec. Co. v. Pub. Util. Comm’n of Cal.*, 475 U.S. 1, 1, 21 (1986) (plurality); *Turner I*, 512 U.S. at 657.

During state elections in 1972, the Miami Herald printed several editorials critical of Pat Tornillo, who was running for state legislature.²⁹¹ “We cannot say it would be illegal,” said one, “but certainly it would be inexcusable of the voters if they sent Pat Tornillo to Tallahassee [as a representative].”²⁹² Tornillo sent responses to the newspaper and asked that they be printed free of charge as guaranteed by a state “right of reply” statute that provided for such a right should a newspaper assail a political candidate’s character or record.²⁹³ Justice Burger held the right of reply statute unconstitutional. The newspaper did not remain free to “say[] anything it wished,” he held, because the “statute exacts a penalty on the basis of the content of a newspaper . . . in terms of the cost of printing and composing time and materials and in taking up space that could be devoted to other material the newspaper may have preferred to print.”²⁹⁴ Even if there were no additional costs, the statute would still have been unconstitutional as an intrusion onto “the exercise of editorial control and judgment” by “[c]ompelling editors or publishers to publish that which reason tells them should not be published.”²⁹⁵

Pacific Gas & Electric involved a challenge to the California Public Utilities Commission’s decision to require a utility company to allow a citizens group to use the “extra space” (*i.e.*, the difference between postage weight and bill weight) in its utility bill envelopes to distribute a newsletter four times a year.²⁹⁶ The utility company had previously been using the space to distribute its own newsletter to customers.²⁹⁷ Although the compulsion was not content-based, as in *Tornillo*, Justice Powell held that *Tornillo* was apposite because the utility company would be effectively forced to choose between responding to the citizens group’s statements or appearing to endorse them.²⁹⁸ The order thus forced the utility company to “associate with the views of other speakers.”²⁹⁹

Turner Broadcasting I involved national “must carry” provisions which required cable television broadcasters to carry the signals of local broadcast television stations.³⁰⁰ Justice Kennedy held that the regulations were content-neutral and thus subject to *O’Brien* intermediate scrutiny.³⁰¹ He distinguished *Tornillo* and *Pacific Gas & Electric* on three grounds. First, the access rules were content-neutral in that they

²⁹¹*Tornillo*, 418 U.S. at 243.

²⁹²*Id.* at n.1.

²⁹³*Id.* at 244.

²⁹⁴*Id.* at 256.

²⁹⁵*Id.* at 258, 256. There is much debate on whether the press gets different First Amendment protection than the average individual or corporation. *See generally* Timothy B. Dyk, *Newsgathering, Press Access, and the First Amendment*, 44 STAN. L. REV. 927 (1992); Eugene Volokh, *Freedom for the Press as an Industry, or for the Press as a Technology? From the Framing to Today*, 160 U. PA. L. REV. 459 (2012). But this reasoning clearly applies outside of the press context as well; indeed, it was cited as support in *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). *See Pacific Gas*, 475 U.S. at 8–9 (plurality).

²⁹⁶*Pacific Gas*, 475 U.S. at 5–7 (plurality).

²⁹⁷*Id.* at 5.

²⁹⁸*Id.* at 16.

²⁹⁹*Id.* at 20.

³⁰⁰*Turner I*, 512 U.S. at 630–32.

³⁰¹*Id.* at 652.

were not triggered by disagreement with a message.³⁰² Second, the access rules did not (1) force cable operators to alter their own messages, (2) pose a danger of causing the cable operators to cease communication to avoid controversy, or (3) make it likely that viewers would associate the channel with the broadcasters.³⁰³ And third, the restriction was justified by a special characteristic of the medium itself: the cable operator's "bottleneck" monopoly on the television programming entering a subscriber's home.³⁰⁴ The rules would finally be fully upheld several years later in *Turner Broadcasting II*.³⁰⁵

II.C.2. Compelled Subsidies and Government Speech

This subsection will consider three categories of cases under the heading of "compelled subsidies." First, it will examine compelled subsidy of private organizations. Second, it will consider compelled commercial subsidies in the form of the food trio of cases. And this will bridge it to the third category, namely, the government speech theory.

The first category, compelled subsidy of private organizations, begins with *Abood v. Detroit Board of Education*.³⁰⁶ But *Abood* itself begins with *International Association of Machinists v. Street*.³⁰⁷ In *Street*, the Supreme Court considered a challenge to §2, Eleventh of the Railway Labor Act (RLA).³⁰⁸ This section authorized union-shop agreements, which required employees as a condition of employment to pay union fees equivalent to membership dues, even if not a member.³⁰⁹ Employees, claiming these fees were used for political purposes with which they disagreed, challenged the statute. Justice Brennan upheld the provision, but interpreted it using the canon of constitutional avoidance so as to bar the use of funds over an employee's objections to support political causes which the employee opposed.³¹⁰ Congress did not abandon freedom of choice, he held, but "made inroads on it for the limited purpose of eliminating . . . [the] free rider [problem]" (*i.e.*, "free riders" who obtain benefits from collective bargaining but do not want to pay in).³¹¹

Abood, 15 years later, considered a challenge to a Michigan statute which also authorized union-shop agreements, here between a state governmental unit and a union (in contrast to between a railroad and a union, as in the federal RLA).³¹² But unlike in the RLA, Michigan's statute explicitly allowed the funds to be used for "other than

³⁰²*Id.* at 655.

³⁰³*Id.*

³⁰⁴*Id.* at 656.

³⁰⁵*Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 181 (1997) [hereinafter *Turner II*].

³⁰⁶*Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 211 (1977).

³⁰⁷*Int'l Ass'n of Machinists v. Street*, 367 U.S. 740 (1961).

³⁰⁸*Id.* at 742, 745-46.

³⁰⁹*Id.* at 743-44.

³¹⁰*Id.* at 749-50.

³¹¹*Id.* at 767-69. Policy-wise, the free rider issue is essentially a collective action problem that springs from the principle that a union with exclusive representation must represent the interests of all employees, member or not. *See Steele v. Louisville & Nashville R. Co.*, 323 U.S. 192, 202-203 (1944).

³¹²*Abood*, 431 U.S. at 218-19, 223-24.

collective bargaining,” *e.g.*, political causes.³¹³ Justice Stewart held that although compelled union support did implicate First Amendment associational freedoms, the governmental interests in avoiding the free rider problem and in labor peace justified the statute.³¹⁴ But, in an attempt at compromise, the Court held partially for both sides. The service charges *could* be used “for the purposes of collective bargaining, contract administration, and grievance adjustment,” the Court found, but the charges could *not* constitutionally be used to finance expenditures on political expression when the contributing employee objected to advancing the expression.³¹⁵ (Voluntarily contributed dues could, of course, still be used for such).³¹⁶ The First Amendment “freedom to associate for the purpose of advancing beliefs and ideas” contains a corollary prohibition on forced association.³¹⁷

This collective bargaining versus political expression distinction from *Street* and *Abood* would be extended to the National Labor Relations Act (NLRA) in 1988 in *Communications Workers of America v. Beck*.³¹⁸ The NLRA wording paralleled the RLA wording; relevantly, it did not explicitly say whether union-shop dues were limited to only use for collective bargaining.³¹⁹ Justice Brennan held that the *Street* statutory analysis was controlling, and §8(a)(3) of the NLRA permitted union-shop agreements but the “membership that may be so required has been whittled down to its financial core.”³²⁰ Of note is the fact that the NLRA applies in the private sector, only *permitting* an employer and union (both private entities) to enter into a union-shop agreement. Thus, the union argued that unlike *Street* and *Abood*, there was no explicit governmental action and thus no reason to strain the meaning of the statute to avoid implicating the First Amendment.³²¹ Justice Brennan countered that reading the statute as *Street* had read the RLA was not straining, but an entirely reasonable interpretation.³²²

The first half of *Abood* is the holding that compelling funds to be used for political expression is unconstitutional. *Keller v. State Bar of California* in 1990 considered the State Bar of California’s use of dues to finance political and ideological activities.³²³ Justice Rehnquist held that *Abood* controlled: the dues could only be used for expenditures “necessarily or reasonably incurred for the purpose of regulating the legal profession or improving the quality of the legal service available to the people of the State.”³²⁴ Use of dues for “activities having political or ideological coloration,” on the other hand, was unconstitutional.³²⁵

³¹³*Id.* at 232.

³¹⁴*Id.* at 224–26.

³¹⁵*Id.* at 225, 235.

³¹⁶*Id.* at 235–36.

³¹⁷*Id.* at 222.

³¹⁸*Comme’ns Workers of Am. v. Beck*, 487 U.S. 735, 738 (1988).

³¹⁹*Id.* at 744–45.

³²⁰*Id.* at 745–46 (citing *NLRB v. Gen. Motors Corp.*, 373 U.S. 734, 742 (1963)).

³²¹*Id.* at 761–62.

³²²*Id.* at 762.

³²³*Keller v. State Bar of California*, 496 U.S. 1 (1990).

³²⁴*Id.* at 14 (citing *Lathrop v. Donohue*, 367 U.S. 820, 843 (1961)).

³²⁵*Id.* at 15.

An enterprising group of university students saw *Abood* and *Keller* and decided to challenge their state university's mandatory student activity fee in *Board of Regents of the University of Wisconsin v. Southworth*.³²⁶ The University disclaimed that the speech for which funding was being compelled was its own (governmental) speech, instead claiming it was only funding student extracurriculars that sprung "from the initiative of the students, who alone give it purpose and content."³²⁷ Justice Kennedy, following in the footsteps of *Abood*'s compromise, held that the University could spend the fees on programs (even ideological ones), but was required to do so in a viewpoint-neutral fashion.³²⁸ *Abood* applied, but *Abood* had said that a union could only use the dues for activities germane to the union's purpose, *i.e.*, collective bargaining.³²⁹ Likewise, *Keller* had limited the bar dues to activities germane to the organization's purpose, *i.e.*, regulating the legal profession.³³⁰ But here, it was "not for the Court to say what is or is not germane to the ideas to be pursued in an institution of higher learning."³³¹ The only workable limit was to prohibit the university from preferring some viewpoints to others.³³²

The other half of *Abood* is the holding that compelling funds to be used for collective bargaining *is* constitutional. This compromise from *Abood* held for just over four decades before being overturned by *Janus v. American Federation* in the Court's 2017 term.³³³ In *Janus*, Justice Alito held the Illinois Public Labor Relations Act to be unconstitutional because it forced objecting public employees to subsidize a union's collective bargaining and related activities, *i.e.*, it forced them "to subsidize private speech on matters of public concern."³³⁴ "Compelling a person to subsidize the speech of other private speakers raises similar First Amendment concerns" to compelling ideological speech, he held, though he declined to decide whether strict or "exacting" scrutiny properly applied because the statute failed even the slightly lower exacting scrutiny test.³³⁵ The interest in avoiding the free rider problem did not justify the statute because it was not a compelling interest, while the interest in labor peace did not justify the statute because significantly less restrictive means were available.³³⁶ In overturning

³²⁶ *Bd. of Regents of the U. of Wis. v. Southworth*, 529 U.S. 217 (2000).

³²⁷ *Id.* at 229.

³²⁸ *Id.* at 230.

³²⁹ *Id.* at 231–32.

³³⁰ *Id.*

³³¹ *Id.* at 232.

³³² *Id.* at 233.

³³³ *Janus v. American Federation*, 138 S. Ct. 2448 (2018). *Janus* did not come as a surprise. Justice Alito had been scowling at *Abood* for years, calling it a "historical accident" and a "remarkable boon for unions" in 2012 and declining to "expand" *Abood* to reach "quasi-public" employees in 2014. *Knox v. Service Employees International Union, Local 1000*, 567 U.S. 298, 312, 317 (2012); *Harris v. Quinn*, 134 S. Ct. 2618, 2623 (2014). The Court had also extended an invitation to request the overturning of *Abood* in 2016, but upon Justice Scalia's death had split 4-4 on the issue. *Friedrichs v. California Teachers Association*, 136 S. Ct. 1083 (2016) (Mem).

³³⁴ *Janus*, 138 S.Ct. at 2460.

³³⁵ *Id.* at 2464–65. Both tests require a compelling state interest, though exacting scrutiny seems to require just slightly less than perfect tailoring. *Id.* ("Under exacting scrutiny, . . . a compelled subsidy must serve a compelling state interest that cannot be achieved through means *significantly* less restrictive.") (quoting *Knox*, 567 U.S. at 310) (internal quotation marks removed) (emphasis added).

³³⁶ *Id.* at 2466.

Abood and holding it to be unconstitutional to compel funds to be used for collective bargaining, *Janus* raised but did not answer the questions of how this would affect *Beck* (*Abood* but in the private sector) or *Keller* and *Southworth* (*Abood* but for lawyers and students). Though there is no immediate reason to question their veracity, it would not be shocking if these issues were revisited in the future.³³⁷

Moving to compelled commercial subsidies, the food trio of cases—*Glickman v. Wileman*, *U.S. v. United Foods*, and *Johanns v. Livestock Marketing Association*³³⁸—are a fine example of how factual situations with less separation than two sheets of filo pastry can produce entirely opposite outcomes. Each considered a food producer’s challenge to subsidies compelled by the Secretary of Agriculture and used for advertising purposes. The trio also serve as an excellent transition between the compelled subsidy of a private entity’s speech cases and the compelled support of government (and government speech) cases.

Glickman v. Wileman, in 1997, concerned assessments on growers, handlers, and processors of California tree fruits, used to pay for generic tree fruit advertising under a marketing order promulgated by the Secretary of Agriculture.³³⁹ Justice Stevens upheld the program, saying that the lower court was wrong to rely on *Abood* and *Central Hudson* because the marketing orders did not (1) impose a restraint on the producer’s freedom to communicate any message; (2) compel a producer to engage in any speech; nor (3) compel a producer to endorse or finance any political or ideological views.³⁴⁰ The generic advertising of fruits was not ideological speech, and was besides “unquestionably germane” to the purposes of the program.³⁴¹ He went on to hold that the program was simply “economic regulation” and thus “should enjoy the same strong presumption of validity that we accord to other policy judgments made by Congress.”³⁴²

United Foods, four years later in 2001, presented similar facts but the opposite outcome.³⁴³ The Secretary of Agriculture, pursuant to the grandly-named Mushroom Promotion, Research, and Consumer Information Act, imposed assessments on mushroom handlers to fund generic advertising to promote mushroom sales.³⁴⁴ Specifically, the promotion advertised mushroom recipes and brochures, including one entitled “LET YOUR LOVE BLOSSOM” which conveyed the message that mushrooms could be the centerpiece of a romantic meal, with recipes such as “Ginger-Mushroom

³³⁷With respect to private sector unions and the NLRA, Justice Alito stated that the idea that “allowing, but not requiring, private parties to enter into union-shop arrangements was sufficient to establish governmental action [and thus implicate the First Amendment] . . . was debatable when *Abood* was decided, and is even more questionable today.” *Id.* at 2479 n.24. (This is why *Beck* turned on statutory rather than constitutional interpretation.) However, he explicitly declined to resolve the question. *Id.* With respect to *Keller* and *Southworth*—the cases more likely to be questioned immediately post-*Janus*—the only mentions of these decisions were in Justice Kagan’s dissent. *Id.* at 2495 n.3, 2498 (Kagan, J., dissenting). Justice Kagan seemed to think *Janus* may be extended, warning that “the majority’s road runs long.” *Id.* at 2502.

³³⁸*Glickman v. Wileman Bros. & Elliot*, 521 U.S. 457 (1997); *United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Johanns v. Livestock Marketing Ass’n*, 544 U.S. 550 (2005).

³³⁹*Glickman*, 521 U.S. at 463–66.

³⁴⁰*Id.* at 469–70.

³⁴¹*Id.* at 473.

³⁴²*Id.* at 477.

³⁴³*United Foods*, 533 U.S. 405.

³⁴⁴*Id.* at 408.

Stir-Fry” and tips including “Candlelight is a must” and “The ancient philosopher Petronius and many others proclaimed mushrooms as a potent aphrodisiac and popular ‘love food.’”³⁴⁵ Justice Kennedy held that the program could not be upheld under *Glickman* or “other precedents” (*i.e.*, *Central Hudson* or *Abood*), because the government was barred from “underwrit[ing] and sponsor[ing] speech with a certain viewpoint using special subsidies exacted from a designated class of persons, some of whom object.”³⁴⁶ Unlike *Glickman*, the assessments were not “ancillary to a more comprehensive program restricting marketing autonomy.”³⁴⁷ Instead, the mushroom advertising was “the principal object of the regulatory scheme.”³⁴⁸ The Government was compelling support of the idea that all mushrooms were worth consuming, while United Foods wished to convey the message that only its brand of mushrooms were worth consuming.³⁴⁹ Justice Stevens in concurrence offered a perhaps clearer distinction between the programs in *Glickman* and *United Foods*. *Abood* had stated that a compelled subsidy was constitutional if germane to a program; here, the subsidy was not *germane* to the program, but the program itself.³⁵⁰

Another four years passed, and another challenge to the Secretary of Agriculture’s food advertising assessments arose. Under authority from the Beef Act, the Secretary imposed an assessment on beef, to be forwarded to the Beef Board, who would then spend it on generic beef promotional campaigns, perhaps the most successful of which was “Beef. It’s What’s for Dinner.”³⁵¹ This was an entirely different situation than that in *Glickman* or *United Foods*, explained Justice Scalia, because this was a permissible “government-compelled subsidy of the government’s own speech.”³⁵² In previous cases, the speech was (or was presumed to be) “that of an entity other than the government itself.”³⁵³ No matter if the funding is exacted via general taxes or a targeted assessment: citizens “have no First Amendment right not to fund government speech.”³⁵⁴ Justice Thomas in concurrence granted that although he would subject all compelled funding of advertisement to strict scrutiny, he “recognize[d] that this principle must be qualified where the regulation compels the funding of speech that is the government’s own.”³⁵⁵ Still, though, he explained that he would grant an as-applied challenge if the advertisements associated their message with the disagreeing organization.³⁵⁶

Justice Breyer in concurrence remained “of the view that the assessments in these cases are best described as a form of economic regulation.”³⁵⁷ However, he “accept[ed]

³⁴⁵*Id.* at appendix (Breyer, J., dissenting).

³⁴⁶*Id.* at 410.

³⁴⁷*Id.* at 411.

³⁴⁸*Id.* at 411–12.

³⁴⁹*Id.* at 411.

³⁵⁰*Id.* at 418 (Stevens, J., concurring).

³⁵¹*Johanns v. Livestock Marketing Ass’n*, 544 U.S. 550, 553–54 (2005)

³⁵²*Id.* at 557.

³⁵³*Id.* at 559.

³⁵⁴*Id.* at 562.

³⁵⁵*Id.* at 567 (Thomas, J., concurring).

³⁵⁶*Id.* at 568 (Thomas, J., concurring).

³⁵⁷*Id.* at 569 (Breyer, J., concurring).

the government speech theory] as a solution to the problem presented by these cases” given that such a theory could carry a majority.³⁵⁸

Justice Souter in dissent also accepted the government speech theory as a general proposition but took the chance to explain his view of it and why it should not have justified the regulation in *Johanns*. The government speech theory was needed, because “[t]o govern, government has to say something, and a First Amendment heckler’s veto of any forced contribution to raising the government’s voice in the ‘marketplace of ideas’ would be out of the question.”³⁵⁹ But the doctrine only applies when the political process can be relied upon to serve as at least a partial check.³⁶⁰ Thus, three factors weighed against the doctrine being applied here: first, the speech was not clearly associated with the government; second, that the Beef Board was not a fully democratically-accountable government entity, and third, that the speech was funded by targeted rather than general taxes.³⁶¹ Justice Scalia’s majority responded to these concerns, holding that the first would be better settled with a facial challenge and the second and third were not necessary prerequisites to the government speech doctrine.³⁶²

The government speech doctrine, a relatively new theory, seems in general to function as a sort of get-out-of-jail-free card when the government is backed into a First Amendment corner. At the outset, it is important to distinguish between two related uses of the phrase: first, “pure” government speech doctrine, which delineates between permissible and impermissible ways in which the government can expressively spend its own money, and second, what this article will term “forum” government speech theory, which finds that expression, if it is the government’s own, is analogous to speech in a nonpublic forum³⁶³ in that it is subject to lesser or no First Amendment scrutiny.

The “pure” government speech theory states that the government can specify conditions that define the limits of its spending programs and can specify the activities that it wishes to subsidize. But it cannot impose conditions that seek to leverage the funding to regulate speech outside the contours of the program itself, for this would be coercing private speech.³⁶⁴ However—and this is key to the “forum” government speech theory as well—government speech with its own money can be viewpoint-specific (traditionally a paradigmatic First Amendment violation).³⁶⁵ In that sense, there are no Court-imposed limits on what the government can express on its own behalf so long as it is simply saying (or funding) the speech. Aside from traditional

³⁵⁸*Id.*

³⁵⁹*Id.* at 574 (Souter, J., dissenting) (citing *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting)).

³⁶⁰*Id.* at 575 (Souter, J., dissenting).

³⁶¹*Id.* at 575–77 (Souter, J., dissenting).

³⁶²*Id.* at 563–565.

³⁶³A nonpublic forum is public property (*i.e.*, the government’s property, as compared to the government’s speech) which has not traditionally been a public forum and for which the government does not intend to turn into a public forum. On such property, content- or speaker-based restrictions are allowed so long as they are reasonable and viewpoint-neutral. *See Cornelius v. NAACP Legal Defense and Educational Fund, Inc.*, 473 U.S. 788 (1985).

³⁶⁴*Agency for Int’l Dev. v. Alliance for Open Soc’y Int’l, Inc.*, 570 U.S. 205 (2013).

³⁶⁵*E.g.*, *Rust v. Sullivan*, 500 U.S. 173 (1991).

constitutional interpretation, this clearly serves immense practical importance—”[t]o govern, the government has to say something.”³⁶⁶

“Forum” government speech theory involves speech on the margins which can be classified as either government speech (in which case the government can say or not say whatever it likes), or private speech (in which case the government cannot compel or restrict the speech unless the compulsion or restriction passes First Amendment analysis). Entities are entitled to use the First Amendment as a shield against government intrusion, but they are not entitled to use the First Amendment as a sword to dictate the conduct of the government.³⁶⁷ As Justice Rehnquist explained in *Keller*, “[i]f every citizen were to have a right to insist that no one paid by public funds express a view with which he disagreed, debate over issues of great concern to the public would be limited to those in the private sector, and the process of government as we know it radically transformed.”³⁶⁸

Thus the usual pattern is the expansion of a First Amendment right, up to a tipping point, at which the government speech theory pushes back. This pattern appears when comparing *Wooley v. Maynard* with *Walker v. Sons of Confederate Veterans*: the government cannot compel an individual to express an ideology in its license plate, but an individual cannot compel the government to do the same. It is also shown by comparing *United Foods* with *Johanns*: the government cannot compel a dissenter to subsidize advertisement, but the dissenter cannot refuse to support the government, and the government can use that support to fund its own advertisements. Another illuminating comparison is between *Capitol Square v. Pinette* and *Pleasant Grove v. Summum*.³⁶⁹ Justice Scalia in *Pinette* invalidated the city of Columbus’ refusal to allow the KKK to erect a large cross in a state-owned plaza, holding the monument to be protected private speech.³⁷⁰ A decade later, *Pleasant Grove* upheld Utah’s denial of a group’s request to erect a religious monument containing the “Seven Aphorisms of Summum” in a park where the city had allowed other groups to erect monuments, but restricted the monument selection to those related to city history.³⁷¹ The monuments, Justice Alito found, were government speech and as such not regulated by the First Amendment.³⁷² (The alternative explanation would be that the Court is more sympathetic towards the KKK and its Christian symbolism than towards minority religions such as Summum.)³⁷³ Though not explicitly government speech, a pattern

³⁶⁶*Johanns*, 544 U.S. 550, 574 (2005) (Souter, J., dissenting).

³⁶⁷Cf. *Regan v. Taxation with Representation of Washington*, 461 U.S. 540 (1983) (holding that the government has no obligation to provide a tax deduction for lobbying, because to hold otherwise would force the government to subsidize the organization’s speech); *Bowen v. Roy*, 476 U.S. 693, 700 (1986) (“The Free Exercise Clause . . . does not afford an individual a right to dictate the conduct of the Government’s internal procedures.”) (Stevens, J., concurring).

³⁶⁸*Keller v. State Bar of California*, 496 U.S. 1, 12–13 (1990).

³⁶⁹*Capitol Square Review and Advisory Bd. v. Pinette*, 515 U.S. 753 (1995); *Pleasant Grove City, Utah v. Summum*, 555 U.S. 460 (2009).

³⁷⁰*Pinette*, 515 U.S. at 769.

³⁷¹*Pleasant Grove*, 555 U.S. at 465.

³⁷²*Id.* at 464.

³⁷³Cf. *McCreary County v. ACLU of Kentucky*, 545 U.S. 844, 893–4 (2005) (faulting the majority for condoning “the demonstrably false principle that the government cannot favor religion over irreligion” and arguing that due to historical practice and the fact that such religions are in the majority, a religion can be publicly acknowledged so long as it is a monotheistic religion) (Scalia, J., dissenting); *Van Orden v. Perry*, 545 U.S. 677, 692 (2005) (“[T]here is nothing unconstitutional in a State’s favoring religion

motivated by the same concerns also occurs in the Free Exercise area: compare *Wisconsin v. Yoder*, which held that a member of the Old Order Amish was entitled to a religious exemption from the requirement that he send his daughter to high school, with *U.S. v. Lee*, which denied an exemption to an Old Order Amish who objected to paying Social Security taxes.³⁷⁴ To allow an exemption in *Lee* would have required exemptions for any dissenting denomination and thus destroyed the viability of the entire tax system.³⁷⁵

So when is speech government speech? One aspect of the government speech theory is the reasoning that democratic checks at least partially replace the need for judicial review.³⁷⁶ A second aspect is the need to limit the government from reframing any speech as its own, *i.e.*, to stop the theory from proving too much.³⁷⁷ The most recent two cases, *Pleasant Grove* and *Walker*, consider three factors: (1) the State must have historically communicated the message; (2) the public must associate the message with the State; and (3) the State must maintain direct control over the messages.³⁷⁸ The second factor, that the public associate the message with the State, ensures that the democratic process will at least partially serve as a check on the speech. The first and third factors serve as limiting principles; the first serves as a check against “recharacterization,” while the third serves to distinguish government speech cases from governmentally-coerced subsidization of private speech cases (*e.g.*, *Janus*). That being said, a word of caution: as Justice Souter stated in his *Johanns* dissent, “[t]he government-speech doctrine is relatively new, and correspondingly imprecise.”³⁷⁹ As such, the factors and principles have by no means solidified into an official “test” as of yet.

II.C.3. Compelled Commercial Disclosure

The last category to consider is that of compelled commercial disclosure. The notion of disclosure is built into the *Central Hudson* test itself, for to even qualify for protection, commercial speech must not be misleading.³⁸⁰ If the government has the power to ban misleading commercial speech, the government must also have to power

generally, honoring God through public prayer and acknowledgement, or, in a nonproselytizing manner, venerating the Ten Commandments.”) (Scalia, J., concurring).

³⁷⁴*Wisconsin v. Yoder*, 406 U.S. 205 (1963); *Lee*, 455 U.S. 252. *See also* *Emp. Division, Dep’t of Hum. Resources of Or. v. Smith*, 494 U.S. 872 (1990) (discussing how allowing religious exemptions from neutral laws of general applicability would turn every citizen into a law unto himself).

³⁷⁵*Lee*, 455 U.S. at 259–60.

³⁷⁶*Johanns v. Livestock Marketing Ass’n*, 544 U.S. 550, 575 (2005) (Souter, J., dissenting) (“Democracy . . . ensures the government is not untouchable when its speech rubs against the First Amendment interest of those who object to supporting it.”); *see also* *Bd. of Regents of the Univ. of Wis. v. Southworth*, 529 U.S. 217, 235 (2000) (“When the government speaks, for instance to promote its own policies or to advance a particular idea, it is, in the end, accountable to the electorate and the political process for its advocacy.”).

³⁷⁷*Cf.* *Boos v. Barry*, 485 U.S. 312 (1988) (limiting the malleable “secondary effects” interest to only the sexually explicit expression realm). This is also seen in the principle that the government cannot recharacterize a traditional public forum as any more limited type of forum. *See generally* *Perry Educ. Ass’n v. Perry Local Educators’ Ass’n*, 460 U.S. 37 (1983); *Cornelius v. NAACP Legal Def. and Educ. Fund, Inc.*, 473 U.S. 788 (1985).

³⁷⁸*Walker v. Tex. Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2248–49 (2015).

³⁷⁹*Johanns*, 544 U.S. at 574 (Souter, J., dissenting).

³⁸⁰*Central Hudson*, 447 U.S. 557, 566 (1980).

to present the speaker with the choice between a ban on the misleading speech or a disclosure to make the speech no longer misleading.³⁸¹

Pre-*Central Hudson*, the right to ban misleading commercial speech was clarified in *Friedman v. Rogers*, which concerned a Texas optometrist who wished to practice using a certain trade name, in violation of regulations under the Texas Optometry Act.³⁸² The Court held that a trade name often conveys information: once in use for enough time, it identified a particular optometry practice and communicated impressions about “the type, price, and quality of services offered for sale in that practice.”³⁸³ The state justified the rule by pointing to an optometrist that had operated under 10 different trade names, commonly purchasing other optometrists’ practices and continuing to use their trade name, or changing the name of his shops though all employees remained identical.³⁸⁴ He also used different trade names on geographically close shops (all under common management) “to give a misleading impression of competitive ownership and management of his shops.”³⁸⁵ Texas’ rule was thus necessary, Justice Powell held, to prevent consumer deception.³⁸⁶ “Rather than stifling commercial speech, [the rule] ensures that information . . . will be communicated more fully and accurately to consumers than it had been in the past when optometrists were allowed to convey the information through unstated and ambiguous associations with a trade name.”³⁸⁷

The first case to explicitly uphold a compelled commercial disclosure was *Zauderer*.³⁸⁸ The attorney in *Zauderer* ran ads stating, “If there is no recovery, no legal fees are owed by our clients” and in another, advising that the clients’ “[f]ull legal fee [would be] refunded if [they were] convicted of DRUNK DRIVING.”³⁸⁹ The State bar took issue with the advertisements, for though no legal *fees* may have been charged in an unsuccessful suit, legal *costs* certainly were.³⁹⁰ Accordingly, the State required the attorney, if choosing to advertise availability on a contingent-fee basis, to disclose that clients would be responsible for legal costs regardless of the success of the suit.³⁹¹

³⁸¹Counterarguments would include the fact that the greater power does not automatically include the lesser power in the commercial speech arena, see *New Orleans Broad.*, 527 U.S. 173, and invoking the unconstitutional conditions doctrine, see *Speiser v. Randall*, 357 U.S. 513 (1958). The first is inapposite because both the greater *and* the lesser power here concern speech (in contrast to regulations concerning gambling or other non-constitutionally-protected products or services, where the speech-related “lesser” power to prohibit advertising by no means was actually “lesser” than the power to prohibit gambling). The second also fails for a similar reason: the unconstitutional conditions doctrine states that the government cannot force a choice between the constitutional right to free speech and “X.” Here, there is no constitutional right to misleading commercial speech. Regardless, perhaps this is why compelled commercial disclosure cases usually, but not always, rely on *Zauderer* rather than directly on *Central Hudson*.

³⁸²*Friedman v. Rogers*, 440 U.S. 1, 3–7 (1979).

³⁸³*Id.* at 11.

³⁸⁴*Id.* at 14.

³⁸⁵*Id.*

³⁸⁶*Id.* at 16.

³⁸⁷*Id.*

³⁸⁸*Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

³⁸⁹*Id.* at 630–31.

³⁹⁰*Id.* at 652.

³⁹¹*Id.*

The attorney argued that the disclosure requirement was subject to the usual *Central Hudson* inquiry, but Justice White rejected such an approach.³⁹² Instead, he held that the disclosure requirements must be “reasonably related to the State’s interest in preventing deception of consumers.”³⁹³ Compelled speech cases, such as *Wooley*, *Tornillo*, and *Barnette*, were relevant, he stated, but “the interests at stake in this case are not of the same order.”³⁹⁴ Unlike the pure compelled speech cases, here:

Ohio has not attempted to prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion The State has attempted only to prescribe what shall be orthodox in commercial advertising, and its prescription has taken the form of a requirement that appellant include in his advertising purely factual and uncontroversial information[.] . . . Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, appellant’s constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.³⁹⁵

Of course, the state could go too far: “unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.”³⁹⁶ But “an advertiser’s rights are adequately protected” so long as the state is regulating to prevent consumer deception.³⁹⁷ In this sense, the disclosure requirement here worked as a sort of prophylactic rule³⁹⁸—the state was not required to prove that absent the disclosure, the commercial speech would be misleading, only there existed a danger of consumer deception that the state was reasonably addressing.³⁹⁹

The Court gave more guidance on this issue in 1994, when the Court rejected the application of *Zauderer* while considering a state Board of Accountancy’s claim that allowing an attorney to use a certain certification in an advertisement was misleading because the Board had failed “to point to any harm that is potentially real,

³⁹²*Id.* at 650.

³⁹³*Id.* at 651.

³⁹⁴*Id.*

³⁹⁵*Id.* (internal citations omitted) (citing *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943); *Virginia Board*, 425 U.S. 748).

³⁹⁶*Zauderer*, 471 U.S. at 651.

³⁹⁷*Id.*

³⁹⁸Though disclosures may be prophylactic, there are still limits. *Id.* at 649 (rejecting “broad prophylactic rules”); *Nat’l Inst. Of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) (stating disclosures must extend “no broader than reasonably necessary”).

³⁹⁹If otherwise, the rule would operate under the regular *Central Hudson* analysis, an analysis that Justice White explicitly rejected. *Zauderer*, 471 U.S. at 650 (Rejecting argument that “the State must establish either that the advertisement, absent the required disclosure, would be false or deceptive or that the disclosure requirement serves some substantial governmental interest other than preventing deception.”); *accord* *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 464 (1978) (authorizing prophylactic rules to guard against lawyer overreach in situations “inherently conducive” to misconduct). Lower courts have not agreed on whether, and to what extent, the state must show that the commercial speech would be misleading. *See infra* sections III.A and III.C; *see also infra* note 406 (explaining Justice Thomas’ view that the speech must actually deceive or be inherently likely to deceive). Current Supreme Court guidance puts the burden on the state to prove that the danger is at least “potentially real.” *Becerra*, 138 S. Ct. at 2377.

not purely hypothetical.”⁴⁰⁰ That is, in *Ibanez*, *Zauderer* did not apply because the government failed to make any showing at all that there existed a danger of consumer deception.⁴⁰¹

In *Millavetz*, the Court applied the *Zauderer* standard, this time determining that it was applicable to justify a law firm disclosure requirement.⁴⁰² *Millavetz* upheld a provision of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 which mandated, in advertisements for debt relief services if the debt relief was bankruptcy, disclosure that the debt relief advertised was in connection to bankruptcy relief.⁴⁰³ The Court found that like *Zauderer*’s costs/fees distinction, advertisement of bankruptcy services as “debt relief” without further disclosure would be “inherently misleading” because it would obfuscate the costs connected with filing for bankruptcy.⁴⁰⁴ Justice Thomas, in concurrence, expressed skepticism of *Zauderer* as not providing sufficient protection for speech.⁴⁰⁵ However, he continued to offer his interpretation of the doctrine as it stands, which was that the government’s interest in preventing consumer deception must be more than “plausibly” implicated in order to justify a disclosure—*i.e.*, the government must prove the advertisement sans disclosure is “inherently likely to deceive” or “has in fact been deceptive.”⁴⁰⁶

Zauderer popped up again in each of the most recent two terms, though neither time did the Court directly apply the test itself. In 2017, the Court implicitly endorsed *Zauderer*’s continuing validity in the general commercial context (as opposed to *Zauderer* and *Millavetz*’ lawyer advertising context). After holding in *Expressions Hair Design* that the price regulation in question did in fact control speech, since it regulated only how sellers communicated their prices rather than the prices themselves, Justice Roberts remanded the case to the Court of Appeals to settle the parties’ dispute as to “whether [the regulation] is a valid commercial speech regulation under *Central Hudson*” or “whether the law can be upheld as a valid disclosure requirement under *Zauderer*.”⁴⁰⁷

And finally, in the 2018 case of *National Institute of Family and Life Advocates v. Becerra*, Justice Thomas considered the constitutionality of a California law that compelled pro-life crisis pregnancy centers to give two types of notices: (1) licensed clinics were required to provide information and a phone number relating to California’s public health programs that offered family planning services, including contraception and abortion, and (2) unlicensed clinics were required to post conspicuous notices that they were not licensed and include such notices in all advertising.⁴⁰⁸ In discussing the licensed clinic notices, Justice Thomas held that *Zauderer* did not apply because the notice did not relate to the services that licensed

⁴⁰⁰*Ibanez v. Fla. Dep’t of Prof’l Regulation*, 512 U.S. 136, 146 (1994).

⁴⁰¹*Id.*

⁴⁰²*Millavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 252–53 (2010).

⁴⁰³11 U.S.C. § 528(a)(3) (2005).

⁴⁰⁴*Millavetz*, 559 U.S. at 250.

⁴⁰⁵*Id.* at 256 (Thomas, J., concurring).

⁴⁰⁶*Id.* at 257 (Thomas, J., concurring).

⁴⁰⁷*Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017).

⁴⁰⁸*Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2368–70 (2018). Procedurally, the Court’s opinion only discussed likelihood of success on the merits, not actual success, because petitioners were asking for a preliminary injunction. *Id.* at 2370.

clinics provided, but instead related to alternative state-sponsored services.⁴⁰⁹ To put it another way, by requiring pro-life centers to notify patients about the availability of state services, including abortion, California was compelling a form of ideological speech rather than compelling a factual disclosure.⁴¹⁰ Though it would ostensibly thus be subject to strict scrutiny, the Court held that the notice could not survive even intermediate scrutiny because the requirement was “wildly underinclusive” with respect to the state’s goal of educating low-income women about its services, and California could accomplish said goal with a public-information campaign or by posting the information on public property near the centers (*i.e.*, via government speech).⁴¹¹

Likely motivated by his previous skepticism of *Zauderer*, Justice Thomas in considering the second requirement declined to decide whether *Zauderer* applied at all because the requirement that unlicensed clinics disclose their unlicensed status failed any level of review.⁴¹² Like in *Ibanez*, the state had failed to make a proper evidentiary showing that the harm to be remedied was “potentially real, not purely hypothetical.”⁴¹³ Additionally, the disclosure applied inconsistently between speakers and was unduly burdensome.⁴¹⁴ Thus, though *Zauderer* is quite clearly still a valid basis for regulation,⁴¹⁵ it has departed slightly from the rational basis review it was patterned on in that the burden is now on the government to prove, without deference,

⁴⁰⁹*Id.* at 2372. Justice Thomas also discarded California’s argument that “professional speech” should be a separate category of speech subject to lower scrutiny and declined to apply Court precedent upholding regulations of conduct that incidentally burden speech (*e.g.*, informed consent laws). *Id.* at 2371–73.

⁴¹⁰*Cf. id.* at 2372 (“[The notice] requires these clinics to disclose information about . . . abortion, anything but an uncontroversial topic.”) (emphasis and quotation marks removed). The meaning of the “uncontroversial” portion of *Zauderer*’s “factual and uncontroversial” requirement has never been made entirely clear. A “controversial” topic must be something more than “I don’t want to say it,” because practically speaking a disclosure is always something the speaker would otherwise not be inclined to say. A good use for this requirement seems to be to separate ideological speech from factual disclosures. Justice Breyer’s dissent takes a different approach, viewing “controversial” as addressing the consensus around whether a statement is factual: “Abortion is a controversial topic and a source of normative debate, but the availability of state resources is not a normative statement or a fact of debatable truth.” *Id.* at 2388 (Breyer, J., dissenting). This seems a sensible and useful interpretation, though *Zauderer* did say “factual and uncontroversial,” not “uncontroversially factual.”

⁴¹¹*Id.* at 2375–76.

⁴¹²*Id.* at 2377.

⁴¹³*Id.*

⁴¹⁴The disclosure was also required to be included in advertising, in same size or larger text and/or contrasting type or color to the speaker’s message, as well as (potentially) being required in several languages. *Id.* at 2378. Writing in dissent, Justice Breyer would have left the question of how burdensome these requirements might be as applied for an actual as-applied challenge. *Id.* at 2391 (Breyer, J., dissenting).

⁴¹⁵Although this would only indirectly bear on the constitutionality of such a practice, mandatory disclosures justified by preventing consumer deception are prevalent throughout U.S. regulatory law, for example in the disclosure of mortgage APRs, SEC-mandated disclosures connected to stock offerings, and even nutrition labels on foods. *See generally* Christopher Robertson & Victoria Laurion, *Tip of the Iceberg II: How the Intended-Uses Principle Produces Medical Knowledge and Protects Liberty*, 11 N.Y.U. J.L. & LIBERTY 770 (2017); *cf.* *Janus v. Am. Fed’n of State, Cty. and Mun. Emps., Council 31*, 138 S. Ct. 2448, 2502 (2018) (Kagan, J., dissenting) (“[A]lmost all economic and regulatory policy affects or touches speech.”).

that there actually exists a danger of consumer deception and that the regulation addresses such a danger appropriately.⁴¹⁶

One last consideration bears mention: how is one to read commercial speech's abhorrence of paternalism⁴¹⁷ with the fact that commercial disclosure regulations are justified as protecting consumers?⁴¹⁸ The abhorrence of paternalism is directed towards regulations that attempt to keep consumers in the dark for fear of how they would respond to the information.⁴¹⁹ By contrast, commercial disclosure regulations seek to give the consumer access to *complete* information.⁴²⁰ *Virginia Board* itself was "paternalistic" in the sense that it displayed concern for protecting "the poor, the sick, and particularly the aged" because they spend so much on pharmaceuticals that "information as to who is charging what becomes more than a convenience."⁴²¹ But the preferred solution, as with most First Amendment issues, was *more* speech.⁴²²

III. SELECTED CURRENT FDA APPROACHES TOWARD FIRST AMENDMENT COMPLIANCE

This section will discuss FDA's approaches to three particular regulatory situations that implicate the First Amendment. First, this section will consider FDA regulation of health claims for dietary supplements. Second, it will cover FDA's ever-evolving approach to regulating the promotion of pharmaceuticals for off-label uses. And third, this section will discuss FDA's short-lived proposal for graphic warning labels on cigarette packages.

III.A. Health Claims for Dietary Supplements

From 1938 until the 1980s, FDA's position on foods bearing health claims⁴²³ was that the inclusion of such claims on a food's label rendered the food a drug subject to the NDA process.⁴²⁴ But throughout the 1980s, FDA became increasingly lenient towards health claims, eventually expressing this new policy of enforcement discretion with proposed regulations on the subject.⁴²⁵ In 1990, Congress entered the

⁴¹⁶*Becerra*, 138 S. Ct. at 2377; *see also* *Ibanez v. Fla. Dep't of Bus. and Prof'l Reg.*, 512 U.S. 136, 146 (1994); *Becerra*, 138 S. Ct. at 2390 (Breyer, J., dissenting) (faulting the majority for applying "a searching standard of review [that is] . . . incompatible with *Zauderer*.").

⁴¹⁷*E.g.*, *Virginia Board*, 425 U.S. 748, 771–72 (1976).

⁴¹⁸*Zauderer v. Off. of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985).

⁴¹⁹*E.g.*, *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577 (2011).

⁴²⁰*Zauderer*, 471 U.S. at 651.

⁴²¹*Virginia Board*, 425 U.S. at 763–64.

⁴²²*E.g.*, *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977).

⁴²³For the purposes of this article, the term "health claims" will be used to refer to claims that use of a food product bears a relationship to either health conditions or diseases (*i.e.*, to both health claims and disease claims). *See* HUTT, *supra* note 5, at 419; 21 C.F.R. § 101.14(a)(1), (5).

⁴²⁴HUTT, *supra* note 5, at 418; 21 U.S.C. § 355.

⁴²⁵FOOD & DRUG ADMIN., *Food Labeling: Public Health Messages on Food Labels and Labeling*, 52 Fed. Reg. 28843 (Aug. 4, 1987); FOOD & DRUG ADMIN., *Food Labeling: Health Messages and Label Statements; Reproposed Rule*, 55 Fed. Reg. 5176 (Feb. 13, 1990).

conversation by passing the Nutrition Labeling and Education Act of 1990 (NLEA).⁴²⁶ The NLEA amended the FDCA to allow health claims for foods and dietary supplements so long as there is “significant scientific agreement” about the claim.⁴²⁷ A health claim is defined as “any claim made on the label . . . of a . . . dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition.”⁴²⁸ Such a claim does not transform the food or dietary supplement into a drug so long as the manufacturer presents the claim and the evidence to FDA for a determination that the significant scientific agreement standard is met and the claim is an “accurate representation . . . [that] enables the public to comprehend the information provided in the claim.”⁴²⁹

What is significant scientific agreement? FDA’s 1993 regulations defined it as a determination “based on the totality of publicly available scientific evidence (including evidence from . . . [traditionally scientific studies]) that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”⁴³⁰ The circularity of this definition did not seem to bother FDA.

The Dietary Supplement industry is unique in that it has sometimes been more willing than other regulated industries to face FDA head-on.⁴³¹ With Senators Orrin Hatch and Tom Harkin on its side, the industry won a battle against FDA’s aggressive regulation of dietary supplements with the Dietary Supplement and Health and Education Act of 1994 (DSHEA).⁴³² The DSHEA established dietary supplements as a new subcategory of food for products that are “intended to supplement the diet” and contain a vitamin, mineral, herb, or another of a specified list of ingredients or products that are presented and labeled as dietary supplements.⁴³³ The DSHEA permitted supplements to make structure/function claims (*i.e.*, claims that describe how a supplement is “intended to affect the structure or function” of the human body) without being classified as drugs.⁴³⁴ And as a subcategory of foods, supplements are also allowed to make health claims (*i.e.*, disease prevention claims) so long as FDA approves under the process stipulated by the NLEA.⁴³⁵

Given the unique nature of the dietary supplement industry, it is no surprise that one of the earliest successful First Amendment challenges to FDA’s regulatory approaches

⁴²⁶Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 301, 321, 337, 343, 345, and 371).

⁴²⁷21 U.S.C. § 343(r)(3)(B); 21 C.F.R. § 101.14(c) (2018).

⁴²⁸21 C.F.R. § 101.14.

⁴²⁹21 C.F.R. § 101.14(d)–(e); 21 U.S.C. § 343(r)(3)(B)(iii) (2012).

⁴³⁰21 C.F.R. § 101.14(c).

⁴³¹See Priyanka Boghani, *Can Regulators Keep Up with the Supplements Industry?*, PBS FRONTLINE (Jan. 19, 2016), <https://www.pbs.org/wgbh/frontline/article/can-regulators-keep-up-with-the-supplements-industry/> [https://perma.cc/YB4G-PPF9].

⁴³²See HUTT, *supra* note 5, at 102; Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417, 108 Stat. 4325 (1994), codified at 21 U.S.C. § 301, 321, 343, 343–2, 350(b); see also Dan Mitchell, *Why the Supplements Industry Is So Powerful*, TIME (Mar. 11, 2015), <http://time.com/3741142/gnc-vitamin-shoppe-supplements/> [https://perma.cc/X2XG-53V6].

⁴³³21 U.S.C. § 321(ff) (2012).

⁴³⁴21 U.S.C. § 343(r)(6)(A) (2012).

⁴³⁵21 U.S.C. § 343(r)(1)(B) (2012).

came from the within its ranks.⁴³⁶ The challenge arose out of a request by two dietary supplement marketers that FDA authorize four health claims, each linking a particular supplement to a particular disease.⁴³⁷ FDA rejected each of the four claims because the evidence for the claims was inconclusive and as such did not meet the level of significant scientific agreement.⁴³⁸ The supplement marketers suggested that FDA permit the claim in conjunction with a disclaimer stating that FDA had determined the evidence was inconclusive, but FDA rejected this suggestion.⁴³⁹ Accordingly, in 1998, the marketers challenged FDA in the district court of the District of Columbia, alleging violations of the First Amendment and the APA.⁴⁴⁰ Upon losing, they appealed to the Circuit Court.

Judge Laurence Silberman of the D.C. Circuit issued a groundbreaking opinion applying the First Amendment and the APA to FDA's actions.⁴⁴¹ The health claims, he held, were indisputably commercial speech.⁴⁴² The government first argued that health claims that lacked significant scientific agreement were inherently misleading, and as such exempted from the First Amendment.⁴⁴³ As a fallback, its second argument was that even if the health claims were not inherently misleading, *Central Hudson* could still justify the speech restrictions and the refusal to consider a disclaimer approach.⁴⁴⁴

If the health claims were inherently misleading, Judge Silberman held, FDA would be entitled to ban them.⁴⁴⁵ However, Silberman held that the claims were at most "potentially misleading because the consumer would have difficulty in independently verifying the[] claims," and because "consumers might actually assume that the government has approved such claims."⁴⁴⁶ Because the speech was not inherently misleading and thus protected, Judge Silberman applied the rest of *Central Hudson*. He found that the government did have a substantial interest in protecting public health and preventing consumer fraud.⁴⁴⁷ But the first interest encountered difficulty with *Central Hudson*'s third factor, because the government offered no evidence that the speech restrictions directly advanced the interest in protecting public health; indeed, any causal connection between the two hinged on the forbidden interest in keeping consumers ignorant out of paternalistic concerns.⁴⁴⁸ And the second interest,

⁴³⁶*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) [hereinafter *Pearson I*].

⁴³⁷*Id.* at 651–52. The four claims were (1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers"; (2) "Consumption of fiber may reduce the risk of colorectal cancer"; (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease"; (4) ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount of foods in common form." *Id.* at 652.

⁴³⁸*Id.* at 653.

⁴³⁹*Id.* at 654.

⁴⁴⁰*Pearson v. Shalala*, 14 F. Supp. 2d 10 (D.D.C. 1998).

⁴⁴¹*Pearson I*, 164 F.3d at 655.

⁴⁴²*Id.*

⁴⁴³*Id.*

⁴⁴⁴*Id.*

⁴⁴⁵*Id.*

⁴⁴⁶*Id.*

⁴⁴⁷*Id.* at 656.

⁴⁴⁸*Id.*

preventing consumer deception, was directly advanced by the regulations, but fell at the fourth prong as lacking reasonable fit.⁴⁴⁹ Judge Silberman pointed out that “disclaimers [are] constitutionally preferable to outright suppression” and that disclaimers could address the concern of consumer misperception.⁴⁵⁰

The opinion finished the analysis by suggesting some disclaimers that would address FDA’s concerns with the weight of the evidence and the possibility that consumers may assume FDA approved a claim,⁴⁵¹ but stating that the task of drafting precise disclaimers would be up to FDA “in the first instance.”⁴⁵² Judge Silberman also left open “the possibility that where evidence in support of a claim is outweighed [either quantitatively or qualitatively] by evidence against the claim, FDA could deem it incurable by a disclaimer and ban it outright.”⁴⁵³ Though “skeptical,” he also left open the possibility that FDA could prove, through empirical evidence, that a disclaimer approach “would bewilder consumers and fail to correct for deceptiveness.”⁴⁵⁴

The supplement marketers had also challenged the agency’s circular definition of “significant scientific agreement” under the First and Fifth Amendments and the APA. Judge Silberman held that “the APA requires the agency to explain why it rejects their proposed health claims” and in the process “giv[e] some definitional content to the phrase ‘significant scientific evidence’” such that “the regulated class [can] perceive the principles which are guiding agency action.”⁴⁵⁵ Such a holding rendered the constitutional claims with respect to the definition of significant scientific agreement no longer relevant.⁴⁵⁶

The Court of Appeals remanded to the district court, which in turn remanded to FDA for compliance.⁴⁵⁷ After some back-and-forth, two years, and a rejected application from the *Pearson* plaintiffs for a preliminary injunction to spur FDA action on the issue, FDA rejected one of the original claims (the folic acid claim), instead suggesting certain alternate claims—an action that was promptly met with another lawsuit.⁴⁵⁸ In the meanwhile, FDA (after 18 months had passed) revoked the regulations held unconstitutional in *Pearson I*, although specifying that the action did

⁴⁴⁹*Id.* at 657.

⁴⁵⁰*Id.*

⁴⁵¹*Id.* at 657–59. The suggested disclaimers for the first three claims were, “The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins [or other supplement at issue], and the effect of these foods on reducing the risk of cancer [or other disease at issue] may result from other components in those foods.” *Id.* The suggested disclaimer for the last claim was, “The evidence in support of this claim is inconclusive.” An additional disclaimer for all products was suggested, “FDA does not approve this claim.” *Id.*

⁴⁵²*Id.* at 659.

⁴⁵³*Id.*

⁴⁵⁴*Id.* at 659–60.

⁴⁵⁵*Id.* at 660–61.

⁴⁵⁶*Id.* at 660.

⁴⁵⁷*Pearson v. Shalala*, 130 F. Supp. 2d 105, 110 (D.D.C. 2001) [hereinafter *Pearson II*].

⁴⁵⁸*Id.* at 111.

not constitute authorization of the claims, only removal of the rejection.⁴⁵⁹ FDA also interpreted the *Pearson I* decision narrowly, setting forth a new “weight of the evidence” process for responding to dietary supplement health claims—a process couched in terms of enforcement discretion rather than constitutional mandates.⁴⁶⁰ If the significant scientific agreement standard was met as determined by FDA, FDA would approve the claim (as it always had).⁴⁶¹ If the standard was not met, but the evidence in support of the claim *outweighed* the evidence against the claim, FDA would “consider exercising enforcement discretion.”⁴⁶² And if the evidence in support of the claim *did not outweigh* the evidence against the claim, FDA would reject the claim as misleading or against public health—though now it would explain its rationale for denial to the petitioner.⁴⁶³

Pearson II, the suit challenging FDA’s denial of the folic acid claim, ended with a grant of a preliminary injunction against FDA.⁴⁶⁴ The court blended the APA analysis with the constitutional analysis, holding that the folic acid claim was only potentially misleading and as such FDA’s determination that the claim was inherently misleading (and thus unprotected by the First Amendment) was arbitrary, capricious, and an abuse of discretion.⁴⁶⁵ The district court remanded to FDA to fulfil its “institutional role to draft accurate, adequate, and succinct health claim disclaimers,” “strongly suggest[ing] that] the agency consider the two disclaimers suggested” in *Pearson I* as well as the plaintiff’s proposed disclaimer.⁴⁶⁶ Instead, FDA moved for reconsideration of the *Pearson II* decision on grounds it was inconsistent with *Pearson I*.⁴⁶⁷ The court in *Pearson III* disagreed and set forth the rules it thought “perfectly clear” from *Pearson I*: “First Amendment analysis applies in this case, and [] if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression”; further, if FDA “wish[es] to totally suppress a particular health claim,” it must satisfy the “very heavy burden” of “demonstrat[ing] with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness.”⁴⁶⁸ Following *Pearson III*, the plaintiffs and FDA reached an agreement on an appropriate disclaimer for the folic acid claim.⁴⁶⁹

But the peace was short-lived—in the meanwhile FDA had rejected the *Pearson* plaintiff’s antioxidant vitamin claim due to a lack of significant scientific

⁴⁵⁹FOOD & DRUG ADMIN., *Food Labeling: Health Claims and Labeling Statements; Dietary Fiber and Cancer; Antioxidant Vitamins and Cancer; Omega-3 Fatty Acids and Coronary Heart Disease; Folate and Neural Tube Defects; Revocation*, 65 Fed. Reg. 58917 (Oct. 3, 2000).

⁴⁶⁰FOOD & DRUG ADMIN., *Food Labeling; Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision*, 65 Fed. Reg. 59855 (Oct. 6, 2000).

⁴⁶¹*Id.*

⁴⁶²*Id.*

⁴⁶³*Id.*

⁴⁶⁴*Pearson II*, 130 F. Supp. 3d at 120.

⁴⁶⁵*Id.*

⁴⁶⁶*Id.*

⁴⁶⁷*Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001) [hereinafter *Pearson III*].

⁴⁶⁸*Id.* at 112.

⁴⁶⁹*Whitaker v. Thompson*, 248 F. Supp. 2d 1, 7 (D.D.C. 2002).

agreement.⁴⁷⁰ Specifically, FDA found that “the weight of the scientific evidence against the relationship [between the antioxidant vitamins and the disease claim] was greater than the weight of the evidence in favor” and thus the claim was inherently misleading and incurable with a disclaimer.⁴⁷¹ Plaintiffs against challenged FDA in *Whitaker*, where the district court again granted a preliminary injunction against FDA and required FDA to design “appropriately short, succinct, and accurate disclaimers” for the health claim.⁴⁷² The decision in *Whitaker* was even easier than in *Pearson II*, for the district court now had the benefit of the Supreme Court’s 2002 *Thompson* decision, which was the first commercial speech case to explicitly state that as part of the *Central Hudson* “reasonable fit” inquiry, speech restrictions must be of last resort.⁴⁷³ The district court held that FDA had failed to show “that suppression of the Antioxidant Vitamin Claim was a *necessary* as opposed to *merely convenient* means of achieving its interest” and instead had only offered “conclusory assertions” that did not “comport with the First Amendment’s clear preference for disclosure over suppression of commercial speech.”⁴⁷⁴

FDA responded to *Whitaker* by releasing interim guidance for industry in July 2003 and requesting comments on proposed rulemaking on alternative methods of regulating health claims for dietary supplements.⁴⁷⁵ The 2003 interim guidance established a four-tier approach to health claims.⁴⁷⁶ The first, and best, tier consisted of the unfortunately-named “unqualified health claims,” which were unqualified in the sense that they fully met the significant scientific agreement standard and were thus approved without any qualifications (*i.e.*, disclaimers or disclosures).⁴⁷⁷ The three remaining tiers, called “qualified health claims” (because they required qualification) represented increasingly lower levels of scientific evidence for the claim and increasingly strongly-worded qualifying language, ranging from descriptions of the evidence as “not conclusive” all the way to “very limited and preliminary.”⁴⁷⁸

Over the next few years, FDA issued several “enforcement discretion” letters for qualified health claims, in each case drafting specific qualifying language to

⁴⁷⁰*Id.*

⁴⁷¹*Id.*

⁴⁷²*Id.* at 8, 17.

⁴⁷³*Thompson v. Western States Medical Center*, 535 U.S. at 371.

⁴⁷⁴*Whitaker*, 248 F. Supp. 2d at 14–15 (quoting *Thompson*, 535 U.S. at 373 and *Pearson I*, 164 F.3d at 659) (emphasis original).

⁴⁷⁵Release of Task Force Report; *Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Food and Human Dietary Supplements; Availability*, 68 Fed. Reg. 41387 (July 11, 2003); *Food Labeling: Health Claims; Dietary Guidance*, 68 Fed. Reg. 66040 (Nov. 25, 2003).

⁴⁷⁶FOOD & DRUG ADMIN., *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements* (July 2003), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053832.htm>.

⁴⁷⁷*Id.*

⁴⁷⁸*Id.* Second level claims required the qualifying language, “although there is scientific evidence supporting the claim, the evidence is not conclusive.” *Id.* Third level claims required the qualifying language, “Some scientific evidence suggests [the claim], however, FDA has determined that this evidence is limited and not conclusive.” *Id.* Fourth level claims required the qualifying language, “Very limited and preliminary scientific research suggests [the claim], FDA concludes that there is little scientific evidence supporting this claim.” *Id.*

accompany the claim.⁴⁷⁹ In 2009, FDA released new guidance for industry.⁴⁸⁰ The 2009 guidance contained an exhaustive explanation of how FDA intended to categorize and evaluate the scientific evidence for a particular claim.⁴⁸¹ It also eliminated the four-tier approach from the 2003 guidance, instead more closely tracking its *de facto* two-tier approach: “[b]ased on the totality of the scientific evidence,” FDA would “determine[] whether such evidence meets the [significant scientific agreement] standard [required for an “unqualified” claim] or whether such evidence is credible to support a qualified health claim for the substance/disease relationship.”⁴⁸² For qualified health claims, a “credible” evidence approach would replace the previous “weight of the evidence” approach, and “the proposed claim for the relationship should include qualifying language that identifies limits to the level of scientific evidence to support the relationship . . . with specificity and accuracy.”⁴⁸³

FDA continued to be closely involved in the drafting of the disclaimer language for qualified health claims, leading to another court challenge, this time in the district court of Connecticut in the 2012 case of *Fleminger v. HHS*.⁴⁸⁴

Fleminger involved a request that FDA authorize a health claim relating consumption of green tea to a reduction in risk of several forms of cancer.⁴⁸⁵ FDA issued an enforcement discretion letter approving a qualified health claim with respect to breast and prostate cancer, and gave specific language for the claims.⁴⁸⁶ *Fleminger* in response sought reconsideration, suggesting different language.⁴⁸⁷ The gap between FDA’s and *Fleminger*’s wordings was quite striking. FDA would have allowed claims that based on “weak and limited” studies “FDA concludes that it is highly unlikely that green tea reduces the risk of breast [and prostate] cancer.”⁴⁸⁸ One wonders how this can even be called a “health claim.” *Fleminger*’s proposed counter-claim was that drinking green tea “may reduce the risk” of breast and prostate cancer given “credible evidence supporting this claim although the evidence is limited.”⁴⁸⁹ Such a claim was a generous reading of the conflicting results of the studies, the majority of which showed no correlation of green tea consumption with the cancers. After a few more

⁴⁷⁹HUTT, *supra* note 5, at 437.

⁴⁸⁰FOOD & DRUG ADMIN., *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims* (Jan. 2009), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm>.

⁴⁸¹*Id.*

⁴⁸²*Id.*

⁴⁸³*Id.*

⁴⁸⁴*Fleminger v. U.S. Dep’t of Health and Human Services*, 854 F. Supp. 2d 192 (D. Conn. 2012). In between *Whitaker* in 2002 and the District Court of Connecticut’s *Fleminger* decision in 2012, the D.C. District Court also considered First Amendment challenges in *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48 (D.D.C. 2010) and *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1 (D.D.C. 2011). Both decisions applied controlling circuit court precedent from *Pearson I*.

⁴⁸⁵*Fleminger*, 854 F. Supp. 2d at 203.

⁴⁸⁶*Id.*; FOOD & DRUG ADMIN., *Letter Responding to Health Claim Petition dated January 27, 2004: Green Tea and Reduced Risk of Cancer Health Claim* (Feb. 24, 2011), <http://wayback.archive-it.org/7993/20171114023211/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072774.htm> [<https://perma.cc/7WQF-3QBF>].

⁴⁸⁷*Fleminger*, 854 F. Supp. 2d at 204.

⁴⁸⁸*Id.*

⁴⁸⁹*Id.*

rounds of letters and petitions, and an FDA loss in the D.C. district court for a similar claim,⁴⁹⁰ Flemingier sued in the Connecticut district court.⁴⁹¹

At issue in the case were the final round of suggested qualified claims. The last salvo from Flemingier was a request for the claim that “Green tea may reduce the risk of breast and prostate cancers. FDA has concluded that there is credible evidence supporting this claim although the evidence is limited.”⁴⁹² In response, FDA offered to authorize the claim that “Green tea may reduce the risk of breast or prostate cancers. FDA does not agree that green tea may reduce that risk because there is very little scientific evidence for the claim.”⁴⁹³ Flemingier alleged that this response violated his First Amendment rights.⁴⁹⁴

Judge Vanessa Bryant held that “[a]lthough the Court is obligated to give deference to the FDA’s assessment of the strength of the scientific evidence for the proposed health claim, such deference does not extend to the determination of whether the FDA’s modified disclaimer violated Flemingier’s commercial speech rights.”⁴⁹⁵ As *Pearson I* was not binding, she then conducted a *Central Hudson* analysis, finding that although the government had substantial interests in preventing consumer confusion, protecting public health, and preventing the assumption that FDA endorses a claim, the claims would need to be altered to ensure a reasonable fit between these interests and the disclosures.⁴⁹⁶ She rejected Flemingier’s proposed claim—that the evidence was implicitly endorsed by FDA and was “credible” but “limited”—as misleading and inaccurate.⁴⁹⁷ But she also rejected FDA’s disclaimer that “FDA does not agree that green tea may reduce the risk” as lacking reasonable fit, since such language “has the effect of negating” the entire claim.⁴⁹⁸ Instead, she found the government’s interests could be adequately served by stating that FDA has concluded that there is “very little scientific evidence” for the claim, and as such upheld the requirement of such a disclaimer.⁴⁹⁹ FDA could require a “short, succinct and accurate disclaimer” indicating FDA’s conclusion as to the weight of the evidence, but it could not “nullify[] the claim altogether” if it is not inherently misleading.⁵⁰⁰ Following *Flemingier*, FDA issued an updated enforcement discretion letter, approving the claim that “[g]reen tea may

⁴⁹⁰*Id.* at 205; *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48, 71 (D.D.C. 2010) (holding that FDA cannot completely negate a claim with a required disclosure where there is credible evidence in support of the relationship). *See also* *Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 24 (D.D.C. 2011) (“Where the evidence supporting a claim is inconclusive, the First Amendment permits the claim to be made [with a properly drafted disclaimer]; FDA cannot require a disclaimer that simply swallows the claim.”).

⁴⁹¹*Flemingier*, 854 F. Supp. 2d at 192.

⁴⁹²*Id.* at 206.

⁴⁹³*Id.*

⁴⁹⁴*Id.*

⁴⁹⁵*Id.* at 207.

⁴⁹⁶*Id.* at 207–19.

⁴⁹⁷*Id.* at 211–15.

⁴⁹⁸*Id.* at 217–18.

⁴⁹⁹*Id.* at 218.

⁵⁰⁰*Id.*

reduce the risk of breast or prostate cancer although FDA has concluded that there is very little scientific evidence for this claim.”⁵⁰¹

Ever since, the area has remained in uneasy truce, with FDA continuing to follow the approach under the 2009 guidance and continuing to refer to the approach as “enforcement discretion” rather than constitutional mandate.⁵⁰² FDA has still not promulgated an official set of regulations clarifying that it will follow the *Pearson I* court’s direction to permit nonmisleading claims or setting forth an official process for determining appropriate disclosure language for claims that are only potentially misleading. Instead, it has followed the general federal agency trend of *de facto* rulemaking via informal guidance documents⁵⁰³ and continues to maintain that it has the authority to ban speech that courts have found constitutionally protected. As of 2018, FDA had issued “Letters of Enforcement Discretion” for 24 distinct qualified health claims, always referring to an exercise of enforcement discretion rather than a lack of legal power to ban.⁵⁰⁴

III.B. Off-Label Pharmaceutical Promotion

The FDCA grants FDA authority to regulate, *inter alia*, pharmaceutical drugs.⁵⁰⁵ FDA exercises authority over prescription drugs via the premarket approval process, which requires a manufacturer to demonstrate, as a precondition to distribution of the drug through interstate commerce, that the drug is safe and effective for its intended uses.⁵⁰⁶ Manufacturers demonstrate this through a series of preclinical and clinical trials, which are notoriously expensive—though studies vary, one study estimated the cost at \$2 billion per drug.⁵⁰⁷ FDA also has authority over the labeling of drugs, and requires labeling to display the drugs’ risks and benefits and give instructions for use.⁵⁰⁸ What constitutes “labeling” is extremely broad; it includes not only of the drug’s package insert, but nearly any form of promotional activity (*e.g.*, speech) for the drug.⁵⁰⁹ Labeling must conform to describing only FDA’s approved use(s).

⁵⁰¹FOOD & DRUG ADMIN., *Letter Updating the Green Tea and Risk of Breast Cancer and Prostate Cancer Health Claim April 17, 2012* (April 17, 2012), <http://wayback.archive-it.org/7993/20171114183707/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm301644.htm>.

⁵⁰²HUTT, *supra* note 5, at 441.

⁵⁰³*See generally* 5 U.S.C. § 553 (2011); David Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276 (2010); Todd Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159 (2000).

⁵⁰⁴*See, e.g., Ground Peanuts and Reduced Risk of Developing Peanut Allergy* (Sept. 7, 2017), <https://www.fda.gov/downloads/Food/LabelingNutrition/UCM575021.pdf>. The qualified health claim letters of enforcement discretion can be found on FDA’s website at <https://www.fda.gov/Food/LabelingNutrition/ucm072756.htm>.

⁵⁰⁵21 U.S.C. § 301 (2011) *et seq.*

⁵⁰⁶21 U.S.C. § 355(a), (b), (j) (2010).

⁵⁰⁷Joseph A. DiMasi, *Cost of Developing a New Drug*, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT (Nov. 18, 2014) <https://csdd.tufts.edu/csddnews/2018/3/9/march-2016-tufts-csdd-rd-cost-study>, [<https://perma.cc/H3Q7-53X3>].

⁵⁰⁸21 U.S.C. § 352(f) (2010).

⁵⁰⁹21 C.F.R. § 202.1–2 (2008). Some forms of promotional activity may not count as speech: for example, bribing a doctor promotes a drug but is not protected as speech. But run-of-the-mill marketing practices would qualify for speech protection.

Once drugs are approved for distribution, physicians are permitted to prescribe the drug for uses other than the originally approved use (“off-label”).⁵¹⁰ This strategy is especially helpful for patients with advanced cancer and for pediatrics, both areas with a dearth of accumulated clinical trial knowledge.⁵¹¹ But this strategy can also be harmful in some circumstances. The fact that a drug has been approved for a use represents the fact that for treating a particular condition, the benefit of the drug outweighs the risks of harmful side effects.⁵¹² That is, the approval of a drug does not mean a drug is “safe” in an ultimate sense of never doing harm.⁵¹³ In a sense FDA approves *uses* for drugs rather than drugs themselves.⁵¹⁴ Thus, prescribing the drug for an off-label use carries with it the possibility that the risks will outweigh the benefits for that use.⁵¹⁵

Through a series of regulations and guidance documents in the 1990s, FDA sought to balance the harmful possibilities of off-label use with the potential benefits. The approach FDA took consisted of targeting perceived potential for overprescription by regulating the marketing practices of manufacturers. Much like the approach taken to drug compounding (seen in *Thompson v. Western States Medical Center* several years later),⁵¹⁶ the fear was that manufacturers would circumvent the new drug approval process by marketing drugs for off-label use, with intention to bring the use “on-label.”⁵¹⁷

The regulations targeted manufacturer promotion of off-label use in two contexts. The first was promotion at Continuing Medical Education (CME) seminars.⁵¹⁸ Under FDA guidance, at CME seminars manufacturers could communicate about off-label uses only if such discussions were “independent of . . . promotional influence.”⁵¹⁹ Whether the forbidden promotional influence was present was determined by a list of

⁵¹⁰*Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments*, 59 Fed. Reg. 59820 (Nov. 18, 1994). A similar analysis also applies to use of medical devices for other than their approved purpose.

⁵¹¹*Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998) [hereinafter *WLF I*]. See also, e.g., James Beck, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 *FOOD & DRUG L.J.* 71, 80 (1998).

⁵¹²Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, in *THE TEXTBOOK OF PHARMACEUTICAL MEDICINE* (John P. Griffin & John O’Craday, eds., 5th ed. 2006) (“Because no drug has ever been shown to be completely safe or effective, in all cases this has been interpreted to mean that the benefits of the drug outweigh its risks under the labeled conditions of use for a significant identified patient population.”).

⁵¹³*Id.*

⁵¹⁴Christopher Robertson, *The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label*, 78 *OHIO ST. L. J.* 1019, 1021–22 (2017).

⁵¹⁵This is also true about prescriptions for on-label use; for that patient, the risks may outweigh the benefits. One essential function of doctors and pharmacists is to calculate these benefits and risks for the patient.

⁵¹⁶This is no coincidence; both approaches were codified by Congress in FDA Modernization Act of 1997. Pub. L. 105-115, 111 Stat. 2296, codified as §§ 551–557 of the Federal Food, Drug, and Cosmetic Act.

⁵¹⁷*WLF I*, 13 F. Supp. 2d at 70.

⁵¹⁸*Id.* at 57.

⁵¹⁹*Final Guidance on Industry Supported Scientific and Educational Activities*, 62 Fed. Reg. 64074 (Dec. 3, 1997).

factors designed to weed out advertising from meaningful scientific discussion.⁵²⁰ The second set of regulations targeted distribution of textbook excerpts and medical and scientific journal articles.⁵²¹ Such articles could be distributed only if their principal subject was regarding FDA-approved uses, there was not a “significant focus” on discussion of off-label use, and the distributor made clear off-label uses were not approved.⁵²²

III.B.1. The Washington Legal Foundation Saga

The Washington Legal Foundation challenged FDA regulations on manufacturer promotion of off-label pharmaceutical use in 1998.⁵²³ In the first round, the United States District Court for the District of Columbia found that FDA’s guidance documents violated the First Amendment.⁵²⁴ The court also declined to find the speech inherently regulable because of FDA’s extensive regulation of the pharmaceutical industry, noting that this would be contrary to past precedent ranging from *Virginia Board* to *Rubin v. Coors*.⁵²⁵ But the court declined to hold that the speech was fully protected as “pure” scientific speech, as the WLF had argued.⁵²⁶ The court noted the similarities between this speech, which clearly proposed a transaction even if in a roundabout way, and the mixed nature of the contraceptive mailings found to be commercial speech in *Bolger*.⁵²⁷ The court then applied the *Central Hudson* analysis.⁵²⁸

First, the speech was found not to be unlawful nor inherently misleading.⁵²⁹ The primary issue was whether the scientific documents and educational activities were misleading. The court held that they were not.⁵³⁰ The court rejected FDA’s argument otherwise, stating that the speech at issue was “not ‘untruthful’ or ‘inherently misleading’ merely because the FDA has not yet had the opportunity to evaluate the claim” and noting that FDA only felt the information would be misleading if a manufacturer conveyed it.⁵³¹

Second, the government had a substantial interest in compelling manufacturers to get off-label treatments on-label.⁵³² Congress had long ago made the policy judgment that requiring pharmaceutical manufacturers to obtain FDA approval overall

⁵²⁰*Id.*

⁵²¹*Advertising and Promotion*, 61 Fed. Reg. 52800 (Oct. 8, 1996).

⁵²²*Id.*

⁵²³See generally Ralph Hall, ‘Off-Label’ Speech: Uncertainty Reigns for Device and Drug Makers, WASHINGTON LEGAL FOUNDATION LEGAL BACKGROUNDER (Dec. 2, 2005), <http://www.wlf.org/upload/120205LBHall.pdf>.

⁵²⁴*WLF I*, 13 F. Supp. 2d at 74.

⁵²⁵*Id.* at 60–61, 63.

⁵²⁶*Id.* at 62–64.

⁵²⁷*Id.* at 62–65.

⁵²⁸*Id.* at 65.

⁵²⁹*Id.* at 65.

⁵³⁰*Id.* at 66–67.

⁵³¹*Id.* at 67–68.

⁵³²*Id.* at 70.

benefitted the public health, and the Supreme Court had upheld this policy.⁵³³ The court did reject FDA's other claimed interest, though. An interest in ensuring physicians were not misled was a rephrased interest in suppressing information out of fear of its effect on its recipients, an interest that has been rejected time and time again.⁵³⁴

Third, the guidance documents were held to directly advance the governmental interest in compelling manufacturers to obtain on-label approval.⁵³⁵ The Court found that FDA's control over the advertising of off-label uses "provides a strong incentive to get the use on-label, in light of the connection between marketing and sales."⁵³⁶

FDA lost on the last prong of *Central Hudson*, however, and the court found the guidance documents to be more extensive than necessary and thus unconstitutional.⁵³⁷ The court noted that "full, complete, and unambiguous disclosure by the manufacturer" would be a less-burdensome alternative to FDA's chosen restrictions.⁵³⁸ Such a scheme would obviously remedy concerns that the message was misleading.⁵³⁹ The court predicted that manufacturers would still seek to gain FDA approval for the uses, because physicians more readily prescribe drugs for FDA-approved uses, and because manufacturers would have a better defense under tort regimes that link the standard of care with FDA approval.⁵⁴⁰ The court also noted that off-label prescriptions constitute helpful treatment in many cases, and the current regime would have the effect of chilling "a great deal of truthful information."⁵⁴¹ And finally, a disclosure regime would "comport[] with the Supreme Court's preference for combating potentially problematic speech with more speech."⁵⁴²

The court then granted an injunction prohibiting FDA from restricting manufacturers from disseminating articles from "a bona fide peer-reviewed professional journal" or textbooks "published by a bona fide independent publisher and otherwise generally available for sale." It also prohibited FDA from banning discussion of off-label use at CMEs.⁵⁴³ The injunction was limited such that FDA retained authority to "sanction the dissemination or redistribution of any material that is false or misleading," and to require disclosure of manufacturers' financial interest in the subject and that the use discussed was not FDA-approved.⁵⁴⁴

But the *WLF* story did not end there. The year before *WLF I*, Congress had passed the FDA Modernization Act of 1997 (FDAMA).⁵⁴⁵ The FDAMA did not address CME

⁵³³*Id.* at 71; *see also* *United States v. Rutherford*, 442 U.S. 544, 557–58 (1979).

⁵³⁴*WLF I*, 13 F. Supp. 2d at 69–70.

⁵³⁵*Id.* at 71.

⁵³⁶*Id.* at 72.

⁵³⁷*Id.*

⁵³⁸*Id.* at 73.

⁵³⁹*Id.*

⁵⁴⁰*Id.*

⁵⁴¹*Id.*

⁵⁴²*Id.*

⁵⁴³*Id.* at 74–75.

⁵⁴⁴*Id.* at 75.

⁵⁴⁵FDA Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296 (codified as §§ 551–557 of the Federal Food, Drug, and Cosmetic Act).

advertisement of off-label use, but it did have a provision directly addressing distribution of medical journals and textbooks discussing off-label uses. Such distribution was to be allowed so long as the manufacturer followed a list of six factors.⁵⁴⁶ The factors largely tracked the later order of the district court with one extra requirement: that the manufacturer, within six months of distributing the material, would file a supplemental NDA for the off-label use (and thereby incur the substantial clinical trial expenses required to do so).⁵⁴⁷ For this reason, few companies saw this as an attractive option.⁵⁴⁸

A few months after *WLF I*, the FDAMA provision with respect to distribution of scientific materials came into effect through implementing regulations.⁵⁴⁹ FDA requested that the court amend its injunction to clarify that it only applied to the FDA guidance documents, and not to the similar provisions in the FDAMA.⁵⁵⁰ The court declined, instead clarifying the opposite: that its decision “must be read to apply to the underlying policies of the FDA, and not merely to the express provisions of the Guidance Documents.”⁵⁵¹ The court then requested supplemental briefing squarely on the matter of whether the FDAMA and its implementing regulations were constitutionally valid.⁵⁵²

Later that year, the district court issued an opinion finding the FDAMA provision concerning distribution of scientific materials discussing off-label uses was not constitutionally valid.⁵⁵³ Once again the court applied *Central Hudson*, and its discussion of prongs one and two was largely similar to that in its previous decision.⁵⁵⁴ For the third prong, the court found that only the requirement that the manufacturers submit a NDA when distributing off-label use materials furthered the government’s interest in getting the use on-label.⁵⁵⁵ All other requirements served an interest in ensuring physicians would receive balanced information, but this interest was not substantial because it was (as decided in *WLF I*) rephrased paternalism.⁵⁵⁶ However,

⁵⁴⁶In order to distribute information with respect to off-label use, manufacturers had to show that: “(1) the drug was approved, (2) the information was not false or misleading; did not otherwise render the drug misbranded, was in the form of an unabridged reprint from a peer-review journal or reference publication, and would not pose a significant risk to public health, (3) the information was not derived from another manufacturer’s research (absent permission), (4) the manufacturer submitted the information to FDA 60 days before its distribution, (5) the manufacturer had submitted a supplemental NDA to FDA for approval of the use described (or certified that a supplemental NDA would be submitted within six months), and (6) the reprint included a prominent statement that the use had not been approved, a copy of the approved labeling, certain disclosures, a bibliography, and a statement if applicable that other products had been approved for the use discussed in the reprint.” PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 549 (Foundation Press 2007) (1980).

⁵⁴⁷*Id.*

⁵⁴⁸*Id.*

⁵⁴⁹Washington Legal Found. v. Friedman, 36 F. Supp. 2d 16, 19 (D.D.C. 1999) [hereinafter *WLF II*].

⁵⁵⁰*Id.* at 18. The provision at stake was FDA Modernization Act of 1997, Pub. L. 105-115, §401, 111 Stat. 2296 (codified as §§ 551–557 of the Federal Food, Drug, and Cosmetic Act). *Id.*

⁵⁵¹*Id.*

⁵⁵²*Id.* at 19.

⁵⁵³Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81, 82 (1999) [hereinafter *WLF III*].

⁵⁵⁴*Id.* at 84–86.

⁵⁵⁵*Id.* at 86–87.

⁵⁵⁶*Id.* at 86.

the surviving requirement—that manufacturers submit a NDA—amounted to “constitutional blackmail,” forcing manufacturers to “comply with the statute or sacrifice [their] First Amendment rights.”⁵⁵⁷ And it was more extensive than necessary to achieve the government’s interest, for the government had other, non-speech-restricting methods, available.⁵⁵⁸ The court finished by amending its previous order “to explicitly declare unconstitutional and unenforceable the FDAMA and its implementing regulations.”⁵⁵⁹ Commentary on the order stated how it “call[ed] into question many of FDA’s existing policies, . . . particularly where disclosure requirements may be substituted for more restrictive prohibitions,” and characterized it as “squarely reject[ing] FDA’s historical attempt to avoid First Amendment scrutiny when developing and applying restrictions on advertising and promotion.”⁵⁶⁰

FDA appealed the district court’s *WLF III* decision to the Court of Appeals for the District of Columbia and made a crucial strategy decision along the way. The government’s appellate position on FDAMA § 401 was that it provided no independent authority to proscribe speech.⁵⁶¹ Instead, FDA asserted that it was merely a “safe harbor” for manufacturers, who would not automatically be prosecuted for misbranding and promotion of off-label use if they did not comply with the Act’s requirements.⁵⁶² Rather, it functioned as a guarantee clarifying pre-existing legislative authority and ensuring that if manufacturers did comport with the Act, their conduct would not be unlawful.⁵⁶³ In light of this clarification, and since the challenge was a facial challenge to the statute and guidance documents (as opposed to a challenge to specific enforcement actions taken under the relevant policy), the court of appeals found that “no constitutional controversy between the parties . . . remain[ed] to be resolved” and declined to rule on a hypothetical application of the statute.⁵⁶⁴

After the Court of Appeal’s decision, FDA published its interpretation of its authority following *WLF IV* in the federal register in March 2000.⁵⁶⁵ As argued in the case, the FDA position remained that the FDAMA requirements constituted a safe harbor for manufacturers.⁵⁶⁶ But “[i]f a manufacturer does not comply, FDA may bring an enforcement action under the FDCA, and seek to use journal articles and reference texts disseminated by the manufacturer as evidence that an approved product is

⁵⁵⁷*Id.* at 87.

⁵⁵⁸*Id.* The court listed the following options as less speech-restricting: (1) banning prescribing drugs for off-label use; (2) prohibiting manufacturers from profiting from off-label prescriptions; (3) fining manufacturers for failing to seek supplemental NDAs; (4) upping enforcement of misbranding; (5) relying on alternate incentives for manufacturers to seek NDAs. *Id.*

⁵⁵⁹*Id.* FDA (as required by the order) then published the entire order in the Federal Register. *Order Granting Summary Judgment and Permanent Injunction*, 64 Fed. Reg. 44025 (Aug. 12, 1999).

⁵⁶⁰*Washington Legal Foundation Decision*, COVINGTON AND BURLING (July 30, 1999), <https://www.cov.com/-/media/files/corporate/publications/1999/07/oid6418.pdf> [<https://perma.cc/23MF-DMNL>].

⁵⁶¹*Washington Legal Found. v. Henney*, 202 F.3d 331, 332 (D.C. Cir. 2000) [hereinafter *WLF IV*].

⁵⁶²*Id.* at 335.

⁵⁶³*Id.*

⁵⁶⁴*Id.* at 336 (drawing authority from *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)).

⁵⁶⁵*Decision in Washington Legal Found. v. Henney*, 65 Fed. Reg. 14286 (Mar. 16, 2000).

⁵⁶⁶*Id.*

intended for a ‘new use.’”⁵⁶⁷ Additionally, with respect to dissemination of off-label use information at CMEs (which was not addressed in the FDAMA), FDA suggested that manufacturers “may wish to become familiar with the CME guidance document, which details the factors FDA intends to take into account in exercising its enforcement discretion,” even though the guidance document “does not itself have the force and effect of law.”⁵⁶⁸

Thus, six years after the WLF and FDA began the dispute, and after FDA had lost in all substance but won in technicality, it seemed the preferred approach of FDA was back to business as usual. The WLF filed yet another challenge in the district court, claiming FDA was violating the court’s order as applied in *WLF I* and *III*.⁵⁶⁹ The district court dismissed, declaring that “[s]ince the injunction has been wholly vacated by the Court of Appeals, there is nothing for the Notice to violate.”⁵⁷⁰ The district court was less than pleased:

After six years’ worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country’s drug manufacturers are still without clear guidance . . . This year, the Court of Appeals was poised to finally galvanize a rule of law in this area. Yet, for whatever reason, the opportunity was spent debating not the U.S. Constitution’s First Amendment, but its Article III case or controversy requirement.⁵⁷¹

The court then dismissed the issue but warned apocryphally that the rest would be only “temporary.”⁵⁷²

III.B.2. Caronia and Beyond

Following *WLF V*, the FDAMA lapsed in 2006.⁵⁷³ In 2009, FDA released new guidance on the issue that had been addressed by the FDAMA, namely, the distribution of scientific materials on off-label use.⁵⁷⁴ Its guidance liberalized the FDAMA approach in that it no longer explicitly required submission of an NDA for the off-label use.⁵⁷⁵ But unlike the FDAMA, compliance with FDA’s requirements no longer constituted an explicit safe harbor.⁵⁷⁶

The warning in *WLF V* proved prescient a decade later in the 2012 *Caronia* case in the Second Circuit.⁵⁷⁷ This time, FDA could not retreat to its “safe harbor” argument, because the case concerned an actual prosecution for promotion of off-label use—

⁵⁶⁷*Id.*

⁵⁶⁸*Id.*

⁵⁶⁹Washington Legal Found. v. Henney, 128 F. Supp. 2d 11, 13 (D.D.C. 2000) [hereinafter *WLF V*].

⁵⁷⁰*Id.* at 15.

⁵⁷¹*Id.* at 16.

⁵⁷²*Id.* at 17.

⁵⁷³HUTT, *supra* note 5, at 549.

⁵⁷⁴FOOD & DRUG ADMIN., *Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, 74 Fed. Reg. 1694 (Jan. 13, 2009).

⁵⁷⁵*Id.*

⁵⁷⁶*Id.*

⁵⁷⁷United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).

specifically, a prosecution for conspiracy to introduce a misbranded drug into interstate commerce, where promotion of off-label use was evidence of distribution without adequate instructions for use, and thus distribution of a misbranded drug.⁵⁷⁸

The pharmaceutical in question was the drug Xyrem, which operated as a central nervous system depressant.⁵⁷⁹ Potential side effects of Xyrem included confusion, difficulty breathing while asleep, depression, nausea and vomiting, and even, if abused, seizures and death.⁵⁸⁰ For this reason, FDA approved it for treatment of narcolepsy but required a severe “black box” warning and limited its distribution to only one pharmacy in order to better track patients suffering from side effects.⁵⁸¹ A 2005 federal investigation concerning off-label promotion of Xyrem produced taped conversations between Caronia, a pharmaceutical sales consultant, and a physician, who unbeknownst to Caronia was working with the government, in which Caronia discussed unapproved uses for Xyrem.⁵⁸² Caronia also recommended the drug for populations under sixteen (for which, as the black box warning stated, there was little clinical evidence concerning) and characterized Xyrem as “a very safe drug.”⁵⁸³

As the Second Circuit described it, at trial “the government’s theory of prosecution identified Caronia’s speech alone as the proscribed conduct.”⁵⁸⁴ Even the jury instructions referred to Caronia’s promotional speech, stating that a “misbranded drug may be shown by a promotion of the drug by a distributor for an intended use different from the use for which the drug was approved by the [FDA].”⁵⁸⁵ After a jury trial, Caronia was found guilty of conspiracy to introduce or deliver for introduction into interstate commerce a drug that was misbranded, and sentenced to one year of probation, 100 hours of community service, and a \$25 special assessment.⁵⁸⁶ Caronia appealed to the Second Circuit.⁵⁸⁷

Just as it had argued a decade earlier in *WLF I*, FDA’s first argument was that the First Amendment was not involved at all. This time, the argument was that because the speech was not prohibited under the FDCA, Caronia was not prosecuted for his speech at all.⁵⁸⁸ Instead, the speech was simply offered as evidence of intent—evidence that Caronia intended Xyrem to be used for purposes for which the labeling did not have instructions, causing the drug to fulfil the definition of misbranding.⁵⁸⁹ The Second Circuit dismissed this contention as “belied by [the government’s] conduct and arguments at trial,” which “confirms overwhelmingly that Caronia was, in fact, prosecuted and convicted for promoting Xyrem off-label.”⁵⁹⁰ The court

⁵⁷⁸*Id.* at 152.

⁵⁷⁹*Id.* at 155.

⁵⁸⁰*Id.*

⁵⁸¹*Id.*

⁵⁸²*Id.* at 156.

⁵⁸³*Id.* at 155–57.

⁵⁸⁴*Id.* at 159.

⁵⁸⁵*Id.*

⁵⁸⁶*Id.* at 159.

⁵⁸⁷*Caronia*, 703 F.3d at 152.

⁵⁸⁸*Id.* at 160.

⁵⁸⁹*Id.* at 160–61.

⁵⁹⁰*Id.* at 161.

concluded that Caronia's speech was "speech in aid of pharmaceutical marketing," which the Supreme Court had protected one year earlier in *Sorrell v. IMS Health*.⁵⁹¹

The Second Circuit then turned to analyzing the speech restriction. First, the court found that the criminalizing of off-label promotion was content- and speaker-based, and as such under *Sorrell*'s analysis it was subject to heightened scrutiny though the *Central Hudson* test.⁵⁹² Second, the court applied *Central Hudson*: (1) promotion of off-label drug use concerned lawful activity and was not in and of itself false or misleading; (2) the government's interests in drug safety and public health were substantial; but (3) the prohibition on off-label promotion did not directly advance the interest, and only directly advanced it in the disallowed paternalistic sense of limiting physicians' access to information; and (4) the prohibition was not narrowly drawn, because several non-speech-restricting methods remained untried.⁵⁹³ The court listed several potential strategies for FDA: directly regulating or prohibiting certain off-label uses; developing warning or disclaimer systems for physicians; developing a system of safety tiers to distinguish between drugs in the off-label market; or creating ceilings or caps on off-label prescriptions.⁵⁹⁴ As the court was ostensibly relying on the canon of constitutional avoidance, which here mandated interpreting the FDCA so as to avoid a potential First Amendment problem, the court concluded that it would "construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs" and thus "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."⁵⁹⁵

Commentary after the Second Circuit *Caronia* decision viewed it as a victory for pharmaceutical companies, stating that the case "hits at the heart of the government's theory [of regulation of off-label promotion]" and predicting that, in the future, FDA would be restricted to focusing only "on the kinds of speech that are more likely to harm consumers, such as false or misleading marketing."⁵⁹⁶ Commentary also mentioned that FDA might seek to continue the litigation by asking for a rehearing *en banc* or for Supreme Court review.⁵⁹⁷ Some commentary criticized the outcome, believing that the interest in protecting the health of the American public outweighed the tangential First Amendment considerations in this factual context.⁵⁹⁸ But other

⁵⁹¹*Id.* at 162; *see generally Sorrell*, 564 U.S. at 557.

⁵⁹²*Caronia*, 703 F.3d at 164–65.

⁵⁹³*Id.* at 165–68.

⁵⁹⁴*Id.* at 168.

⁵⁹⁵*Id.* at 162, 169 ("To the extent there is any ambiguity as to whether off-label promotion is tantamount to illegal misbranding, we construe the FDCA narrowly to avoid a serious constitutional question [W]e decline the government's invitation to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction . . . would run afoul of the First Amendment.").

⁵⁹⁶Thomas Sullivan, *The Impact of Caronia Case: What Happens Next?*, POLICY & MEDICINE (Jan. 17, 2013), <http://www.policymed.com/2013/01/the-impact-of-caronia-case-what-happens-next.html> [<https://perma.cc/2KT4-KHU4>]; Katie Thomas, *Ruling Is Victory for Drug Companies in Promoting Medicine for Other Uses*, N.Y. TIMES (Dec. 3, 2012), <http://www.nytimes.com/2012/12/04/business/ruling-backs-drug-industry-on-off-label-marketing.html> [<https://perma.cc/S7MH-SHV3>].

⁵⁹⁷Sullivan, *supra* note 596.

⁵⁹⁸*Second Circuit Holds That Prohibiting Truthful Off-Label Promotion of FDA-Approved Drugs by Pharmaceutical Representatives Violated First Amendment*, 127 HARV. L. REV. 795, 802 (2012) ("The First

commentary argued that nothing much would change, as FDA already tended to target false or misleading promotion, the recoveries tended to be large and settled outside of courts, and the opinion was only binding at the time in the Second Circuit.⁵⁹⁹

It was this last prediction that proved true: FDA's approach was to once again return to business as usual. The case was constrained to its facts and interpreted at its word: it would apply only to simple off-label promotion, *i.e.*, situations in which a representative would be charged for her speech alone.⁶⁰⁰ The post-*Caronia* approach was to go after cases of speech *plus* some other form of misconduct, *e.g.*, speech plus false claims, or speech plus alleged kickback schemes.⁶⁰¹ And manufacturers continued settling with FDA rather than asserting a First Amendment defense, for waging a court battle brings with it a risk of “the kind of corporate indictment that is a disaster for a corporation”—alienating shareholders, affecting stock price, and potentially resulting in conviction and debarment.⁶⁰² Guidance from FDA maintained the previous position—that a manufacturer could distribute journal articles discussing off-label use so long as it disclosed clearly that FDA had not approved the off-label use.⁶⁰³

In 2015 the manufacturer Amarin did in fact choose to assert a First Amendment defense to an FDA misbranding allegation.⁶⁰⁴ Amarin's drug Vascepa was approved by FDA for treating adult patients with extremely high triglyceride levels, but not for patients with moderately, but persistently, high triglyceride levels.⁶⁰⁵ FDA denied Amarin's application for this second use because studies had demonstrated that the drug significantly reduced triglyceride levels, but had not shown that these reduced levels reduced the risk of cardiovascular events.⁶⁰⁶ FDA stated in its response letter to Amarin that the drug Vascepa “may be considered to be misbranded” if Amarin marketed using the results of the trial “before approval of [a] supplemental

Amendment can, and should, accommodate reasonable restraints on off-label promotion in support of legitimate regulatory objectives.”)

⁵⁹⁹Veronica Nannis, *What Effect Will United States v. Caronia Have On Civil Off-Label Cases?*, ABA HEALTH ESOURCE (Apr. 2013), https://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1304_nannis.html [<https://perma.cc/KY6Z-LJ3H>]; *see also Abbot Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, UNITED STATES DEPARTMENT OF JUSTICE (May 7, 2012), <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html> [<https://perma.cc/R2HY-YEYJ>].

⁶⁰⁰*Caronia*, 703 F.3d at 169; Thomas Sullivan, *US v. Caronia, One Year Later: FDA's Position on Off-Label Promotion Remains the Same, But Changes are Looming*, POLICY & MEDICINE (May 6, 2018), <http://www.policymed.com/2014/02/us-v-caronia-one-year-later-fdas-position-on-off-label-promotion-remains-the-same-but-changes-are-looming.html> [<https://perma.cc/QT8X-P5BD>].

⁶⁰¹Sullivan, *supra* note 596.

⁶⁰²Robert Radick, *Caronia And The First Amendment Defense to Off-Label Marketing: A Six-Month Re-Assessment*, FORBES (May 29, 2013), <https://www.forbes.com/sites/insider/2013/05/29/caronia-and-the-first-amendment-defense-to-off-label-marketing-a-six-month-re-assessment/#ecaa05a380e4> [<https://perma.cc/N34W-MPD7>].

⁶⁰³*Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices*, FOOD AND DRUG ADMINISTRATION (Feb. 2014), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf> [<https://perma.cc/JY4N-8C4R>].

⁶⁰⁴Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 212 (S.D.N.Y. 2015).

⁶⁰⁵*Id.* at 209.

⁶⁰⁶*Id.* at 211–12.

application.”⁶⁰⁷ Amarin brought suit in the Southern District of New York and sought a preliminary injunction prohibiting FDA from bringing a misbranding case against it for making statements to doctors about the results of the study.⁶⁰⁸ After the parties failed to reach an agreement, the district court held arguments and then decided to grant the injunction.⁶⁰⁹

The court disagreed with FDA’s position “that the Second Circuit’s [*Caronia*] ruling was limited to the fact of *Caronia*’s particular case.”⁶¹⁰ Instead the court found that “under *Caronia*, FDA may *not* bring such an action” of misbranding based on truthful and non-misleading speech evincing the intent to promote an off-label use “consistent with the First Amendment.”⁶¹¹ The court rejected FDA’s argument that deciding in this way would “eviscerate [the] FDA drug approval regime,” stating that the regime predated modern First Amendment commercial speech law but must be judged by today’s standards.⁶¹² The court also rejected FDA’s argument (as in *Caronia*) that the speech would only be used to prove *intent*, because the situation at issue was the *act* of promoting off-label use via truthful, non-misleading speech, and that was what *Caronia* protected.⁶¹³

However, the district court did leave the manufacturer with a word of warning, recommending that it work with FDA, consider FDA guidance, and vet its sales force’s scripts in advance:

[A manufacturer giving its promoters discretion to] converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (*e.g.*, one-sided or incomplete) representations result. *Caronia* leaves FDA free to act against such lapses Prior consultation with FDA may prove a helpful prophylactic, and may avert misbranding charges where FDA and the manufacturer would take different views of a statement. In the end, however, if the speech at issue is found truthful and non-misleading, under *Caronia*, it may not serve as the basis for a misbranding action.⁶¹⁴

The court finished by considering the particular communications that Amarin proposed to make to doctors regarding the off-label use of Vascepa and concluding that with full disclosure they would be truthful and non-misleading, and thus protected by the First Amendment against a misbranding prosecution under *Caronia*.⁶¹⁵

In September 2016, FDA announced that it would be holding a two-day public hearing in November 2016 to seek input on its review of regulations and policies regarding communications about unapproved use of medical products—an issue that

⁶⁰⁷*Id.* at 212.

⁶⁰⁸*Id.* at 215.

⁶⁰⁹*Id.* at 215–19, 237.

⁶¹⁰*Id.* at 224.

⁶¹¹*Id.*

⁶¹²*Id.* at 226 (referring to framework set up in 1962).

⁶¹³*Id.* at 227–28.

⁶¹⁴*Id.* at 228–29.

⁶¹⁵*Id.* at 229–38.

includes off-label use of medical drugs.⁶¹⁶ After the meeting, FDA held the docket open through January 9, 2017 for comments.⁶¹⁷ But on January 19, 2017, FDA reopened the docket through April 19, 2017 to ensure sufficient discussion of First Amendment considerations.⁶¹⁸ FDA also released a memorandum intended to clarify its First Amendment views—and which demonstrated that these views remained essentially unchanged.⁶¹⁹

In the memorandum, FDA identified its key concern behind maintaining control over the approval process and minimizing off-label use: in the premarket approval process, FDA “considers whether the established health benefits of the product for a particular use outweigh the identified risks of the product . . . [A] product considered safe in one setting might not be considered safe in another setting.”⁶²⁰

Though this goal is a sympathetic and noble one, the role of government in furthering this goal through the limiting of marketing speech was implicitly rejected in *Thompson v. Western States Medical Center*, the case that considered drug compounding regulations.⁶²¹ Justice Breyer in dissent in *Thompson* had proposed the governmental interest in separating out the cases where compounding was *necessary* from cases where compounding was *convenient*.⁶²² The government should regulate the latter cases, he proposed, because they posed a great chance of doing more harm than good.⁶²³ Justice O’Connor’s majority characterized this approach as the forbidden paternalism approach—the government’s ban on advertising for compounded drugs was a ban on information due to fear of its effects on the recipients.⁶²⁴ As applied to advertisement of off-label drug use, FDA memorandum’s argument is that it must separate the cases where off-label use is necessary from those for which it is convenient, for in the latter ones the harm is likely to outweigh the benefit. This is true,

⁶¹⁶*Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Request for Comments*, 81 Fed. Reg. 60299 (Sept. 1, 2016).

⁶¹⁷*Id.*

⁶¹⁸*Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Availability of Memorandum; Reopening of the Comment Period*, 82 Fed. Reg. 6367 (Jan. 19, 2017). That this was the day before an administration change is likely not a coincidence.

⁶¹⁹*Memorandum from the FDA on Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products* (Jan. 2017) [hereinafter Jan. 2017 First Amendment Memo]. See also *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, 2209 (Jan. 9, 2017) (stating that the “FDA is separately examining . . . broader policy questions and the related First Amendment issues,” repeating much the same criticisms of *Caronia* and *Amarin* as in the Jan. 2017 First Amendment Memo, and asserting that current policy is constitutional); see generally *Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”*; *Proposed Partial Delay of Effective Date*, 83 Fed. Reg. 2092, 2093 (Jan. 16, 2018) (stating that as of January 2018 the rule on Tobacco Products had been delayed until March 19, 2018 based on, *inter alia*, First Amendment concerns). This may demonstrate a partial shift in the Trump Administration FDA’s views.

⁶²⁰Jan. 2017 First Amendment Memo, *supra* note 619, at 2–3.

⁶²¹*Thompson*, 535 U.S. at 357.

⁶²²*Id.* at 379–80 (Breyer, J., dissenting).

⁶²³*Id.* at 380.

⁶²⁴*Id.* at 374.

but *Thompson* seems to foreclose FDA's ability to use speech restrictions to accomplish this task.⁶²⁵

FDA memorandum went on to defend its policies as motivating studies that produce safety and efficacy data, preventing harm to the public by protecting against misrepresentation, bias, and the diversion of resources toward ineffective treatments, and ensuring labeling is complete and accurate, as well as a host of secondary benefits.⁶²⁶ It characterized its past approach to communication of unapproved uses of approved medical products as generous, referring to its 2014 guidance allowing distribution of medical journal articles (as would have been required by the *WLF I* injunction 14 years earlier), its position on communications at CME seminars (referring to the 1997 guidance document that was found unconstitutional by the *WLF I* court), and its longstanding position that manufacturers could respond to unsolicited requests for information.⁶²⁷ The memorandum asserted that notwithstanding *Amarin*, FDA practice was not to directly restrict speech, but to use speech to demonstrate intent to introduce misbranded products into interstate commerce.⁶²⁸ *Caronia* itself, the memorandum continued, was limited to the particular factual situation and did not evaluate FDA's general approach.⁶²⁹ Further, the *Caronia* decision failed to evaluate all of the public health interests at stake, and "did not have the benefit of considering the significant findings" of a 2016 study that found association between unapproved uses and adverse drug events.⁶³⁰

The memorandum continued by asserting that, contrary to the *Caronia* court's analysis, FDA's use of speech was not speaker- or content-based, because it was being used for purposes of demonstrating intent.⁶³¹ But "alternatively, even if these restrictions on firm activity were viewed as commercial speech restrictions, they are necessarily both speaker- and content-based as part of a reasonable government regulation of particular industries in the interest of the greater public good."⁶³² For this last point, the memorandum cited the dissents from *Sorrell* and *Caronia*.⁶³³ The memorandum concluded by listing 12 alternate, less-speech-restricting, approaches that had been suggested by courts and by commentators, and systematically rejecting each approach.⁶³⁴

III.B.3. *The Speech as Intent Theory*

FDA's theory that prosecution for off-label promotion does not violate the First Amendment because speech is not criminalized but instead offered as evidence of

⁶²⁵See *Thompson*, 535 U.S. at 374; see also *Becerra*, 138 S. Ct. at 2376 ("[T]he First Amendment does not permit the State to sacrifice speech for efficiency") (quoting *Riley*, 487 U.S. at 795).

⁶²⁶Jan. 2017 First Amendment Memo, *supra* note 619, at 3–16.

⁶²⁷*Id.* at 20–21.

⁶²⁸*Id.* at 22.

⁶²⁹*Id.* at 23.

⁶³⁰*Id.* at 23–24.

⁶³¹*Id.* at 24.

⁶³²*Id.* at 24–25.

⁶³³*Id.* at 25, n.82; see *44 Liquormart*, 517 U.S. at 516; *New Orleans Broad.*, 527 U.S. at 185–87 (rejected the notion that thoroughly regulated industries have lesser speech rights); accord *Becerra*, 138 S.Ct. at 2375 (rejecting the idea that "professional speech" has lesser protection).

⁶³⁴*Id.* at 26–34.

intent bears further explaining because—though seemingly rejected in *Caronia* and *Amarin*—FDA has seen some recent success with this theory. The theory draws support from *Wisconsin v. Mitchell*, a case in which the Court unanimously upheld a Wisconsin statute that increased the penalty for an offense if a victim was selected due to their race; in Mitchell’s case his speech was used as evidence that he had done so when he encouraged his friends to beat a white boy and steal his shoes.⁶³⁵ The Wisconsin statute targeted not speech but instead “bias-inspired conduct.”⁶³⁶ “The First Amendment,” stated Justice Rehnquist, “does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.”⁶³⁷

The intent theory as described by Christopher Robertson states that:

[Targeting off-label promotion] can be understood as a classic regulation of conduct (actus reus) with a mens rea (intent) element [T]he product may be sold in interstate commerce without this illicit intent (intending that it be used for an approved purpose or for some other nondrug purpose altogether), and avoid criminal liability. In such cases, there is actus reus (sale) without illicit mens rea (intent for an unapproved use), and thus no crime. And likewise, those who speak, encouraging the use of a given drug for unapproved purposes, but do not sell it in interstate commerce, face no criminal liability. In such cases, there may be a mens rea but no actus reus, and thus no crime. The speech, on this theory, is not regulated whatsoever; the government regulates only acts with specific intent. The speech simply serves as evidence revealing a criminal intent, *i.e.*, that the product be used for an unapproved purpose.⁶³⁸

Confusion on the topic seems to stem from a conflation of two different concepts. At first level there is the specific promotional activity that is used to promote a drug for off-label use. At second level there is the theory for why off-label promotion itself is illegal. This theory can be simplified to the fact that “any labeling for prescription drugs must disclose all intended uses; otherwise, the product is misbranded.”⁶³⁹ However, properly labeling with an intended use requires the expensive process of bringing a use “on-label,” or it too violates the statute.⁶⁴⁰

In *Mitchell*, the first level was the racially-tinged speech. The second level was the aggravated battery—*i.e.*, conduct. Thus, what was actually targeted was conduct, with the effects on speech taking a backseat.⁶⁴¹ For off-label promotion, the first level is the

⁶³⁵*Wisconsin v. Mitchell*, 508 U.S. 476, 480 (1993).

⁶³⁶*Id.* at 487.

⁶³⁷*Id.* at 489.

⁶³⁸Robertson, *supra* note 514, at 1031–32.

⁶³⁹Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. ONLINE 124, 131 (2016).

⁶⁴⁰*Id.* at 132.

⁶⁴¹See *Becerra*, 138 S.Ct. at 2372–73 (characterizing an informed-consent requirement as “regulation of professional conduct” that “incidentally involves speech”); *Expressions Hair Design*, 137 S.Ct. at 1150–51 (stating that a law with an impact on speech that is “only incidental to its primary effect on conduct” does not receive First Amendment protections); *Sorrell*, 564 U.S. at 567 (“[T]he First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech.”); Jeffrey Chasnow & Geoffrey Levitt, *Off-Label Communications: The Prodigal Returns*, 73 FOOD & DRUG L. J. 257, 264 (2018).

specific promotional activity. But the second level—the substantive core of the crime—hinges on what is on the labeling of the drug—*i.e.*, speech. Thus, with off-label promotion, both the speech that is used as evidence of intent *and* the crime for which intent must be shown are speech-related. Yet courts considering the question have focused on the role of the off-label promotional speech rather than considering the underlying question of whether FDA can constitutionally enforce its misbranding provisions at all. As Jane Bambauer notes, “*Caronia* has exposed the uncomfortable fact that much of FDA’s work is geared toward regulating information, not products.”⁶⁴²

Neither industry nor FDA has an incentive to test the constitutionality of the misbranded drug theory, however. The industry lacks incentive because asking a court to declare merely a marketing practice protected is a much surer deal than asking a court to question the constitutionality of the theories underlying FDA’s entire premarket approval process, while FDA is also less than eager to roll the same die due to the stakes involved. But the simpler question being asked seems inextricably bound to the harder question being avoided.⁶⁴³ And, as both the industry and FDA seem to sense, it is not at all clear how the harder question would come out.⁶⁴⁴

Nevertheless, FDA has scored several recent partial victories using its speech as intent theory. In February 2016, a jury acquitted the CEO of Vascular Solutions (“VSI”) in a trial regarding marketing of a medical device for an unapproved use—a closely related issue to marketing of a drug for an off-label use.⁶⁴⁵ The judge gave jury instructions to the effect that truthful and nonmisleading promotional speech, even about unapproved uses, would not violate the law.⁶⁴⁶ However, the court also stated that FDA would be allowed to prove a misbranding violation by relying on conduct, and that speech could be used as an overt act required for a conspiracy.⁶⁴⁷ Though

⁶⁴²Jane R. Bambauer, *Snake Oil Speech*, 92 WASH. L. REV. 73, 106 (2017).

⁶⁴³Robertson, *supra* note 514, at 1025 (“If it were problematic for the law to use speech as evidence of intent, it would seem to undermine the entire premarket approval regime.”). Robertson notes that arguments supporting a constitutional defense to off-label promotion would also support a constitutional defense to no-label promotion (*i.e.*, a new use for a product that was not previously approved for any medical use). Such a defense would protect advertisers such as Louis Smith, who was convicted in May 2015 of selling what was essentially an industrial-strength bleach—an otherwise legal product—as a cure for, *inter alia*, cancer, AIDS, and the common cold. *Id.* at 1029. Examples such as this support a *reductio* argument for upholding restrictions for both off-label and no-label promotion.

⁶⁴⁴Striking the foundations of FDA’s preapproval regime would bring into question much of federal regulatory law. *See generally* Robertson, *supra* note 514; Shanor, *supra* note 73.

⁶⁴⁵*U.S. v. Vascular Solutions, Inc.*, No. 5:14-CR-00926 (W.D. TX. Feb. 26, 2016).

⁶⁴⁶The jury instructions included the reminder: “It is [] not a crime for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI’s promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.” Jennifer Newberger, *Another Court Weighs in on Whether Off-Label Promotion is Per Se Illegal; Jury Finds Both Defendants Not Guilty on All Counts*, FDA LAW BLOG (Feb. 27, 2016), <http://www.fdalawblog.net/2016/02/another-court-weighs-in-on-whether-off-label-promotion-is-per-se-illegal-jury-finds-both-defendants/> [<https://perma.cc/9EQK-TL6S>].

⁶⁴⁷Lynn C. Tyler, *U.S. v. Facticeau: Will FDA’s Partial Victory Hold Up?*, TOP FOOD AND DRUG CASES, 2016 & CASES TO WATCH, 2017 3, 9 (2017), <https://www.fdi.org/wp-content/uploads/2017/05/Top-Cases-2016-17.pdf> [<https://perma.cc/JF99-6NE7>].

partially winning on the law, FDA eventually lost on the facts when the jury acquitted VSI and its CEO.⁶⁴⁸

In summer 2016, FDA finally received a win after a jury found the defendant in *U.S. v. Facticeau* guilty of two misdemeanor counts—causing the introduction of an adulterated device into interstate commerce and the same for a misbranded device.⁶⁴⁹ The court largely adopted FDA’s speech as intent theory, as shown in the jury instructions:

The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded [T]o convict, there must be a criminal act. Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.⁶⁵⁰

Thus, the skirmishes between industry and FDA have produced mixed results with no clear winner, though commentary has noted that FDA has the upper hand through the deterrent effect the legal fees and potential criminal penalties can have and has stated that “the first amendment still appears to be better deployed as a shield after a company’s employee(s) have gone astray (despite thorough training) than as a sword with which to blaze a trail of off-label promotion.”⁶⁵¹

FDA’s approach may have scored partial wins in a few district courts, but it has also scored losses in several district and circuit courts. After each circuit court loss, FDA has chosen not to appeal to the Supreme Court. But despite these strategic choices, FDA has afterwards portrayed decisions as incorrectly decided, or at least as constrained to the particular facts of the case. FDA’s approach is unsustainable over the long term, because even should the speech as intent theory become accepted, it still invites an eventual challenge to FDA’s entire theory of misbranding. As Justice Breyer stated in *Sorrell* in reference to, *inter alia*, the premarket approval process and related marketing restrictions, “[n]o one has yet suggested that substantial portions of federal drug regulation are unconstitutional.”⁶⁵² And yet he was dissenting on behalf of only three justices. Preserving the integrity of the drug and medical device approval process may very well be a substantial or compelling governmental interest, but that is a game of Russian roulette FDA should feel uncomfortable playing given the Roberts Court’s pro-business leanings.⁶⁵³

⁶⁴⁸*Id.*; see also Varun Saxena, *FDA loss in Vascular Solution off-label promotion case foreshadowed Amarin settlement*, FIERCE BIOTECH (Mar. 9, 2016), <https://www.fiercebiotech.com/medical-devices/fda-loss-vascular-solution-off-label-promotion-case-foreshadowed-amarin-settlement> [<https://perma.cc/UQ5C-VC4K>].

⁶⁴⁹*U.S. v. Facticeau*, No. 1:15-CR-10076-ADB (D. Mass. Aug. 22, 2016); Tyler, *supra* note 647, at 10. The convictions were misdemeanors because the jury found that the defendants did not have the intent to defraud or mislead in committing the crimes.

⁶⁵⁰Tyler, *supra* note 647, at 9–10.

⁶⁵¹*Id.* at 11.

⁶⁵²*Sorrell v. IMS Health Inc.*, 564 U.S. 552, 586, 598 (2011) (Breyer, J., dissenting).

⁶⁵³See, e.g., Jedediah Purdy, *The Roberts Court v. America*, DEMOCRACY (2012), <https://democracyjournal.org/magazine/23/the-roberts-court-v-america/> [<https://perma.cc/D8QV-Z8BV>]; John C.

It is true that FDA has the crucial policy objective of protecting the health of Americans, and the monumental task of regulating the safety and efficacy of the medical drug and equipment fields. But First Amendment jurisprudence has evolved since FDA's approach was first laid out in 1962, and it is time for FDA to seek new ways of fulfilling its objectives while more fully accommodating the speech rights of the industries it regulates.⁶⁵⁴

III.C. Graphic Cigarette Label Warnings

In 1996, FDA, via rulemaking, asserted jurisdiction under the FDCA to regulate tobacco products.⁶⁵⁵ The basis for this jurisdiction was the theory that nicotine is a drug (as it is intended to affect the structure or function of the body) and cigarettes are thus drug delivery devices.⁶⁵⁶ The United States Supreme Court disagreed.⁶⁵⁷ Based on the reasoning that the tobacco products did not fit within the FDCA's regulatory scheme (as the FDCA read literally would require them to be banned), and drawing inferences from Congress' post-FDCA tobacco-specific legislation (which did not grant authority to FDA), Justice O'Connor concluded in *FDA v. Brown & Williamson Tobacco* that "Congress intended to exclude tobacco products from the FDA's jurisdiction."⁶⁵⁸

But *Brown & Williamson* was merely the first round. In 2009, Congress passed and President Obama signed the Family Smoking Prevention and Tobacco Control Act ("Tobacco Act").⁶⁵⁹ Its express purpose was to amend the FDCA in order "to provide authority to the Food and Drug Administration to regulate tobacco products."⁶⁶⁰ The Tobacco Act required new warning labels on cigarette packages to "comprise the top 50 percent of the front and rear panels."⁶⁶¹ Additionally, the Tobacco Act required that "[no] later than 24 months after June 22, 2009, [FDA] shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the [warning statements]."⁶⁶²

FDA followed this directive by proposing 36 potential graphics for new warning labels and asking for public comment in late 2010.⁶⁶³ FDA also conducted an internet survey, which measured the graphics along three dimensions: (1) whether they increased intention to quit smoking; (2) whether they increased knowledge of the health risks of smoking; and (3) whether they were salient, defined as whether they

Coates IV, *Corporate Speech & the First Amendment: History, Data, and Implications*, 30 CONST. COMMENT. 223, 223–24 (July 8, 2015).

⁶⁵⁴See *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 226 (S.D.N.Y. 2015).

⁶⁵⁵*Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44396 (Aug. 28, 1996), 21 C.F.R. 801, 803, 804, 807, 820, 897.

⁶⁵⁶*Id.*

⁶⁵⁷*Food and Drug Admin. v. Brown and Williamson Tobacco Corp.*, 529 U.S. 120, 120 (2000).

⁶⁵⁸*Id.* at 142, 156.

⁶⁵⁹Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (2009).

⁶⁶⁰21 U.S.C. § 387 Note; Purpose (Pub. L. No. 111–31, Div. A, § 3).

⁶⁶¹15 U.S.C. § 1333(a)(2).

⁶⁶²15 U.S.C. § 1333(d).

⁶⁶³*Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (June 22, 2011).

caused viewers to feel “discouraged” or “afraid.”⁶⁶⁴ The following year, FDA promulgated final regulations requiring nine of the images to be displayed on cigarette packages along with the new warning statements.⁶⁶⁵

Five tobacco companies sued FDA claiming violation of their First Amendment rights specifically for the matter of the graphic warning labels, and won on summary judgment in district court.⁶⁶⁶ FDA appealed the district court’s ruling to the D.C. Circuit in *R.J. Reynolds v. FDA* in late 2012.⁶⁶⁷ In an opinion by Circuit Judge Janice Brown, the D.C. Circuit affirmed the district court’s grant of summary judgment for the tobacco companies.⁶⁶⁸

“This case contains elements of compulsion and forced subsidization,” began the opinion, citing *Wooley v. Maynard* (compelled speech) and *United Foods* (compelled subsidization of non-governmental speech).⁶⁶⁹ The threshold question was the applicable level of scrutiny “when [the government] seeks to compel a product’s manufacturer to convey the state’s subjective—and perhaps even ideological—view that consumers should reject [an] otherwise legal, but disfavored, product.”⁶⁷⁰ The court stated that while the background level on content-based restrictions (including compelled speech, as here) is strict scrutiny, in the commercial speech context, restrictions on speech are subject to *Central Hudson*’s intermediate scrutiny and purely factual and uncontroversial disclosures are subject to a form of rational basis review, *i.e.*, they must be reasonably related to preventing consumer deception under *Zauderer*.⁶⁷¹

The court rejected FDA’s argument that *Zauderer*’s low level of scrutiny should apply, characterizing precedent as establishing that disclosure requirements are “only appropriate if the government shows that, absent a warning, there is a self-evident—or at least ‘potentially real’—danger that an advertisement will mislead consumers.”⁶⁷² As opposed to the factual and uncontroversial information required in *Zauderer*, the images were “a much different animal” because many could be misinterpreted by consumers, several “do not convey *any* warning information at all,” and the images overall were “inflammatory[,] . . . unabashed attempts to evoke emotion . . . and browbeat consumers into quitting.”⁶⁷³ After rejecting *Zauderer* as a test, the court determined (following circuit precedent) that the appropriate level of scrutiny to apply

⁶⁶⁴*Id.* Salient is more traditionally defined as “standing out conspicuously” or “of notable significance.” *Salient*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/salient> [<https://perma.cc/8WPU-HKJZ>].

⁶⁶⁵*Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (June 22, 2011).

⁶⁶⁶*R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266 (D.D.C. 2012).

⁶⁶⁷*R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

⁶⁶⁸*Id.* at 1208.

⁶⁶⁹*Id.* at 1211.

⁶⁷⁰*Id.* at 1212.

⁶⁷¹*Id.*

⁶⁷²*Id.* at 1214.

⁶⁷³*Id.* at 1216–17.

to the compelled commercial speech would be *Central Hudson* intermediate scrutiny.⁶⁷⁴

The court was skeptical that FDA's only asserted interest, reducing smoking rates, could be considered substantial given that such an interest amounted to "discouraging consumers from purchasing a lawful product, even [though it is] one that has been conclusively linked to adverse health consequences."⁶⁷⁵ However, given the fact that the Supreme Court had called smoking "perhaps the single most significant threat to public health in the United States" in *Brown & Williamson*, the court was willing to assume the interest was substantial.⁶⁷⁶ But even then, the court found that FDA had failed to offer substantial evidence that the graphic warnings directly advanced the interest to a material degree, instead faulting FDA for "not provid[ing] a shred of evidence" demonstrating the graphics would reduce American smoking rates and leaning on amorphous "international consensus" rather than actual evidence.⁶⁷⁷

Circuit Judge Judith Rogers in dissent would have found the warning labels justified under *Zauderer* as factually accurate information aimed at addressing misleading commercial speech.⁶⁷⁸ She also faulted the majority for too readily dismissing FDA's asserted interest in conveying information about the negative health consequences of smoking to consumers (for which the majority had described as too vague to justify the labels, and further found that the labels extended beyond conveying such and into ideological territory).⁶⁷⁹

In March 2013, Attorney General Eric Holder announced that FDA would not appeal the D.C. Circuit's opinion to the Supreme Court.⁶⁸⁰ Instead, FDA would "undertake research" to propose alternate graphic labels, which if challenged in the future "will [present] an opportunity to seek full Supreme Court review at that time."⁶⁸¹

But no new graphic labels were suggested, and the provision of the Tobacco Act requiring the labels has remained unenforced ever since. In 2016, a study provided the evidence the D.C. Circuit found missing in *Reynolds*—evidence that graphics help

⁶⁷⁴*Id.* at 1217. The circuit precedent mentioned also concerned compelled disclosure (of corrective statements) by tobacco companies. *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095 (D.C. Cir. 2009). The Supreme Court has never squarely addressed compelled commercial speech generally, only addressing compelled commercial disclosure in *Zauderer* and compelled commercial funding of private speech in *United Foods* and of government speech in *Johanns*. For views of circuits other than the D.C. Circuit on the question of compelled commercial speech, see *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509 (6th Cir. 2012); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006).

⁶⁷⁵*R.J. Reynolds*, 696 F.3d at 1218 n.13.

⁶⁷⁶*Id.* (citing *Williamson*, 529 U.S. at 161).

⁶⁷⁷*R.J. Reynolds*, 696 F.3d at 1219. *Cf.* *AFL-CIO v. FEC*, 33 F.3d 169, 175 (D.C. Cir. 2003) (applying no *Chevron* deference to an agency decision when it implicates First Amendment rights).

⁶⁷⁸*R.J. Reynolds*, 696 F.3d at 1222 (Rogers, J., dissenting).

⁶⁷⁹*Id.* at 1223 (Rogers, J., dissenting).

⁶⁸⁰*FDA's graphic cigarette labels rule goes up in smoke after U.S. abandons appeal*, CBS NEWS (Mar. 19, 2013), <https://www.cbsnews.com/news/fdas-graphic-cigarette-labels-rule-goes-up-in-smoke-after-us-abandons-appeal/> [<http://perma.cc/RPX4-RAGT>]. See also Bayer et al., *FDA and Graphic Cigarette-Pack Warnings—Thwarted by the Courts*, 369(3) N. ENG. J. MED. 206 (July 2013), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1306205> [<http://perma.cc/R7ZV-ZPVJ>].

⁶⁸¹Eric Holder, *Letter to the Honorable John Boehner Re: R.J. Reynolds v. Food & Drug Administration, No. 11-5332 (D.C. Cir.)* (Mar. 15, 2013), <https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/03-15-2013.pdf> [<http://perma.cc/85LL-3ML6>].

smokers quit.⁶⁸² Although commentary suggested this would make future graphic labels an easy shot for FDA,⁶⁸³ even the availability of such evidence would not assuage the D.C. Circuit's concerns of the appropriateness of a governmental interest in regulating speech to reduce consumption of legal products, or the ideological rather than informational tilt of certain graphics. In October 2016, several groups, including the American Academy of Pediatrics, filed a lawsuit against FDA alleging that FDA violated the Administrative Procedure Act by shirking "its nondiscretionary statutory duty to issue a final rule implementing Section 201 [of the Tobacco Act]" and asking the court to "compel [] FDA to comply with the agency's nondiscretionary statutory duty to promulgate a lawful graphic warning label rule."⁶⁸⁴ No opinion on the case has been issued,⁶⁸⁵ though it seems unlikely that a court will hold the requirement nondiscretionary and force FDA action.⁶⁸⁶ As of 2018, FDA states that it "has been undertaking research related to graphic health warnings since [*Reynolds*]."⁶⁸⁷

Although *Reynolds* has thus shown itself to be an endpoint for the original graphic warning label requirements, two other pieces of the story remain to be told. The first concerns a case in the Sixth Circuit in early 2012, a few months before *Reynolds* was decided, in which the Sixth Circuit upheld the general statutory provision granting FDA the authority to require warning labels on cigarettes (as opposed to *Reynolds*, which invalidated the specific warning labels that FDA had promulgated).⁶⁸⁸ And the second concerns another D.C. Circuit case decided two years after *Reynolds*, in which the court upheld commercial disclosure requirements in a different context: this time, for country-of-origin labeling requirements.⁶⁸⁹

The same year as the D.C. Circuit considered the challenge in *Reynolds* to FDA's rule promulgating specific graphic warnings, the Sixth Circuit considered what was

⁶⁸²Brewer et al., *Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior*, 176(7) JAMA INTERN MED. 905 (July 2016), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/252667> [<http://perma.cc/5LDX-GK2V>].

⁶⁸³Nicholas Bakalar, *Graphic Cigarette Warnings Deter Smokers*, N.Y. TIMES (June 8, 2016), <https://well.blogs.nytimes.com/2016/06/08/graphic-cigarette-warnings-deter-smokers/> [<http://perma.cc/6L2S-9J38>].

⁶⁸⁴Melissa Jenco, *AAP, health groups file lawsuit pushing for graphic cigarette warnings*, AAP NEWS (Oct. 4, 2016), <http://www.aapublications.org/news/2016/10/04/FDALawsuit100416> [<http://perma.cc/UZA7-DWWK>]. A copy of the complaint is available at https://www.tobaccofreekids.org/assets/content/press_office/2016/2016_10_04_fda_complaint.pdf [<http://perma.cc/RM9A-QLQP>].

⁶⁸⁵*American Academy of Pediatrics v. U.S. Food & Drug Administration No. 16-11985 (D.D.C. 2016)*, PUBLIC HEALTH LAW CENTER, <http://www.publichealthlawcenter.org/content/american-academy-pediatrics-v-us-food-drug-administration> [<http://perma.cc/Q7DG-QJK6>].

⁶⁸⁶Judicial review of agency inaction is a muddy area of law, but forcing agency action is generally viewed as a high hurdle. See generally *Heckler v. Chaney*, 470 U.S. 821 (1985); see also Sunstein et al., *The Law of "Not Now": When Agencies Defer Decisions*, 103 GEO. L.J. 157 (2014).

⁶⁸⁷*Cigarette Graphic Health Warnings*, U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/tobaccoproducts/labeling/labeling/ucm257774.htm> [<https://perma.cc/YB9P-G8CT>].

In 2018, the D.C. district court enjoined FDA from enforcing its related cigar and pipe tobacco warning requirements pending an appeal of an order denying plaintiffs' motion for summary judgment, noting that there may be constitutional issues in light of *Becerra's* requirement that disclosures be no broader than necessary. Barry Schaevitz & Beth Oliva, *Case Note: Cigar Association of America v. FDA*, FOOD AND DRUG LAW INSTITUTE, <https://www.fdli.org/2018/06/update-case-note-cigar-association-america-v-fda/> [<https://perma.cc/NPZ6-TACU>].

⁶⁸⁸*Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012).

⁶⁸⁹*American Meat Institute v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014).

analyzed as a facial challenge against certain provisions of the Tobacco Act, including the general requirement for graphic warnings.⁶⁹⁰ The court set forth the standard for analyzing commercial speech under circuit precedent: restrictions on non-misleading commercial speech get *Central Hudson* intermediate scrutiny, while disclosure requirements applied to “inherently misleading” or “potentially misleading” speech get *Zauderer* rational basis review.⁶⁹¹ The opinion noted the difference between the mandated text disclosures and the mandated graphics disclosures: “in contrast to the textual warnings, there can be no doubt that FDA’s choice of visual images is subjective, and that graphic, full-color images, because of the inherently persuasive character of the visual medium, cannot be presumed neutral.”⁶⁹² Because of this, the court found the argument that strict scrutiny should apply to the graphics to be “not wholly unpersuasive,” but ultimately felt that *Zauderer* should still apply since disclosures may appear in any form “as [is] necessary to prevent [commercial speech from] being deceptive.”⁶⁹³

The court also noted that “the government has a significant interest in preventing juvenile smoking and in warning the general public about the harms associated with the use of tobacco products,” although this must be balanced against the tobacco manufacturers’ interest in conveying truthful information about a lawful activity (*i.e.*, the legal sale and use of tobacco products).⁶⁹⁴ While the court up to this point had been unanimous in analyzing the warning requirements, this is where the three judges split. A majority of the panel upheld the constitutionality of the graphic warning labels requirement against the facial challenge.⁶⁹⁵ Circuit Judge Eric Clay, however, dissented on the issue of the graphic warnings.⁶⁹⁶ Rather than being “properly or reasonably tailored [in] response to address th[e] harm” caused by a failure of consumers to understand smoking risks, he argued that “the color graphic warning labels are intended to create a visceral reaction in the consumer.”⁶⁹⁷ It would be permissible for the government to require disclosure of truthful, even if frightening, information to consumers, he stated. But “it is less clearly permissible for the government to simply frighten consumers or to otherwise attempt to flagrantly manipulate the emotions of consumers as it seeks to do here.”⁶⁹⁸

Though Judge Clay’s concerns seem to follow Supreme Court precedent—including *Zauderer* itself, which applied to uphold disclosure of only “purely factual and uncontroversial information”⁶⁹⁹—it was still the dissent in the case. And as neither

⁶⁹⁰*Disc. Tobacco City*, 674 F.3d at 522.

⁶⁹¹*Id.* at 522–24.

⁶⁹²*Id.* at 526.

⁶⁹³*Id.* at 526–27.

⁶⁹⁴*Id.* at 519–20. On a technical level, it would seem that only the second interest—warning the general public about the harms associated with smoking—would serve to advance the government’s argument if *Zauderer* applied to the disclosure, since *Zauderer* requires reasonable relation to an interest in preventing consumer deception (as opposed to a general interest in the welfare of underage smokers).

⁶⁹⁵*Id.* at 518, 551.

⁶⁹⁶*Id.* at 527 (Clay, J., dissenting).

⁶⁹⁷*Id.* at 528 (Clay, J., dissenting).

⁶⁹⁸*Id.* at 529 (Clay, J., dissenting).

⁶⁹⁹*Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626, 651 (1985). For more on the meaning of “uncontroversial,” see *supra* note 410.

the Sixth Circuit facial challenge to the statute nor the D.C. Circuit challenge to the regulations was appealed to the Supreme Court, FDA properly retains its authority (and perhaps responsibility) to promulgate color graphic warning labels under the Tobacco Act.

The final case of interest is the 2014 D.C. Circuit case of *American Meat Institute*, which partially overruled the same court's 2012 *Reynolds* decision.⁷⁰⁰ *American Meat Institute* involved a group of meat trade associations' challenge to the Secretary of Agriculture's labeling rule that required disclosure on meat products of the country location of each production step (e.g., "Born in Canada, Raised and Slaughtered in the United States").⁷⁰¹ In a decision for an *en banc* court, Circuit Judge Stephen Williams upheld the rules against the First Amendment challenge.⁷⁰² The first order of business was overruling previous circuit precedent, including *Reynolds*, "[t]o the extent that [the] other cases . . . may be read as . . . limiting *Zauderer* to cases in which the government points to an interest in correcting deception."⁷⁰³ That is, a governmental interest in preventing consumer deception—and a corollary requirement that the speech, absent disclosure, be either inherently or potentially misleading—was not required to uphold a disclosure requirement.⁷⁰⁴

The court declined to decide whether a "lesser interest" (*i.e.*, a merely legitimate governmental interest as required by rational basis review, on which *Zauderer* was ostensibly patterned) would qualify, because the government's interest here in mandating country-of-origin disclosures was a "substantial" interest (*i.e.*, an interest that would satisfy *Central Hudson* and other forms of intermediate scrutiny).⁷⁰⁵ Several factors demonstrated the substantiality of the government's interest: (1) the context and historical practice of such disclosures, which enable consumers to purchase American-made products; (2) the demonstrated consumer interest in such information; and (3) the health interest in the event of food-borne illness outbreaks.⁷⁰⁶

But the court explained that it would not require the government to give "evidence of a measure's effectiveness" as usually required under *Central Hudson*.⁷⁰⁷ Instead, it would keep *Zauderer*'s stipulation that "by acting only through a reasonably crafted disclosure mandate, the government meets its burden of showing that the mandate advances its interest in making [information available]"—in a sense, a presumption of effectiveness for the regulation.⁷⁰⁸ The only further hurdle was that "the disclosure

⁷⁰⁰*Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22 (D.C. Cir. 2014).

⁷⁰¹*Id.* at 21.

⁷⁰²*Id.* at 20.

⁷⁰³*Id.* at 22.

⁷⁰⁴Rebecca Tushnet frames the inquiry as whether the government's purpose must be remedial (*i.e.*, correcting deception) or may be educational (*i.e.*, when "the government is trying to add information that it believes consumers will find useful"). Rebecca Tushnet, *Cool Story: Country of Origin Labeling and the First Amendment*, 70 FOOD DRUG L.J. 25 (2015). The proposition that more speech is generally better and the fact that commercial speech was initially protected at all due to its informational value support *American Meat Institute*'s finding of the latter, though the Court's trend towards treating commercial and noncommercial speech equally makes it possible it would disagree.

⁷⁰⁵*Am. Meat Inst.*, 760 F.3d 18, 23 (D.C. Cir. 2014).

⁷⁰⁶*Id.*

⁷⁰⁷*Id.* at 26.

⁷⁰⁸*Id.*

mandated must relate to the good or service offered by the regulated party.”⁷⁰⁹ Of note is that such a presumption of effectiveness would not have saved the regulations in *Reynolds* if we take that decision at its word. Although the regulation’s downfall was the lack of evidence, the *Reynolds* court had also held that *Zauderer* did not apply to the graphic disclosures at all given their ideological nature and appeals to emotions, rather than solely facts.⁷¹⁰ Given that *Reynolds* was not applying *Zauderer*, but instead purely applying *Central Hudson*, any presumption of effectiveness or liberalization of the governmental interest requirement would not have altered the outcome in 2012.⁷¹¹

Since the government established a substantial interest in the country-of-origin labeling and the mandated disclosures related to the meat producers’ goods, the court upheld the disclosure requirements.⁷¹² The court also rejected the meat producers’ argument that country-of-origin was “controversial,” explaining that the requirements would be upheld unless they were “so one-sided or incomplete that they would not qualify as factual and uncontroversial” or they were “so burdensome that [they] essentially operate[] as a restriction on constitutionally protected speech.”⁷¹³

So, what was FDA’s downfall in *Reynolds*, and what is the lay of the regulatory landscape post-*American Meat Institute*? Some disclosures are clearly constitutionally permitted—namely, uncontroversial fact-based disclosures where the communication absent the disclosure is misleading. For example, the requirement for a disclaimer that FDA has not approved certain health claims for a food when consumers would otherwise assume FDA approval would fall in this category. Another category of disclosures would be clearly constitutionally barred—disclosures that are extremely one-sided, incomplete, or are burdensome to such an extent that they operate as a speech restriction. For example, a requirement that (for whatever reason) 100% of a food carton be covered with a disclosure, leaving no room for a manufacturer’s desired message, would belong in this category.

But there is yet another category of disclosures where the constitutional rule is unclear. In this category are controversial (but arguably factual) disclosures, disclosures where it is not clear they are needed to correct consumer misperception or to further another legitimate or substantial governmental interest, and disclosures that operate not to correct misperception, but instead that function directly to suppress demand for a product or service. And it is these situations that FDA struggled with in its initial cigarette graphic warning labels.

Daniel Kahneman’s 2011 book, *Thinking, Fast and Slow*, lays out a theory that humans operate on two different modes of thought.⁷¹⁴ “System 1” thinking involves fact, instinctive, emotional, and subconscious decision-making. “System 2” thinking

⁷⁰⁹*Id.*; see also *Nat’l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (declining to apply *Zauderer* to a notice requirement because the subject of the notice “in no way relate[d] to the services” offered by a clinic).

⁷¹⁰*R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012), *overruled by Am. Meat Inst. v. United States Dep’t of Agric.*, 760 F.3d 19 (D.C. Cir. 2014).

⁷¹¹An alternate argument could be made that the *Reynolds* court would have applied *Zauderer* given a more liberal governmental interest requirement. Whether this would hold true depends on whether *Reynolds* used the evidence of ideology and emotional appeal as evidence to show the governmental interest went beyond disclosure, or whether these were mentioned as separate issues with the regulation.

⁷¹²*Am. Meat Inst.*, 760 F.3d at 27.

⁷¹³*Id.*

⁷¹⁴DANIEL KAHNEMAN, *THINKING, FAST AND SLOW* (2011).

involves slow, logical, deliberative, and conscious decision-making. The difference between disclosures aimed at producing an emotional response (System 1) or a deliberative response (System 2) is relevant when assessing the constitutionality of a disclosure. But it is not that System 1 disclosures are always unconstitutional, while System 2 disclosures are automatically upheld. Rather, the relevant distinction is between disclosures that seek to correct misperception back to a neutral, “truthful,” level, and disclosures that seek to *overcorrect* a misperception in order to further a different governmental goal, for example, to suppress demand for cigarettes. The latter situation does not describe a correcting message, but a positive message in its own right, and thus should be subject not to the tests for commercial disclosure, but to the more-stringent caselaw concerning private subsidization of another entity’s speech.⁷¹⁵

System 2 deliberative disclosures are more likely to attempt to correct to the neutral level, *e.g.*, to ensure consumers adequately perceive the risks of smoking. For example, displaying of text stating that smoking increases the risk of developing lung cancer by 25 times would be a System 2 disclosure aimed at ensuring consumers adequately perceive risks.⁷¹⁶ And if System 2 deliberative disclosures seek to *overcorrect* misperceptions, this is usually quite obvious and easily struck by courts, as the disclosure will need to be literally and facially untruthful in order to cause consumers to misperceive the risks associated with a product or activity. For example, a disclosure that states a smoker is certain to contract lung cancer (or one that merely overstates the risk) would seek to *overcorrect* by disseminating untruthful information.⁷¹⁷

System 1 emotional disclosures can also be useful tools to combat consumer misperception. For example, evidence that consumers tend to underestimate the long-term increased risk of developing lung cancer after smoking means that shocking graphics can help consumers more accurately perceive the long-term risks by making the risks more salient. Or the graphics may serve simply to draw attention to the textual System 2 disclosure already on the cigarette package, which is otherwise more easily ignored. But where System 1 emotional disclosures differ from System 2 deliberative disclosures is in their capability to *overcorrect* and mislead consumers in the opposite direction, *e.g.*, change consumers from *underestimating* the risks to *overestimating* the risks. The difference is between disclosures that adequately convey to consumers the risks of their consumption of a product and those that are “inflammatory[,] . . . unabashed attempts to evoke emotion . . . and browbeat consumers.”⁷¹⁸ For example, a photo of a corpse on a cigarette package⁷¹⁹ may be communicating the untruthful “you are certain to contract cancer” message just as the

⁷¹⁵See Bryan M. Haynes, Anne Hampton Andrews & C. Reade Jacob, Jr., *Compelled Commercial Speech: The Food and Drug Administration’s Effort to Smoke Out the Tobacco Industry Through Graphic Warning Labels*, 68 FOOD DRUG L.J. 329, 356 (arguing that graphic warning labels should be subject to strict scrutiny because “by mandating graphic warning labels, the government is essentially commanding the public to ‘not smoke.’”).

⁷¹⁶*Smoking & Tobacco Use: Health Effects of Cigarette Smoking*, CDC, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm [<https://perma.cc/E6K6-P6GP>].

⁷¹⁷*Id.*

⁷¹⁸*R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012), *overruled by* *Am. Meat Inst. v. United States Dep’t of Agric.*, 760 F.3d 19 (D.C. Cir. 2014).

⁷¹⁹See *FDA’s Graphic Cigarette Label Rule Goes up in Smoke After U.S. Abandons Appeal*, CBS NEWS (Mar. 19, 2013), <https://www.cbsnews.com/news/fdas-graphic-cigarette-labels-rule-goes-up-in-smoke-after-us-abandons-appeal> [<https://perma.cc/XX34-LBQN>].

textual System 2 message discussed above communicated it. But System 1 disclosures are much more susceptible to this kind of abuse since the message is conveyed with less clarity. This is because the content of a System 1 disclosure is inherently emotional, causing there to be more variation in the way the specific message is understood by individual consumers.⁷²⁰

IV. SUGGESTED FUTURE FDA APPROACHES TOWARD FIRST AMENDMENT COMPLIANCE

IV.A. Suggested Guidelines

This subsection will not seek to offer a specific solution to FDA's future approach toward First Amendment compliance. There is no panacea. Instead, this subsection will offer general guidelines: a list of suggested "dos" and "do nots" for FDA in crafting approaches to First Amendment compliance for individual issues. Some of these approaches would be achievable via regulation under current statutory authorization; other approaches may require further action on Congress' part to give FDA regulatory authority. Regardless, the crucial aspect is that although past, speech-restricting approaches may have been effective, this should not act as a bar against searching for new, non-speech-restricting approaches that may prove to be just as effective. This subsection begins with approaches to avoid, before continuing with suggestions for approaches to try.

Approaches to Avoid

1. *Business as Usual.* Do not seek to continue on "business as usual." Such an approach is not sustainable in the long run. Hiding behind selective use of prosecutorial discretion, strategic expansion of the gray area between what is authorized and what is banned, and calculated decisions not to appeal can only work for so long. Sooner or later, the Supreme Court will hear the issue, and historically, regulatory approaches that do not properly address First Amendment concerns have not fared well.⁷²¹ Relatedly, do not seek to articulate a standard that respects speech

⁷²⁰Robert Post proposes that the proper line is whether "a reasonable reader would interpret the graphic images" as communicating opinion rather than information. Robert Post, *Compelled Commercial Speech*, 117 W. VA. L. REV. 867, 909 (2015).

⁷²¹*See, e.g.,* Thompson v. W. States Med. Ctr., 535 U.S. 357, 373 (2002) ("[R]egulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try.").

Recent scholarship has contended that "the First Amendment by its terms does not apply to executive or judicial actions," relying on the fact that the Amendment expressly applies to "Congress." *See* GARY LAWSON & GUY SEIDMAN, *THE CONSTITUTION OF EMPIRE: TERRITORIAL EXPANSION & AMERICAN LEGAL HISTORY* 43 (2004); Nicholas Quinn Rosenkranz, *The Object of the Constitution*, 63 STAN. L. REV. 1005 (2011). The extent to which agencies such as FDA are exercising executive or legislative (or judicial) power in first, rulemaking and second, adjudicating or deciding the status of individual applications under those rules, is a matter of administrative constitutional law beyond the scope of this article. Recent scholarship has argued that even if the First Amendment does apply only to Congress, "executive action that encroaches upon First Amendment freedom is either (a) action authorized by a statute, in which case the statute itself violates the First Amendment, or (b) ultra vires executive action that runs afoul of the Fifth Amendment's Due Process Clause." Daniel J. Hemel, *Executive Action and the First Amendment's First Word*, 40 PEPP. L. REV. 601, 604 (2013). Such reasoning would apply to FDA action violating the First Amendment.

rights, while applying another standard that does not. Such an approach would fly against the APA, the rule of law, and the First Amendment.⁷²²

2. *FDA Exceptionalism.* Do not continue on the assumption that principles of FDA constitutional exceptionalism, grounded in the important public safety goals of FDA, will apply in the First Amendment realm. Circuit court evidence has shown this is not the case;⁷²³ so has Supreme Court precedent.⁷²⁴ While it may continue to hold for the *Park* doctrine and the Fourth Amendment pervasively regulated businesses exception, First Amendment commercial speech jurisprudence has evolved over the past few decades to reject such an approach.

3. *Evasion.* Do not seek to evade commercial speech jurisprudence or otherwise ignore the spirit of the caselaw. Such an approach is also not sustainable: few district courts, fewer circuit courts, and certainly not the Supreme Court will go along with such an approach. If an interest amounts to limiting consumers' or intermediaries' access to information about lawful activities based on a fear of what they will do with the information, the interest will not justify regulation, even if otherwise squeezed into *Central Hudson*.⁷²⁵ If a speech-limiting approach is taken without at least analyzing the feasibility of less-speech-restricting approaches, the regulation will not be upheld.⁷²⁶

Approaches to Try

1. *Disclosures.*⁷²⁷ As a general matter, the First Amendment answer to potentially harmful speech is more speech.⁷²⁸ And the Supreme Court has repeatedly pointed out that as remedies go, disclaimers are constitutionally preferable to

⁷²²*Cf.* Allentown Mack Sales & Service, Inc. v. NLRB, 522 U.S. 359, 376–77 (1998) (“Because reasoned decision making demands it, and because the systemic consequences of any other approach are unacceptable, [agencies] must be required to apply in fact the clearly understood legal standards that [they] enunciate in principle Reviewing courts are entitled to take those standards to mean what they say, and to conduct substantial-evidence review on that basis.”); SEC v. Chenery Corp., 318 U.S. 80, 87 (1943) (holding that in arbitrary and capricious review under the APA, agency action can be analyzed only on the grounds articulated by the agency).

⁷²³*See, e.g.*, United States v. Caronia, 703 F.3d 149 (2012); R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012), *overruled by* Am. Meat Inst. v. United States Dep’t of Agric., 760 F.3d 19 (D.C. Cir. 2014).

⁷²⁴*See, e.g.*, *Thompson*, 535 U.S. at 371 (rejecting the argument that restrictions on commercial speech were justified by, *inter alia*, a public health interest).

⁷²⁵*E.g., id.* at 374; Sorrell v. IMS Health Inc., 564 U.S. 552, 577 (2011).

⁷²⁶*E.g., Thompson*, 535 U.S. at 373. Creating a paper trail by summarily dismissing available less-speech-restricting alternatives in public statements—presumably the strategy behind the Jan. 2017 First Amendment Memo—also seems unlikely to succeed, as courts have been hesitant to apply deference to factual determinations that predicate First Amendment issues. *See* Fleming Inc. v. United States HHS, 854 F. Supp. 2d 192, 207 (D. Conn. 2012); *cf.* AFL-CIO v. FEC, 33 F.3d 168, 175 (D.C. Cir. 2003); Nat’l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2377 (2018).

⁷²⁷For more on disclosures, see *supra* section II.C.3.

⁷²⁸*Whitney v. California*, 274 U.S. 357, 376–77 (1927) (“Fear of serious injury cannot alone justify suppression of free speech and assembly. Men feared witches and burnt women. It is the function of speech to free men from the bondage of irrational fears If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence.”) (Brandeis, J., concurring).

suppression.⁷²⁹ As such, disclosures should be a favored regulatory approach. A few guidelines for a disclosure approach should be kept in mind. First, disclosures are compelled speech, and as such they are still subject to limits. But they are certainly allowed so long as they address the issue of consumer deception.⁷³⁰ Disclosures may also be allowed in order to address other governmental interests.⁷³¹ Second, disclosures should not be overly burdensome, nor should their scope go beyond disclosure of factual information. When disclosures are overly burdensome, they transform into speech restrictions;⁷³² likewise, when disclosures cross the line from factual to persuasive, they transform into compelled ideology or subsidization.⁷³³

2. *Government Speech.*⁷³⁴ If FDA wishes to actively put forth a certain message or viewpoint (e.g., smokers should quit smoking), disclosures are not the approach to take. Instead, FDA should seek to disseminate these messages on its own behalf, justified under the government speech jurisprudence. Such speech could even be funded by assessments on the regulated industry itself, though care must be taken to distinguish such an approach from compelled subsidization.⁷³⁵ The most crucial aspect of the government speech area is that the speech must be associated with the government itself rather than with the regulated industry.⁷³⁶ Other than this grounding, the jurisprudence relating to government speech is new and unsettled enough that no other fixed rules have yet emerged. Other guidelines include that such a message should have some historical basis for coming from the government—which health-related messages seem to fulfill—and that the government should retain control over the message—which seems like good policy regardless.⁷³⁷ The newness of the government speech area should allow room for some creative solutions and new approaches to furthering FDA’s public health mission by speaking directly to consumers.

3. *Direct Regulation.* Instead of directly banning certain goods or services, FDA has often implemented hands-off secondary approaches such as regulation of advertising or labeling.⁷³⁸ Unfortunately, these secondary approaches often regulate

⁷²⁹E.g., *In re R.M.J.*, 455 U.S. 191, 206 n.20 (1982); *Shapero v. Kentucky Bar Ass’n*, 486 U.S. 466, 478 (1988); see also *Pearson I*, 164 F.3d at 657.

⁷³⁰See *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626, 651 (1985). Whether the speech sans disclosure needs to be inherently misleading or merely potentially misleading to warrant a disclosure is an open question. See *Am. Meat Inst. v. United States Dep’t of Agric. Institute*, 760 F.3d 18, 22 (D.C. Cir. 2014). At the very least disclosures must address an issue that is “potentially real [and] not purely hypothetical.” *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation*, 512 U.S. 136, 146 (1994); *Becerra*, 138 S. Ct. at 2377.

⁷³¹*Am. Meat Institute*, 760 F.3d at 22.

⁷³²See *Zauderer*, 471 U.S. at 651; cf. *Miami Herald Pub. Co., Div. of Knight Newspapers, Inc. v. Tornillo*, 418 U.S. 241, 256 (1974); *Pacific Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 16 (1986) (plurality); *Becerra*, 138 S. Ct. at 2377.

⁷³³See *supra* section III.C.; *R.J. Reynolds*, 696 F.3d at 1211.

⁷³⁴For more on government speech, see *supra* section II.C.2.

⁷³⁵The assessment would have to be part of a broader regulatory scheme, as in *Glickman v. Wileman Bros. & Elliot*, 521 U.S. 473, 473 (1997), or the program must qualify as government speech under *Johanns v. Livestock Mktg. Ass’n*, 544 U.S. 550, 558-59 (2005).

⁷³⁶*Walker v. Tex. Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2248 (2015).

⁷³⁷*Id.*

⁷³⁸See generally HUTT, *supra* note 5, at 379, 332, 925. Many of the regulated industries likely prefer such hands-off approaches to command-and-control approaches, but “what is sauce for the goose is normally

speech. But it is easy to forget that a more direct approach, that is, direct regulation of products or services, remains a viable solution—and one that does not restrict speech. If a product or service is extremely dangerous, it can be banned. Even less dangerous products or services can be regulated more directly; for example, by restricting sales of the restricted good or service to a certain percentage of a provider's sales, by discouraging sales via taxation or minimum prices, or by forbidding a manufacturer to profit from sales of a restricted item.

4. *Speech Restrictions, When Absolutely Necessary.* Although the Supreme Court has not upheld a commercial speech restriction in the last two decades, they remain a viable option at least in theory—but only if they are truly the last remaining option and all speech-neutral approaches have been studied or attempted and have proven ineffective. This does not mean that summarily rejecting potential approaches in the federal register will make a speech-restrictive approach bulletproof; speech restrictions must truly be of last resort. And of course, any speech restriction would have to pass the *Central Hudson* four-prong test, which has been applied as an extremely strict version of intermediate scrutiny in recent years.⁷³⁹

IV.B. Selected Applications

As with the previous subsection, the goal of this subsection is not to recommend a single best approach for any particular regulatory issue. Instead, it is to offer a short discussion of some possible approaches to regulatory situations covered in this article for which the previous solutions have run into First Amendment issues. Some approaches could be adopted via regulation; others would require new statutory authorization. Of course, detailed policy analysis would be required before any approach should be adopted to ensure such an approach would directly address the public health goals of FDA.

The first two issues are the similar issues of advertisement of compounded drugs⁷⁴⁰ and advertisement of drugs for off-label uses.⁷⁴¹ Both of these situations require individualized assessments of costs and benefits, for which a disclosure approach seems especially apt, as it ensures the maximum amount of information is available (and, if FDA takes part in designing the disclosure, that the information is of maximum quality as well as quantity). Take regulation of drug compounding. The interest in such cases is ensuring that consumers (*i.e.*, patients and doctors) adequately understand the risks and do not overestimate the benefits. Disclosing that a compounded drug has not been approved by FDA, along with disclosure of any other known health risks and

sauce for the gander” and free speech challenges seem to be forcing FDA’s hand. *Nat’l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2385 (2018) (Breyer, J., dissenting) (quoting *Heffernan v. City of Paterson*, 136 S.Ct. 1412 (2016)). Scholarship notes that the relatively recent preference for “lighter-touch regulatory tools . . . in place of or in addition to command-and-control regulation” has enhanced the entire administrative state’s conflict with the concurrently evolving commercial speech jurisprudence. Shanor, *supra* note 73, at 163–76. Others warn that “[e]liminating [speech-burdening approaches] from the agency’s repertoire could push FDA to look to other—frequently more paternalistic—options.” Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO ST. L.J. 1053, 1060 (2017). Whatever the advantages of lighter-touch tools, the First Amendment—or at least the currently-prevailing interpretation of the First Amendment—has made the choice between speech and efficiency. *Becerra*, 138 S.Ct. at 2376.

⁷³⁹See *supra* section II.B.3.

⁷⁴⁰See generally *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

⁷⁴¹See *supra* section III.B.

potential side effects, addresses this interest. A doctor or patient who mistakenly believes a compounded drug has been FDA-approved is bound to overestimate the safety and efficacy of the compounded drug—thereby underestimating potential risks and overestimating potential benefits. Full disclosure to doctors and patients alleviates this concern.

The same holds true for regulation of off-label drug promotion. The interest in such cases is ensuring that doctors and consumers adequately perceive the risks and benefits of using the drug for the unapproved use. Full disclosure of the studies on which a manufacturer relies, and of those studies' strengths and weaknesses, can allow the doctor and patient to conduct an individualized cost/benefit analysis for the patient's particular use of the drug. If doctors or patients are systematically biased such that they overestimate the benefits of an off-label use, FDA can inform them of such bias to help counteract it; such an approach would be best taken in FDA's own name and justified under the government speech caselaw.

If FDA is worried that a manufacturer is going to "manufacture" a new drug under the guise of compounding without going through the NDA process, there are non-speech direct regulations it can use to solve the issue. It can stipulate that only a certain percentage of the manufacturer's drugs can be compounded, put in place a hard cap on the amount of a drug that can be compounded before submission of an NDA, or directly limit the profits a manufacturer can make from a drug sold off-label. It can restrict compounding services to companies of a certain size or to only certain companies. If a compounded drug proves dangerous, it can be banned. In short, FDA can still regulate the compounding of drugs—but this does not require regulating speech about the compounding of drugs. Similarly, FDA could take the approach of directly regulating off-label drug prescription and use; this does not require regulating speech about off-label drug prescription and use.

The next issue is the issue of graphic cigarette warning labels.⁷⁴² The problem of the approach taken in the 2011 graphic warning label regulations was the conflation of two interests—the private health interest in ensuring consumers have adequate information about the risks of smoking, and the public health interest in convincing more consumers to stop smoking—and the application of the disclosure solution for both interests. The interests are of course related; one would hope that a consumer who adequately perceives the long-term costs of smoking would stop. But this connection is not automatic, and so the same approach cannot serve both interests.

To ensure that consumers have adequate information about the risks of smoking, FDA (and Congress with the Tobacco Act) was correct in selecting the disclosure approach. There are nuances to the issue: for example, how misleading exactly is a cigarette package sans warning? Should the extremely high risk levels play a part? The addictive nature of tobacco, which would cause consumers to irrationally discount risks? What about tobacco companies' past behavior in deliberately misleading consumers about the risks? But at root a disclosure regime seems appropriate in this sort of case, where consumers are purchasing a product without fully understanding the harm it causes. With complete information, consumers can make their own choices about whether to continue purchasing the product.

In contrast, to carry out its public health interest in convincing people to quit smoking, a better approach for FDA to use is the government speech approach.

⁷⁴²See *supra* section III.C.

Disclosure is inappropriate because beyond the objective information about a product, requiring any further advocating looks like compelled ideological speech. But if FDA follows the contours of the jurisprudence, it can speak on the government's behalf to disseminate its own advertisements convincing consumers to quit.⁷⁴³

The direct regulation approach is also, theoretically, a possibility. But like the commercial speech cases involving other vice products, such as alcohol and gambling, although the government would retain the power to ban products like tobacco, it seems politically untenable to actually carry out such a ban. However, perhaps a middle ground could be found by setting a minimum price for cigarettes, or discouraging consumption with a heavy tobacco tax—these approaches present no First Amendment issues. Indeed, FDA has recently moved toward this approach by, for the first time, attempting to directly regulate the nicotine content in cigarettes.⁷⁴⁴ This approach is related to a disclosure approach in that less nicotine means less addictiveness, which like disclosure is another method to help consumers adequately perceive the risks of the product. And unlike disclosure or advertising restrictions, there is no First Amendment protected right to sell cigarettes with high levels of nicotine.

The last application is in the context of health claims for dietary supplements.⁷⁴⁵ Here, not much remains to be discussed; the D.C. Circuit has provided that the preferred approach is disclaimers. The disclosures should be designed to be as neutral as possible while still correctly communicating to consumers the support (and lack of support) for the particular health claim. And if there is no, or close to no, basis for the health claim, the claim is rendered false and a speech restriction is indeed justified.

FDA has a crucial mission of supporting public health and in many ways is a unique agency, tasked not only with addressing harm after-the-fact but also with stopping harm before it even happens. In focusing on its mission, it has in a sense been lapped by the Supreme Court's rapidly evolving commercial speech jurisprudence. But the proper response is not to fight against the newly exposit constitutional rules, nor is it to ignore them. Instead, FDA must seek to balance its public health responsibilities with the free speech rights of its regulated industries by exploring, researching, and preemptively seeking out new, constitutionally-acceptable methods of achieving its mission.

⁷⁴³Graphic cigarette package inserts, while perhaps less effective because they are not seen at point of sale, may also be a possibility under the government speech theory, if the scheme is designed carefully. Eric N. Lindblom, Micah L. Berman & James F. Thrasher, *FDA-Required Tobacco Product Inserts & Onserts—and the First Amendment*, 72 *FOOD DRUG L.J.* 1, 13–14 (2017).

⁷⁴⁴FOOD & DRUG ADMIN., *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*, 83 Fed. Reg. 11843 (Mar. 16, 2018).

⁷⁴⁵*See supra* section III.A.