

SNAKE OIL SALESMEN OR PURVEYORS OF KNOWLEDGE: OFF-LABEL PROMOTIONS AND THE COMMERCIAL SPEECH DOCTRINE

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The Second Circuit's December 2012 decision in United States v. Caronia striking down the prohibition on off-label marketing of pharmaceutical drugs has profound implications for economic regulation in general, calling into question the constitutionality of restrictions on the offer and sale of securities under the Securities Act of 1933, the solicitation of shareholder proxies and periodic reporting under the Securities Exchange Act of 1934, mandatory labels on food, tobacco, and pesticides, and a wide range of privacy protections. In this Article we suggest that Caronia misconstrues the Supreme Court's holding in Sorrell v. IMS Health, which was motivated by concerns of favoring one industry participant over another rather than a desire to return to the anti-regulator fervor of the Lochner era. Reexamining the theoretical justification for limiting truthful commercial speech shows that a more nuanced approach to regulating off-label marketing with the purpose of promoting public health and safety would pass constitutional muster. We argue that as long as the government both has a rational basis for subjecting a particular industry to limits on commercial speech intended to further a legitimate public interest, rather than unfounded paternalism, and does not discriminate against disfavored industry participants, those limits should be subject to intermediate scrutiny under the Central Hudson standard. We believe that our articulation of the commercial speech doctrine post-Sorrell will help resolve the current split in the Circuits on the appropriate standard of review in cases involving both restrictions on commercial speech and mandated speech. Finally, we critique the FDA's 2011 Guidance for Responding to Unsolicited Requests for Off-Label Information (draft) and present a proposal for new rules for regulating the off-label marketing of pharmaceutical drugs based on transparency, the sophistication of the listener and the type of information

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offered, and the requirement that the pharmaceutical company comply with ongoing duties of training, monitoring, reporting, and auditing.

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INTRODUCTION

In December 2012, the U.S. Court of Appeals for the Second Circuit dealt a potentially fatal blow to the Food and Drug Administration’s ban on off-label promotions of pharmaceuticals in a sweeping decision with profound implications for the regulation of commercial speech.¹ The Second Circuit based its decision in substantial part on the U.S. Supreme Court’s invalidation of a Vermont statute banning the sale of prescriber-identifying information without the physician’s consent in *Sorrell v. IMF Health, Inc.*² The Second Circuit’s reasoning has the potential to undermine the constitutionality of numerous areas of federal regulation,³ including regulation of the offer and sale of securities under the Securities Act of 1933; the solicitation of shareholder proxies and periodic reporting under the Securities Exchange Act of 1934; mandatory labels on food,⁴ tobacco,⁵ and pesticides; and a wide range of privacy protections.⁶ As Justice Breyer warned in his dissent in *Sorrell*, this undue expansion of the Free Speech rights of commercial actors, if left unchecked, threatens a return to the anti-regulatory fervor of the *Lochner* era.⁷ In particu-

¹ U.S. v. Caronia, 703 F.3d 149 (2d Cir. 2012).

² 131 S. Ct. 2653 (2011).

³ See Jennifer L. Pomeranz, *No Need to Break New Ground: A Response to the Supreme Court’s Threat to Overhaul the Commercial Speech Doctrine*, 45 LOY. L.A. L. REV. 389, 405–06 & n.89 (2012).

⁴ Nutrition Labeling and Education Act of 1990 § 2, 21 U.S.C. § 343(q) (2006); Food Allergen Labeling and Consumer Protection Act of 2004 § 203, 21 U.S.C. § 343(w).

⁵ See, e.g., R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1222 (D.C. Cir. 2012) (striking down requirement of graphic warning labels on cigarette packages).

⁶ David Orentlicher, *The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm*, 37 AM. J.L. & MED. 299, 311 (2011). These include laws protecting medical information, video rental records, and certain consumer credit card information.

⁷ *Sorrell*, 131 S. Ct. at 2675 (“To apply a ‘heightened’ standard of review in such cases as a matter of course would risk what then-Justice Rehnquist, dissenting in *Central Hudson*, described as a ‘retur[n] to the bygone era of *Lochner* v. *New York*, 198 U.S. 45 (1905), in which it was common practice for this Court to strike down economic regulations adopted by a

lar, mandating a laissez-faire “marketplace” of commercial promotions as if that were the natural order bears an uncanny resemblance to *Lochner*’s invalidation of a statute that interfered with employers’ right to contract with workers on whatever terms the labor market would bear.⁸

But it is possible to prohibit discriminatory restraints on commercial speech while preserving the federal government’s power to regulate the activities of specific actors in commerce to protect health and safety pursuant to a fair reading of the police power. Indeed, even though the FDA chose not to appeal the Second Circuit’s ruling in *Caronia*, the issue of commercial speech is sure to come before the Supreme Court in the not-too-distant future. For example, the U.S. District Court for the District of Columbia Circuit noted in May 2013 in *Association of Manufacturers v. SEC* the split in the circuits as to whether certain types of commercial speech should be judged under intermediate or strict scrutiny.⁹ A careful look at *United States v. Caronia*,¹⁰ then, not only provides guidance for

State based on the Court’s own notions of the most appropriate means for the State to implement its considered policies.’”) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 589 (1980) (Rehnquist, J., dissenting)).

⁸ See Cass R. Sunstein, *Lochner’s Legacy*, 87 COLUM. L. REV. 873, 874 (1987) (arguing that the *Lochner* Court erroneously believed that “[m]arket ordering under the common law was . . . part of nature rather than a legal construct . . .”). For a contrary view, see David E. Bernstein, *Lochner’s Legacy’s Legacy*, 82 TEX. L. REV. 1 (2003).

⁹ No. 13-cv-635, 2013 WL 3803918, at *28 (D.D.C. July 23, 2013) (“While some circuits apply strict scrutiny once the case is found to fall outside of the *Zauderer* [*v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985)] standard, our Circuit has rejected this dichotomous approach, holding instead that in evaluating the constitutionality of compelled commercial speech, any ‘burdens imposed . . . receive a lower level of scrutiny from courts.’”) (quoting *Philip Morris v. FDA*, 566 F.3d 1205, 1142–43)). Under the *Zauderer* standard, “‘purely factual and uncontroversial’ disclosures are permissible if they are ‘reasonably related to the State’s interest in preventing deception of consumers,’ provided the requirements are not ‘unjustified or unduly burdensome.’” *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C.Cir. 2012) (internal quotations omitted). *Compare* *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 554 (6th Cir. 2012) (“If a commercial-speech disclosure requirement fits within the framework of *Zauderer* and its progeny, then we apply a rational-basis standard. If it does not, then we . . . apply strict scrutiny.”) with *R.J. Reynolds*, 696 F.3d at 1212, 1215 (government must establish that the disclosures “directly and materially advance[]” a “substantial” government interest (citing *Central Hudson*, 447 U.S. at 566) unless “the government shows that, absent a warning, there is a self-evident—or at least ‘potentially real’—danger that an advertisement will mislead consumers.”). Because the conflict minerals disclosures mandated by the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111–203, 124 Stat. 1376, and the Securities and Exchange Commission regulation *Conflict Minerals*, 77 Fed.Reg. 56,274 (Sept. 12, 2012) (codified at 17 C.F.R. §§ 240, 249b), at issue in *Manufacturers Assoc. v. SEC*, “are not aimed at preventing misleading or deceptive speech,” they were subject to intermediate scrutiny under *Central Hudson*—“a concession that, under this [D.C.] Circuit’s precedent, removes this case from the *Zauderer* framework.” *Id.* at 1214. After evaluating both Dodd-Frank’s and the SEC’s requirements for the mandatory public disclosure of whether certain minerals used in the production of publicly traded firms’ products are Republic of the Congo “conflict-free,” the U.S. District Court for the District of Columbia concluded that the required disclosures satisfied the test of intermediate scrutiny.

¹⁰ 703 F.3d 149 (2d Cir. 2012).

future challenges to the commercial speech doctrine, but also provides the opportunity to articulate a new standard for evaluating speech in regulated industries.¹¹

We argue that as long as the government has a rational basis for subjecting a particular industry to limits on commercial speech pursuant to an “ordinary economic regulatory program[]”¹² intended to further a legitimate public interest rather than unfounded paternalism, and does not discriminate against “disfavored” industry participants, those limits should be subject to intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission*.¹³ This would enable the Court to confine the heightened scrutiny applied in *Sorrell* to those cases in which the government has played favorites among market participants or sought to promote pure paternalism. We believe that our proposed standard would close the “Pandora’s Box of First Amendment challenges”¹⁴ to commercial regulations opened by *Sorrell* as long as “the government seeks typical regulatory ends” with “speech-related consequences [that] are indirect, incidental, and entirely commercial” and thereby eliminate the risk of “reawaken[ing] *Lochner*’s pre-New Deal threat of substituting judicial for democratic decisionmaking where ordinary economic regulation is at issue.”¹⁵

In Part I we discuss the development of the commercial speech doctrine and its erosion in the U.S. Supreme Court’s decisions in *Sorrell*. We then analyze the Second Circuit’s decision in *Caronia* and argue that it improperly extended *Sorrell* to ban virtually any restriction on off-label promotions. In Part II we articulate a theoretical justification for regulating truthful commercial speech based on the public interest and suggest a new standard drawing on a key lesson from *Sorrell* and the analogous case of *Brown v. Entertainment Merchants Ass’n*—that the government may not favor certain industry participants over others. In Part III, we then discuss the FDA’s 2011 *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* draft¹⁶ and analyze it under our proposed standard.

¹¹ This could apply not only to the traditional area of food and drug safety but also to more controversial topics, such as regulating fast food ads directed to children, restrictions on alcohol commercials when children are likely to be watching TV, or bans on tobacco-company sponsorships of televised sporting events.

¹² *Sorrell*, 131 S. Ct. at 2675 (Breyer, J., dissenting).

¹³ 447 U.S. 557 (1980).

¹⁴ *Sorrell*, 131 S. Ct. at 2685 (Breyer, J., dissenting).

¹⁵ *Id.* at 2685.

¹⁶ CTR. FOR DRUG EVALUATION AND RESEARCH ET AL., U.S. DEP’T OF HEALTH & HUMAN SERV., GUIDANCE FOR INDUSTRY: RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES (2011) [hereinafter 2011 DRAFT GUIDANCE], available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf>.

We draw on certain analogous provisions in the securities laws to guide the development of a more narrowly tailored approach that balances the need for dissemination of truthful and nonmisleading information about off-label uses of prescription drugs with the need to prevent the widespread sale of potentially dangerous drugs without adequate testing and labeling.

I. *SORRELL AND CARONIA: THE EROSION OF THE COMMERCIAL SPEECH DOCTRINE*

A. *Commercial Speech and the First Amendment: From Valentine v. Chrestensen to Central Hudson*

Prior to the 1970s, commercial speech enjoyed no protection under the First Amendment.¹⁷ The first case to specifically address the question of constitutional protection for advertising was *Valentine v. Chrestensen*.¹⁸ F.J. Chrestensen, the owner of a decommissioned U.S. Navy submarine, distributed printed handbills in New York City advertising exhibitions of the submarine for profit.¹⁹ The New York City Police Department prohibited further distribution of the handbills, claiming that it violated the City Sanitary Code, which “forbids distribution in the streets of commercial and business advertising matter” but not “handbills solely devoted to ‘information or a public protest.’”²⁰ When Chrestensen then printed a double-faced handbill with a political protest on one side and the advertisement on the other, the police told him that the two-sided handbill was prohibited as well.²¹ The Court upheld the prohibition stating summarily that “the Constitution imposes no such restraint on government as respects purely commercial advertising.”²²

Thus began a period during which there seemed to be few limitations on the state’s ability to restrict commercial advertising. In *Breard v. City of Alexandria*,²³ for example, the Court refused to strike down an

¹⁷ 2 SMOLLA & NIMMER ON FREEDOM OF SPEECH § 20:1 (2011) (“For many years commercial speech was regarded as outside the protection of the Constitution.”).

¹⁸ 316 U.S. 52 (1942). Some, however, point to Justice Roberts’ dicta in *Schneider v. State* as the forerunner of the commercial speech doctrine: “We are not to be taken as holding that commercial soliciting and canvassing may not be subjected to such regulation as the ordinance requires.” 308 U.S. 147, 165 (1939); see, e.g., Lawrence Alexander, *Speech in the Local Marketplace: Implications of Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc. for Local Regulatory Power*, 14 SAN DIEGO L. REV. 357 (1977); Alex Kozinski & Stuart Banner, *The Anti-History and Pre-History of Commercial Speech*, 71 TEX. L. REV. 747, 771–72 (1993).

¹⁹ 316 U.S. at 53.

²⁰ *Id.*

²¹ *Id.* at 53.

²² *Id.* at 54.

²³ 341 U.S. 622 (1951).

ordinance prohibiting door-to-door advertising of commercial products.²⁴ Writing for the majority, Justice Reed emphasized that the First Amendment does not extend to commercial speech:

Only the press or oral advocates of ideas could urge this [First Amendment] point. It was not open to the solicitors for gadgets or brushes. . . . We agree that the fact that periodicals are sold does not put them beyond the protection of the First Amendment. The selling, however, brings into the transaction a commercial feature.²⁵

In the 1976 case of *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*,²⁶ the Supreme Court changed direction. The case concerned a Virginia state law that barred the publication and advertising of prescription drug prices.²⁷ The ban hurt consumers, who were often unaware that a particular drug could be found more cheaply at a nearby pharmacy or in another city.²⁸ The Court overruled *Valentine v. Chrestensen*²⁹ and held that the statute violated the First Amendment. The Court condemned Virginia's "highly paternalistic approach" towards truthful information,³⁰ reasoning that "information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."³¹

The Court highlighted the importance of the free flow of information to facilitate efficient economic transactions:

Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. 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.³²

²⁴ *Id.* at 625.

²⁵ *Id.* at 641–42.

²⁶ 425 U.S. 748 (1976).

²⁷ *Id.* at 749–50.

²⁸ *Id.* at 754.

²⁹ *Id.* at 762.

³⁰ *Id.* at 772.

³¹ *Id.* at 770.

³² *Id.* at 765 (citations omitted).

Virginia State Board of Pharmacy extended constitutional protection for commercial speech under an anti-paternalism, pro-free market of ideas theory. But the Court did not articulate a doctrinal standard for evaluating the constitutionality of commercial speech until its decision in *Central Hudson Gas & Electric Corp. v. Public Service Commission*³³ in 1980.

Central Hudson involved an order by the New York Public Service Commission requiring electric utilities to cease promotional advertising that encouraged the use of electricity because of a shortage of fuel in the 1973–74 winter.³⁴ *Central Hudson* challenged the prohibition under the First Amendment, but the New York Court of Appeals upheld it, ruling that advertising in the “noncompetitive market in which electric corporations operate” had little economic benefit.³⁵

The Supreme Court reversed in an 8–1 decision. Although the Court reiterated that commercial speech is protected by the First Amendment,³⁶ it explained that commercial speech is entitled to “lesser protection”³⁷ than the political speech at the heart of the First Amendment. Instead of subjecting commercial speech to strict scrutiny, the Court adopted a four-part intermediate scrutiny test: (1) to be protected, the speech must concern a lawful activity, (2) the governmental restriction must serve a substantial interest, (3) the regulation must directly advance this interest, and (4) the regulatory scheme must be no more extensive than necessary to achieve this substantial interest.³⁸ Although the Court found that the advertising concerned lawful activity and the governmental regulation directly sought to advance the substantial interest of energy conservation and the fairness and efficiency of utility rates,³⁹ the Court ruled that the prohibition failed the final requirement of being non-excessive: “the energy conservation rationale . . . cannot justify suppressing information about electric devices or services that would cause no net increase in total energy use . . . no showing has been made that a more limited restriction on the content of promotional advertising would not

³³ 447 U.S. 557 (1980).

³⁴ *Id.* at 558–59.

³⁵ *Id.* at 561 (quoting *Consol. Edison Co. v. Pub. Serv. Comm’n*, 390 N.E.2d 749, 757 (N.Y. 1979)).

³⁶ *Id.*

³⁷ *Id.* at 563.

³⁸ *Id.* at 563–64. *See also* *National Ass’n of Mfrs. v. SEC*, No. 13–cv–635, 2013 WL 3803918, at *30 (D.D.C. Jul. 23, 2013) (“[I]t is well established that “‘the least restrictive means’ is not the standard; instead, the case law requires a reasonable ‘fit between the legislature’s ends and the means chosen to accomplish those ends.’”).

³⁹ *Id.* at 568–69.

serve adequately the State's interests."⁴⁰ Accordingly, the Court held that the order was unconstitutional.⁴¹

B. *Chipping Away at Intermediate Scrutiny*

Even after *Central Hudson*, it was unclear whether the state may "keep citizens in the dark" by "completely suppress[ing] the dissemination of concededly truthful information about entirely lawful activity."⁴² The Court upheld outright prohibitions on truthful speech in *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*,⁴³ concluding that if the government has the power to prohibit an activity (in this case, gambling), then it has the power to prohibit advertising of that activity. Similarly, in the 1993 case *United States v. Edge Broadcasting Co.*,⁴⁴ the Court refused to strike down a federal statute prohibiting broadcasters from advertising lotteries other than those operated by the state that licensed the station.⁴⁵ Despite the absence of any false or misleading content, the Court held that "this congressional policy of balancing the interests of lottery and nonlottery States" qualified as a "substantial government interest that satisfies *Central Hudson*."⁴⁶

The Court dramatically changed course a mere three years later when it struck down a Rhode Island ban on advertising liquor prices in *44 Liquormart v. Rhode Island*.⁴⁷ The plurality opinion penned by Justice Stevens condemned the "State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely."⁴⁸

In a similar vein, in *Thompson v. Western States Medical Center*, the Court struck down a prohibition on manufacturers' soliciting and advertising compounded pharmaceutical drugs under the *Central Hudson* framework.⁴⁹ Compounding is a technique of combining existing drugs to more suitably tailor the treatment to the needs of individual patients. The Food and Drug Administration Modernization Act of 1997 permits compounding without FDA preapproval provided that a number of requirements are met, including that the prescription is "unsolicited" and—most critically—that the pharmacist "not advertise or promote the com-

⁴⁰ *Id.* at 570.

⁴¹ *Id.* at 572.

⁴² *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 773 (1976).

⁴³ 478 U.S. 328 (1986).

⁴⁴ 509 U.S. 418 (1993).

⁴⁵ *See* 18 U.S.C. §§ 1304, 1307 (2006).

⁴⁶ *Edge Broadcasting*, 509 U.S. at 428.

⁴⁷ 517 U.S. 484 (1996).

⁴⁸ *Id.* at 487.

⁴⁹ 535 U.S. 357 (2002).

pounding of any particular drug, class of drug, or type of drug.”⁵⁰ The Court recognized that “[p]reserving the effectiveness and integrity of the FDCA’s new drug approval process is clearly an important governmental interest, and the Government has every reason to want as many drugs as possible to be subject to that approval process.”⁵¹ Nonetheless, it held that the government had failed to articulate a sufficient justification for the broad prohibition on advertising, rejecting the paternalistic notion that “people would make bad decisions if given truthful information about compounded drugs.”⁵² The Court also identified several less restrictive alternatives available to Congress, including prohibiting the use of commercial-scale manufacturing or testing equipment for compounding, prohibiting compounding in advance of anticipated prescriptions, banning the sale of compounded drugs at wholesale prices, limiting out-of-state sales or capping overall sales of compounded drugs.⁵³

In *Educational Media Co. v. Swecker*, the Fourth Circuit upheld a prohibition on alcohol advertisements in two college newspapers.⁵⁴ With respect to the third and fourth prongs of the *Central Hudson* test, the court deferentially concluded that the “link between [the advertising prohibition] and decreasing demand for alcohol by college students” is “amply supported by the record.”⁵⁵ Moreover, the court emphasized, it “only prohibits certain types of alcohol advertisements,” “allows restaurants to inform readers about the presence and type of alcohol they serve,” “only applies to college student publications—campus publications targeted at students under twenty-one,” and “does not, on its face, affect all possible student publications on campus.”⁵⁶

The key distinction between *Swecker* and the seemingly contradictory line of reasoning in *44 Liquormart* and *Western States Medical* is that the advertising prohibition sought to reduce “the serious problem of underage drinking and abusive drinking by college students,” which the *Swecker* court found to be a substantial government interest.⁵⁷ This interest is one of public safety and health, rather than a mere paternalistic restriction on individual decision-making by consumers legally permitted to buy a product. Abusive drinking affects society as a whole, not just a single individual, and we suggest this difference is not only descriptively relevant to distinguishing between outcomes in *Swecker*, *44 Liquormart*, and *Western States Medical*, but is also normatively valuable in con-

⁵⁰ 21 U.S.C. § 353a(c) (2006).

⁵¹ *Thompson*, 535 U.S. at 369.

⁵² *Id.* at 386.

⁵³ *Id.* at 372.

⁵⁴ *Educational Media Co. v. Swecker*, 602 F.3d 583 (4th Cir. 2010).

⁵⁵ *Id.* at 590.

⁵⁶ *Id.* at 590–91.

⁵⁷ *Id.* at 589.

structuring a theory of the proper bounds of limits on commercial speech. It is worth keeping this animating distinction in mind in the following discussion of *Sorrell* and our critique of *Caronia* in Section 0.

C. *Sorrell v. IMS Health*

It is apparent, then, that *Sorrell v. IMS Health*⁵⁸ was decided against the backdrop of increasing suspicion concerning paternalistic prevention of the dissemination of truthful information. The case arose out of a 2007 law enacted by the Vermont state legislature that prohibited pharmaceutical manufacturers from using records of pharmacy prescriptions for purposes of marketing to physicians.⁵⁹ Prior to the 2007 law, pharmacies would sell physician-identifying prescribing information to companies engaged in “data mining,” which would then lease this information to pharmaceutical manufacturers. The manufacturers would use this information to more effectively target brand name drug marketing efforts to each doctor in light of his or her prescribing history.⁶⁰

The legislative findings accompanying the statute emphasized that “the goals of marketing programs are often in conflict with the goals of the state” and the “marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors.”⁶¹ This causes “doctors [to] prescribe[e] drugs based on incomplete and biased information.”⁶² Even though the legislature made additional findings regarding the effect of such marketing, such as “increas[ing] the cost of health care and health insurance,”⁶³ the primary justification for the prohibition was the need to avoid a cognitive process that distorted physicians’ choice of brand-name drugs instead of the generic alternatives.⁶⁴ These rationales evidenced a strong paternalistic motive.

Rejecting the need to protect physicians from themselves, the *Sorrell* Court emphasized the importance of the free flow of information, quoting from its 1976 decision in *Virginia Bd. of Pharmacy v. Virginia*

⁵⁸ *Sorrell v. IMS Health*, 131 S. Ct. 2653 (2011).

⁵⁹ See An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information, 2007 Vt. Acts & Resolves 635, 650–53 (codified as amended at VT. STAT. ANN. tit. 18, § 4631 (2013)).

⁶⁰ *Sorrell*, 131 S. Ct. at 2660.

⁶¹ 2007 Vt. Acts & Resolves at 635.

⁶² *Id.*

⁶³ *Sorrell*, 131 S. Ct. at 2661 (citing 2007 Vt. Acts & Resolves at 637). Although Vermont also defended the statute as necessary to protect the privacy of the prescribing physician, that rationale was rejected because the prescriber-identifying information was made available to the government and other “favored” listeners. *Id.* at 2668.

⁶⁴ See *id.* at 2670 (“If prescriber-identifying information were available for use by detailers, the State contends, then detailing would be effective in promoting brand-name drugs that are more expensive and less safe than generic alternatives.”).

Citizens Consumer Council, Inc.: “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”⁶⁵ The Court pointed out that “[t]hese precepts apply with full force when the audience, in this case prescribing physicians, consists of ‘sophisticated and experienced’ consumers.”⁶⁶ The Court also recognized that the First Amendment protects not just the rights of listeners but also the rights of speakers—here, the data miners and drug manufacturers.

We will have more to say on the theoretical issues surrounding the free-market-of-information approach to regulating commercial speech in Part II. But it is worth noting at this juncture that, while many areas of existing regulation of truthful commercial speech—such as the regulation of offers of securities under the Securities Act of 1933—are geared towards unsophisticated consumers, not all are. Indeed, if the Court’s stated rationale in *Sorrell* were limited to sophisticated consumers, the ambit of its decision might not be as far-reaching. But the Court went much further, striking down the Vermont law because

[t]he State has imposed content- and speaker-based restrictions on the availability and use of prescriber-identifying information. So long as they do not engage in marketing, many speakers can obtain and use the information. But detailers cannot. Vermont’s statute could be compared with a law prohibiting trade magazines from purchasing or using ink. Like that hypothetical law, § 4631(d) imposes a speaker- and content-based burden on protected expression, and that circumstance is sufficient to justify application of heightened scrutiny.⁶⁷

As we explain in Part II.D.2, we prefer to read this narrowly in light of the legislature’s intentional discrimination against brand-name manufacturers in favor of their generic competitors. But a less charitable interpretation might conclude that the Court is imposing strict scrutiny simply because the regulation at issue only applies to a certain group within the population at large (a “speaker-based burden”) and only with respect to certain types of dialogue (a “content-based burden”). As others have noted,⁶⁸ such a reading would represent a dramatic expan-

⁶⁵ *Id.* at 2671 (quoting 44 *Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495, 1508 (1996)).

⁶⁶ *Id.* at 2671.

⁶⁷ *Id.* at 2667 (citing *Minneapolis Star & Tribune Co. v. Minn. Comm’r of Revenue*, 460 U.S. 575 (1983)).

⁶⁸ See, e.g., Isabelle Bibet-Kalinyak, *A Critical Analysis of Sorrell v. IMS Health, Inc.: Pandora’s Box at Best*, 67 *FOOD & DRUG L.J.* 191 (2012); John N. Joseph et al., *Is Sorrell the Death Knell for FDA’s Off-Label Marketing Restrictions?*, *J. HEALTH & LIFE SCI. L.*, Feb.

sion of First Amendment protection for commercial speech and the practical elimination of the *Central Hudson* intermediate scrutiny standard.

These implications were not lost on the three dissenting Justices. In an opinion authored by Justice Breyer, the dissenting Justices cited Justice Holmes's well-known dissent in *Lochner v. New York* and pointed out:

[G]iven the sheer quantity of regulatory initiatives that touch upon commercial messages, the Court's vision of its reviewing task threatens to return us to a happily bygone era when judges scrutinized legislation for its interference with economic liberty. History shows that the power was much abused and resulted in the constitutionalization of economic theories preferred by individual jurists. By inviting courts to scrutinize whether a State's legitimate regulatory interests can be achieved in less restrictive ways whenever they touch (even indirectly) upon commercial speech, today's majority risks repeating the mistakes of the past in a manner not anticipated by our precedents.⁶⁹

In short, the essence of Justice Breyer's critique is that most forms of substantive regulation have some effect on commercial speech. Any transaction between two parties necessarily involves speech—restricting the transaction is often impossible without restricting the speech.

Indeed, numerous areas of federal regulation restrict speech antecedent to or in parallel with economic transactions. For example, section 5(c) of the Securities Act of 1933 prohibits making an “offer to sell or offer to buy . . . any security, unless a registration statement has been filed as to such security.”⁷⁰ As offers are plainly commercial speech, subjecting the prohibition on making offers for unregistered securities to strict scrutiny could lead to the conclusion that section 5(c) is unconstitutional.⁷¹ We discuss this and other concerning possibilities at length in

2012, at 1; Pomeranz, *supra* note 3; Richard Samp, *Sorrell v. IMS Health: Protecting Free Speech or Resurrecting Lochner?*, 2010–2011 CATO SUP. CT. REV. 129, 130.

⁶⁹ *Sorrell*, 131 S. Ct. at 2679 (Breyer, J., dissenting) (citing *Lochner v. New York*, 198 U.S. 45, 75–76 (1905)).

⁷⁰ 15 U.S.C. § 77e(c) (2006).

⁷¹ Similarly, Section 17(b) of the Securities Act of 1933, 15 U.S.C. § 77q(b) (2006), prohibits a person from receiving compensation from an issuer in exchange for writing about a security unless the compensation is fully disclosed. As explained by Samp, *supra* note 68, at 142, the U.S. Court of Appeals for the D.C. Circuit subjected the limitations in Section 17(b) to “limited First Amendment scrutiny,” reasoning: “In areas of extensive federal regulation—like securities dealing—we do not believe that the Constitution requires the judiciary to weigh the relative merits of particular regulatory objectives that impinge upon communications occurring within the umbrella of an overall regulatory scheme.” *SEC v. Wall St. Publ'g Inst.*, 851 F.2d 365, 373 (D.C. Cir. 1988).

Part II.A, but suffice it to say that an expansive reading of the Court's reasoning in *Sorrell* suggests the extinction of the commercial speech doctrine. At the very least, *Sorrell* suggests that the intermediate scrutiny standard in *Central Hudson* may not be so intermediate after all.

D. United States v. Caronia: *Prohibiting Truthful Marketing of Off-Label Use by Prescription Drug Manufacturers*

1. Background and Context

The original Pure Food and Drug Act of 1906 did not require preapproval of pharmaceutical drugs.⁷² The predominant paradigm was one of *ex post* enforcement through litigation over false claims.⁷³ But in 1911, the Supreme Court held that the antifraud prohibition did not extend to claims relating to the effect of a drug on a patient's health but only factual descriptions such as the drug's ingredients.⁷⁴ Despite the enactment of a subsequent statutory amendment in 1912 prohibiting fraud,⁷⁵ the standard of intentional misrepresentation proved too high a burden to effectively reduce false claims in drug advertising.⁷⁶ Yet it took another twenty-six years, after more than one hundred people died from a poisonous "Elixir Sulfanilamide," before Congress enacted the Federal Food, Drug and Cosmetic Act (FDCA) in 1938.⁷⁷

The sulfanilamide fiasco led to the imposition of a requirement in the FDCA for preapproval before a drug may be marketed,⁷⁸ reflecting the recognition that *ex post* litigation provided insufficient deterrence. Section 505(a) of the FDCA states plainly, "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."⁷⁹ The remainder of section 505 specifies detailed requirements for such an application and prescribes the process by which approval of a new drug may be granted.⁸⁰

⁷² Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938). For a detailed overview of the history of the FDCA, see generally Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420 (1981).

⁷³ See Janssen, *supra* note 72, at 427.

⁷⁴ United States v. Johnson, 221 U.S. 488 (1911).

⁷⁵ Sherley Amendment, Pub. L. No. 62-301, 37 Stat. 416 (1912).

⁷⁶ See Janssen, *supra* note 72, at 427-28.

⁷⁷ Pub. L. No. 75-717, 52 Stat. 1040 (1938); Janssen, *supra* note 72, at 429.

⁷⁸ *Id.* ("Drug manufacturers were required to provide scientific proof that new products could be safely used before putting them on the market—the sulfanilamide experience had started what is now the major system of U. S. drug regulation.")

⁷⁹ 21 U.S.C. § 355(a) (2006).

⁸⁰ See *id.* § 355(b)-(w).

Two essential aspects of this approval process are the requirements that a new drug be “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof” and that it may “responsibly be concluded . . . that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.”⁸¹ Accordingly, marketing a drug for a use other than that which appears on the proposed labeling would seem to raise concerns regarding safety and efficacy.⁸² The FDCA, however, does not expressly prohibit marketing a drug for “off-label” uses. Rather, it prohibits “misbranding,” which is defined as “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded.”⁸³ This circular language ultimately turns on the definition of “misbranded,” which the statute defines to include labeling that lacks “adequate directions for use.”⁸⁴ The statutory definition makes no reference to marketing, promotion, or even approved uses.

The FDA, however, enacted regulations that go beyond simple mislabeling. They define “adequate directions for use” to include “directions under which the layman can use a drug safely and for the purposes for which it is intended.”⁸⁵ “Intended use” is further defined as

the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. *It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.*⁸⁶

Accordingly, under these FDA regulations, the government may establish misbranding by showing that the drug’s labeling diverges from the “intended use” by its manufacturer, which may be shown by statements made by its representatives. Misbranding is a crime punishable by up to

⁸¹ *Id.* § 355(d).

⁸² That said, questions regarding the safety of a drug are less important for new indications than those of effectiveness. Most off-label use is tangential to an existing approved use and thus has an applicable and often robust safety profile. Furthermore, the industry is often seeking to promote off-label use through the dissemination of clinical studies.

⁸³ 21 U.S.C. § 331(a) (2006).

⁸⁴ *Id.* § 352(f).

⁸⁵ 21 C.F.R. § 201.5 (2013).

⁸⁶ *Id.* § 201.128 (emphasis added).

three years in prison or \$10,000 in fines per occurrence,⁸⁷ which can accumulate to millions or even billions of dollars. It is essential to observe that this convoluted statutory and regulatory scheme means that misbranding is a crime that applies to *manufacturers* and their representatives only—any other party may freely discuss and even promote a drug for unapproved uses because they do not fall within the ambit of the labeling statute.

Indeed, the Department of Justice has recently pursued misbranding cases that have led to multi-billion dollar judgments. In July 2012, GlaxoSmithKline LLC pled guilty and agreed to pay \$3 billion in fines and forfeitures over charges of misbranding the drugs Paxil, Wellbutrin, and Avandia.⁸⁸ In May 2012, Abbott Laboratories pled guilty and agreed to pay \$1.6 billion to settle charges that it had illegally marketed Depakote.⁸⁹ In 2010, Pfizer similarly paid \$2.3 billion to resolve charges of misbranding Bextra and illegally promoting Geodon, Zyvox, and Lyrica.⁹⁰ In all of these cases, a primary theory of liability was marketing for an unapproved use, not necessarily that the advertised use was false or misleading.⁹¹

As several commentators have noted, *Sorrell v. IMS Health* reflects a substantial weakening of the commercial speech doctrine set out in *Central Hudson*, which calls into question the constitutionality of the

⁸⁷ 21 U.S.C. § 333(a)(2).

⁸⁸ Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data: Largest Health Care Fraud Settlement in U.S. History (Jul. 2, 2012), available at <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.

⁸⁹ Terry Frieden & Tom Watkins, *Abbott Laboratories to Pay \$1.6 Billion Over Misbranding Drug*, CNN.COM, <http://www.cnn.com/2012/05/07/justice/abbott-fine-drug> (May 7, 2012, 6:29 PM).

⁹⁰ Press Release, U.S. Dep't of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sep. 2, 2009), available at <http://www.justice.gov/opa/pr/2009/September/09-civ-900.html>.

⁹¹ Affirming a conviction for medical device sales without FDA approval, the Second Circuit acknowledged the classic objection to commercial speech regulation in this context:

[I]f a given use is lawful, and thus can be written about freely in newspapers or blogs, and discussed among hospitals . . . doesn't it make a good deal of sense to allow speech by the manufacturer, which after all will have the best information? Why privilege speech by the uninformed?

United States v. Caputo, 517 F.3d 935, 939 (7th Cir. 2008). But the court rejected this argument, concluding that "if a manufacturer's promise to the FDA to avoid speech about off-label uses is unenforceable, the FDA may respond by withholding any approval of drugs or devices that have questionable additional uses." *Id.*; see also *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). Some have advocated that off-label use should constitute the standard of care in a medical malpractice action because it reflects "the safest, most effective, state-of-the-art treatment." Mark Herrmann & Pearson Bownas, *Keeping the Label Out of the Case*, 103 Nw. U. L. REV. COLLOQUY 477, 486 (2009).

FDA's regulation of off-label marketing.⁹² In *United States v. Caronia*,⁹³ the Second Circuit took the erosion of the intermediate scrutiny standard for commercial speech to a new level. The facts of *Caronia* are straightforward. Alfred Caronia was a sales representative for Orphan Medical, Inc., manufacturer of Xyrem, a drug approved by the FDA to treat narcolepsy.⁹⁴ Along with co-defendant Dr. Peter Gleason,⁹⁵ Caronia marketed Xyrem to doctors at various events and one-on-one meetings.⁹⁶ In one such meeting, Caronia was secretly recorded promoting Xyrem for uses not approved by the FDA such as chronic pain, fatigue, and fibromyalgia.⁹⁷ Caronia was charged with promoting an unapproved use of a pharmaceutical drug in violation of the FDCA, a federal crime through a convoluted interaction of statutory language and FDA rulemaking.

The appeal in *Caronia* was limited to the question of whether these regulations are constitutional under the First Amendment. The constitutional question arises from the selective nature of the prohibition on promoting off-label uses: again, only manufacturers and their representatives are subject to the restriction under this unique statutory and regulatory scheme. Congress and the FDA could have prohibited off-label promotion entirely, but they did not, likely for political reasons, as others have suggested.⁹⁸ Moreover, the prohibition on off-label marketing is not restricted to false or misleading statements, which would be independently actionable under the existing law of fraud. This is simply an outright ban on promoting the off-label uses of a drug that applies solely to manufacturers and their representatives.

In a 2–1 opinion, the Second Circuit vacated Caronia's conviction, holding that prosecution solely for promoting off-label uses violated the First Amendment.⁹⁹ In its appeal, the government attempted to argue it

⁹² See, e.g., Joseph, *supra* note 68; Kate Maternowski, Note, *The Commercial Speech Doctrine Barely Survives Sorrell*, 38 J.C. & U.L. 629 (2012); Samp, *supra* note 68, at 130 (“Several justices have expressed a willingness to eliminate the doctrinal distinctions between commercial speech and other forms of speech[] . . . [but] the Court’s majority is not yet willing to take that step.”).

⁹³ U.S. v. Caronia, 703 F.3d 149 (2d Cir. 2012).

⁹⁴ *Id.* at 155.

⁹⁵ Dr. Gleason and Orphan Medical pled guilty to charges of misbranding under the FDCA. *Id.* at 158.

⁹⁶ *Id.* at 156.

⁹⁷ *Id.*

⁹⁸ See, e.g., Coleen Klasmeier & Martin H. Redish, *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 AM. J.L. & MED. 315, 323 (2011) (“What began as an effort to control off-label prescribing by physicians thus shifted to the use of a federal statute to constrain manufacturer speech about such prescribing—purely, it would seem, because physicians so vociferously objected to any insinuation by the FDA into decisions relating to the circumstances in which lawfully marketed drugs would be used.”).

⁹⁹ U.S. v. Caronia, 703 F.3d 149, 160 (2d Cir. 2012).

was not prosecuting Caronia for the speech per se but rather was using the off-label marketing solely as proof of intent to distribute misbranded drugs, in line with the text of the FDA regulation.¹⁰⁰ The court, however, rejected that argument, emphasizing that the trial record “confirms overwhelmingly that Caronia was, in fact, prosecuted and convicted for promoting Xyrem off-label.”¹⁰¹ Moreover, the court emphasized, “[t]he government never argued in summation or rebuttal that the promotion was evidence of intent,” and indeed:

[T]he government never suggested that Caronia engaged in any form of misbranding other than the promotion of the off-label use of an FDA-approved drug. The government never suggested, for example, that Caronia conspired to place false or deficient labeling on a drug. Rather, the record makes clear that the government prosecuted Caronia *for* his promotion and marketing efforts.¹⁰²

Accordingly, the Second Circuit analyzed the constitutionality of Caronia’s prosecution under the theory that the off-label marketing alone constituted a violation of the FDCA.

The majority based its holding on two seemingly independent theories: first, that the FDA regulations are content-based and speaker-based restrictions on speech, thus justifying strict scrutiny under *Sorrell*; and second, that the FDA regulations fail even the more lenient test of intermediate scrutiny under *Central Hudson*. As we explain, however, it is doubtful that the court’s application of these tests are truly independent. Indeed, the approach taken by the majority has profound implications.

2. Analogy to *Sorrell* and Strict Scrutiny

In its first justification for finding Caronia’s prosecution unconstitutional, the majority heavily relied on *Sorrell*, identifying two fatal flaws in the FDA’s prohibition of off-label marketing: (a) the prohibition only applies to speech with specific content; and (b) it applies solely to pharmaceutical manufacturers.¹⁰³ The majority analogized both of these to the data mining law in *Sorrell* that was found unconstitutional by the Supreme Court. As in *Sorrell*, the majority suggested, the FDA is seeking to restrict a specific type of speech—marketing off-label drug uses—while the underlying conduct remains entirely legal.¹⁰⁴ Moreover, like

¹⁰⁰ *Id.* at 160–61.

¹⁰¹ *Id.*

¹⁰² *Id.* (citations omitted).

¹⁰³ *Id.* at 165.

¹⁰⁴ *Id.* (“Indeed, the content of the regulated speech drives this construction of the FDCA; as in *Sorrell*, the ‘express purpose and practical effect’ of the government’s ban on promotion

Sorrell, this restraint “targets one kind of speaker—pharmaceutical manufacturers—while allowing others to speak without restriction.”¹⁰⁵ It is a straightforward application of the Supreme Court’s holding in *Sorrell*, the majority concluded, to subject the FDA’s content-based and speaker-based prohibition on commercial speech to strict scrutiny. Indeed, the criminal charges against Caronia justify “more careful scrutiny” than the one applied in *Sorrell*, which concerned civil liability.¹⁰⁶

A more careful look at the two cases, however, suggests that this analogy is less straightforward than the majority suggests. The Supreme Court emphasized that the law in *Sorrell* had the “express purpose and practical effect” of “diminish[ing] the effectiveness of marketing by manufacturers of brand-name drugs.”¹⁰⁷ In other words, the regulation did not merely target a specific segment of the public but actively discriminated between brand-name and generic manufacturers; the court thus noted: “it appears that Vermont could supply academic organizations with prescriber-identifying information to use in countering the messages of brand-name pharmaceutical manufacturers and in promoting the prescription of generic drugs.”¹⁰⁸ Indeed, as we explain more fully below, there is a key distinction between restricting the scope of regulation to its functionally justified target—i.e., the segment of society that must be brought within its scope for the regulation to function effectively—and discriminating between parties in an arbitrary and unfair manner, i.e., to the benefit of one and detriment of another.¹⁰⁹

Indeed, this concern of arbitrarily favoring one industry participant or type of good over another seemed to animate the Court’s decision in *Brown v. Entertainment Merchants Ass’n*, where it struck down a prohibition on the sale of violent video games to minors.¹¹⁰ While *Brown* was a core speech case, the Court emphasized the analogous point that “California has singled out the purveyors of video games for disfavored treatment—at least when compared to booksellers, cartoonists, and movie producers—and has given no persuasive reason why.”¹¹¹ In our view, as a descriptive matter this fundamental consideration moves the Court.

is to ‘diminish the effectiveness of [off-label drug] marketing by manufacturers.’”) (quoting *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2663 (2011)).

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* (citing 21 U.S.C. § 333(a) (2006); *Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2724 (2010)).

¹⁰⁷ *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2663 (2011) (emphasis added).

¹⁰⁸ *Id.*

¹⁰⁹ Indeed, an additional unique aspect of *Sorrell* was that federal and state governments are large purchasers of pharmaceutical drugs as well. Government is acting both as a buyer and regulator when it prohibits data mining, and thus seems to have an inherent conflict of interest in favoring generics.

¹¹⁰ 131 S. Ct. 2729, 2740–42 (2011).

¹¹¹ *Id.* at 2740.

Moreover, as we explain in Part III, we suggest that the principle of not favoring one industry participant over another should constitute a foundational principle of a comprehensive revision of the FDA's approach to regulating off-label marketing.¹¹²

Similarly, the D.C. Circuit in *R.J. Reynolds Tobacco Co. v. FDA* recently struck down the FDA's mandatory graphic labeling for cigarette packaging under *Central Hudson*.¹¹³ The court formally decided the case by finding that the FDA failed to provide any evidence that the graphic warnings would "directly advance" the FDA's interest in reducing smoking,¹¹⁴ but its presentation of the question is telling: "how much leeway should this Court grant the government when it seeks to compel a product's manufacturer to convey the state's subjective—and perhaps even ideological—view that *consumers should reject this otherwise legal, but disfavored, product.*"¹¹⁵ It seems that the court was particularly disturbed by the discrimination among equally legal products in an industry. This view is consistent with our proposal to subject restrictions on truthful commercial speech to more deferential intermediate scrutiny under *Central Hudson* as long as the truthful commercial speech does not favor one industry participant over another.

The *Caronia* majority's content-based argument is even more suspect. In *Sorrell*, the Court emphasized the legislature's "expressed statement of purpose" to "target those speakers and their messages for disfavored treatment," i.e., "messages that 'are often in conflict with the goals of the state.'"¹¹⁶ This was the content-based restriction the Court found to justify strict scrutiny—an explicit legislative intent to prohibit messages that contradicted its *ex ante* goals for ideal public discourse on the advantages and disadvantages of various pharmaceuticals. There was no such intent in the development of the FDA's off-label marketing regu-

¹¹² Indeed, our approach can guide the resolution of a recent split between the Second and Sixth Circuits over the applicable standard of review when regulating truthful commercial speech. In *Discount Tobacco City & Lottery v. United States*, the Sixth Circuit held that strict scrutiny applies to such restrictions. *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 554 (6th Cir. 2012) ("If a commercial-speech disclosure requirement fits within the framework of *Zauderer* and its progeny, then we apply a rational-basis standard. If it does not, then we . . . apply strict scrutiny.") (citations omitted). The U.S. District Court for the District of Columbia expressly disagreed with this position in *National Association of Manufacturers v. SEC*, emphasizing the contrary precedent of the D.C. Circuit. *National Ass'n of Mfrs. v. SEC*, No. 13-cv-635, 2013 WL 3803918, at *28 (D.D.C. Jul. 23, 2013) ("While some circuits apply strict scrutiny once the case is found to fall outside of the *Zauderer* standard, our Circuit has rejected this dichotomous approach, holding instead that in evaluating the constitutionality of compelled commercial speech, any 'burdens imposed . . . receive a lower level of scrutiny from courts.'") (citations omitted).

¹¹³ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1208 (D.C. Cir. 2012).

¹¹⁴ *Id.* at 1219.

¹¹⁵ *Id.* at 1212 (emphasis added).

¹¹⁶ *Id.* (quoting 2007 Vt. Acts & Resolves 635).

lations, which sought to promote public health by preventing the needless purchase of ineffective drugs and exposure of patients to unnecessary potential safety risks.¹¹⁷ Controlling unduly paternalistic opinion restrictions on commercial speech is fundamentally different from preventing misallocation of resources and protecting patient health.

The FDA was not seeking to silence contrary opinion but rather to discourage the use of drugs in ways that are potentially ineffective or unsafe. If anything, the FDA's regulation was arguably content-neutral—it did not prohibit the *content* of marketing messages, e.g., specific words or phrases. Rather, it sought to ensure that, regardless of the precise marketing message, manufacturers' inherent interest in selling their products would not unnecessarily endanger patients' health. The requirement of obtaining FDA approval for specific uses before the products may be legally marketed can be understood as a prophylactic means of achieving this goal. Now, this restriction currently sweeps too far in our view—but that does not imply that the FDA intended to suppress a certain viewpoint, as the Vermont legislature did in *Sorrell*. Accordingly, *Sorrell* does not seem to justify the application of strict scrutiny in *Caronia*.

Moreover, as Richard Samp, Chief Counsel of the Washington Legal Foundation, points out,¹¹⁸ the *Sorrell* Court acknowledged that limits on commercial speech might be warranted to protect against fraud,¹¹⁹ to suppress false commercial speech or commercial speech that proposes an illegal transaction,¹²⁰ or to protect privacy.¹²¹ As we explained above, the FDA does not ban the discussion of off-label uses *per se*. It bans the promotion of misbranded drugs, which do not bear adequate warnings. Because it is illegal to sell misbranded drugs, such promotions might be viewed as proposing an illegal transaction.

Indeed, the First Amendment doctrine with respect to *noncommercial* speech takes a deferential approach to content-neutrality, i.e., time, place, or manner, restrictions. In *Ward v. Rock Against Racism*, the Court upheld a New York City ordinance that required use of a sound technician and amplification equipment approved by the City in order to

¹¹⁷ See Klasmeier & Redish, *supra* note 98, at 320–21.

¹¹⁸ Samp, *supra* note 68, at 138.

¹¹⁹ *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2672 (2011) (“The Court has noted, for example, that ‘a State may choose to regulate price advertising in one industry but not in others, because the risk of fraud . . . is in its view greater there.’” (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 388–89 (1992))).

¹²⁰ *Id.* at 2664 (reasoning that bans on false commercial speech and a ban on commercial speech that proposes an illegal transaction are “restrictions directed at commerce or conduct” that impose only “incidental burdens on speech”).

¹²¹ *Id.* at 2668 (noting that the medical record privacy provisions in the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-2, “would present quite a different case”).

prevent excessive music volume at outdoor concerts.¹²² The Court emphasized that a content-neutral regulatory scheme “need not be the least restrictive or least intrusive means” of accomplishing the governmental interest.¹²³ Similarly, the Court emphasized that the content-neutral test applies whenever the government has not “adopted a regulation of speech because of disagreement with the message it conveys.”¹²⁴ Here, the FDA has plainly not adopted its restrictions in order to target a specific economic actor or a group of actors. The agency’s regulations limit off-label promotion by brand-name and generic drug manufacturers alike. Accordingly, by analogy to noncommercial speech, lower scrutiny should apply to this content- and speaker-neutral restriction. Indeed, reading *Sorrell* as broadly as the majority suggests would have profound implications for the constitutionality of several federal regulatory regimes, as we discuss further below.

3. *Central Hudson*: Intermediate Scrutiny in Name Only?

The second justification given by the *Caronia* majority for vacating *Caronia*’s conviction was that the FDA regulation failed the traditional four-prong intermediate scrutiny test of *Central Hudson* for the constitutionality of a restriction on commercial speech.¹²⁵ As explained above, under *Central Hudson* as long as the commercial speech (1) concerns lawful activity and is not false or misleading, a prohibition will be upheld only if it advances (2) a substantial government interest, (3) directly advances that interest, and is (4) “not more extensive than is necessary to serve that interest.”¹²⁶ While the *Caronia* majority found that the first two elements of the *Central Hudson* test were satisfied, it held that the third and fourth were not.

With respect to the third element, the majority concluded:

As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government’s goals of preserving the efficacy and integrity of the FDA’s drug approval process and reducing patient exposure to unsafe and ineffective drugs.¹²⁷

¹²² 491 U.S. 781, 803 (1989).

¹²³ *Id.* at 798.

¹²⁴ *Id.* at 791.

¹²⁵ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566, 571–72 (1980).

¹²⁶ *Id.* at 566.

¹²⁷ *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012).

Of course, this conclusory finding shows no deference to the agency's determination regarding the effect of off-label marketing or even an explanation why this does not "directly" further the goal of protecting patient safety. Reducing the marketing of off-label drug usage would seem to have some corresponding effect on actual use. And since off-label usage has not undergone FDA review for safety and effectiveness, it seems reasonable to suppose that on average, unapproved uses of a drug are less effective or more risky than approved uses. Accordingly, it does not take particularly strong assumptions to reach the conclusion that reducing off-label marketing would tend, on average, to directly improve allocative efficiency—the expenditure of resources on drugs that are most effective—and patient safety. That is not to say that these are the only relevant considerations, but the *Caronia* majority's summary conclusion that there is *no* such direct effect seems unfounded. A failure to prohibit the underlying activity—off-label usage—does not imply that prohibiting off-label marketing would not achieve a similar end.

It is interesting to note that the majority follows this conclusory assertion with a citation to *Sorrell* and a parenthetical explanation: "holding government interest in protecting physician privacy not directly served when law made prescriber-identifying information available to 'all but a narrow class of disfavored speakers.'"¹²⁸ This suggests that the *Caronia* majority is actually applying the strict scrutiny analysis it employed previously, despite referring to *Central Hudson* and its "less rigorous intermediate test."¹²⁹ Indeed, one has to wonder if this is merely intermediate scrutiny in name only. The court showed no deference to the FDA's view on the link between marketing and usage and, by citing *Sorrell* yet again, the court seems to be fixated on the supposed speaker-based restriction. Interestingly, the bulk of its discussion of the third prong focuses not on the distinction between "direct" and "indirect" furtherance of a governmental interest, but on the policy rationales weighing against the FDA's regulation:

[P]rohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use "paternalistically" interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions.¹³⁰

¹²⁸ *Id.* at 166.

¹²⁹ *Id.* at 164.

¹³⁰ *Id.* at 166.

However, as we explain in Part II, the implications of applying strict scrutiny to this type of regulation—even when semantically applying *Central Hudson*—are wide-reaching and threaten to undermine entire blocks of federal regulation, such as the Securities Act of 1933. The theoretical and policy considerations implicated in this issue are complex and require a fundamental discussion of First Amendment theory in the context of commercial speech.

Similarly, the *Caronia* majority's discussion of the fourth *Central Hudson* prong consists of a summary conclusion that "the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests."¹³¹ An analytic discussion of this fourth prong would begin by considering how precisely this interest should be defined. Again, prohibiting off-label marketing by manufacturers is highly likely to lead to a reduction in off-label usage. If the governmental interest is promoting patient safety, it is hard to conceive of anything more necessary to achieve that interest than a reduction in off-label usage, however slight—and the marketing restriction is likely to have more than a slight effect. Indeed, the Supreme Court has made it clear that

[t]he Government is not required to employ the least restrictive means conceivable, but it must demonstrate narrow tailoring of the challenged regulation to the asserted interest—"a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served."¹³²

Indeed, there is a fundamental difference between an irrational prohibition and one that achieves a marginal effect.¹³³ Conceptually, the notion of "more extensive than necessary" implies that some aspect of the restriction is ineffective at achieving the result. If a marginal effect cannot be narrowly tailored, then only regulation that succeeds at completely eliminating the undesired phenomenon would pass. This is unrealistic and again shows the majority's application of a strict scrutiny standard that seems impossible to meet. Part II discusses the policy implications

¹³¹ *Id.* at 167.

¹³² *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999) (quoting *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989)).

¹³³ *Cf. WV Ass'n of Club Owners and Fraternal Servs., Inc. v. Musgrave*, 553 F.3d 292, 304–05 (4th Cir. 2009) ("The Court has struck down restrictions in cases where the program is irrational . . . or where there is specific evidence that goes against the claimed linkage." (citing *Greater New Orleans Broadcasting, 527 U.S.* at 190; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506 & n.17 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995); *Edenfield v. Fane*, 507 U.S. 761, 771–73 (1993))).

of such a fundamental limitation on the government's capacity to restrain commercial speech in light of the theory behind the First Amendment.

II. THE CHALLENGE OF REGULATING COMMERCIAL SPEECH

A. *Public Interest v. Paternalism in Regulation of Commercial Speech: Information Dissemination or Protecting Unwary Consumers?*

1. The Theory of Protecting Commercial Speech Under the First Amendment

Despite appearing deceptively simple, numerous theoretical questions surrounding commercial speech—what precisely it is, whether it is entitled to protection under the First Amendment, and what the extent of such protection should be—are maddeningly complex. As Robert Post noted in his famous essay in the *UCLA Law Review*, “[c]ommercial speech differs from public discourse because it is constitutionally valued merely for the information it disseminates, rather than for being itself a valuable way of participating in democratic self-determination.”¹³⁴ The problem, of course, is that it is far from clear how much protection the dissemination of information should receive. Post suggests that, as a starting point, the First Amendment should apply “only when the stream of information flows among strangers who can be conceived as independent and rational,” which implies that “information must be dispersed under conditions that are constitutive of a public communicative sphere.”¹³⁵

This principle permits identifying those cases of “dependence or reliance” where commercial speech receives no First Amendment protection because it will be generally regarded as “‘linked inextricably’ with the commercial arrangement in which it occurs,” so that regulation of the arrangement can also restrict the speech by which the arrangement is constituted.”¹³⁶ However, this categorization is less helpful for judging the appropriateness of a government restraint of protected commercial speech that is truthful, and particularly the degree of scrutiny courts should impose. On this issue, Post suggests that the guiding theory should be a distinction between truly paternalistic regulation and advancing the public interest:

In *Linmark Associates, Inc. v. Township of Willingboro*, for example, the government forbade “for sale” signs in

¹³⁴ Robert C. Post, *The Constitutional Status of Commercial Speech*, 48 *UCLA L. REV.* 1, 4 (2000).

¹³⁵ *Id.* at 24.

¹³⁶ *Id.* at 24–25 (footnote omitted) (quoting *Edenfield* 507 U.S. at 767 (1993)) (quoting *Friedman v. Rogers*, 440 U.S. 1, 10 n.9 (1979)).

order to prevent the blockbusting of a racially integrated neighborhood. The regulation had nothing to do with the “good” of individual buyers or sellers, but was instead enacted to preserve the possibility of integrating housing. The ordinance was not paternalistic It did not regulate the behavior of individuals in order to protect them from themselves; it sought instead to achieve a public good.¹³⁷

While some scholars have suggested that paternalism historically played little role in the Court’s adjudicatory process,¹³⁸ it held great importance in *Sorrell*¹³⁹ and was explicitly emphasized by the Second Circuit in *Caronia*.¹⁴⁰ The fear of paternalism—and a corresponding commitment to consumer autonomy—seems to underlie this most recent trend of decisions that are chipping away at the intermediate scrutiny standard.¹⁴¹

Scholars have penned a variety of responses to the concern that excessive paternalism undermines the liberty and autonomy of individual citizens. For example, Robert Post takes the view that the normative superiority of individual autonomy in the context of democracy and the First Amendment is misplaced: “democracy is not about individual self-government, but about collective self-determination,” which means that “[u]nlike various forms of liberalism, democracy does not focus on the protection of individual autonomy outside of participation within this

¹³⁷ *Id.* at 51 (footnotes omitted) (citing *Linmark Assocs., Inc. v. Twp. of Willingboro*, 431 U.S. 85, 87–91 (1997)).

¹³⁸ *E.g.*, Daniel Hays Lowenstein, “*Too Much Puff*”: *Persuasion, Paternalism, and Commercial Speech*, 56 U. CIN. L. REV. 1205, 1242 (1988) (“[I]n the absence of any cases involving truly paternalistic restrictions of the strong type, the Court ought to be taken at its anti-paternalistic word.”).

¹³⁹ *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2670–72 (2011) (“[T]he ‘fear that [consumers] would make bad decisions if given truthful information’ cannot justify content-based burdens on speech.” (quoting *Thompson v. Western States Medical Ctr.*, 535 U.S. 357, 374 (2002) and citing *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 769–70 (1976))). The Second Circuit cited this statement in *Caronia*. *United States v. Caronia*, 703 F.3d 149, 166, 181 (2d Cir. 2012).

¹⁴⁰ *Caronia*, 703 F.3d at 166.

¹⁴¹ In our view, the ideological opposition to paternalism is the more compelling explanation for the recent case law rather than a genuine belief in the natural efficiency of a market of free information in the commercial sphere. The notion that consumers make better-informed decisions, as an empirical matter, when there are no restrictions on the free flow of information strains credulity. One need only look at the success of advertising campaigns for cigarettes among youth to realize that the truth does not always win in the market of commercial ideas regarding the desirability of products or services. *See, e.g.*, Lowenstein, *supra* note 138, at 1208. Indeed, the inability of consumers to accurately internalize the economic costs and benefits in response to lengthy, confusing disclosure and conflicting commercial messages has been well-documented in the empirical literature. *See generally, e.g.*, Martin J. Eppler & Jeanne Mengis, *The Concept of Information Overload: A Review of Literature from Organization Science, Accounting, Marketing, MIS, and Related Disciplines*, 5 INFO. SOC’Y 325 (2004) (summarizing the relevant literature across disciplines).

public sphere.”¹⁴² Post’s approach implies, then, that paternalism—limiting individual autonomy—is justified if it is necessary to promote the collective enterprise of democracy.

But this view is far from predominant. Other scholars emphasize that American democracy is indeed a *liberal* democracy, in which individual autonomy is a value inherently worthy of normative respect. Martin Redish, for example, argues that “speech concerning commercial products and services can facilitate private self-government in much the same way that political speech fosters collective self-government,” and in his view, “[b]oth private and collective self-government are grounded in identical normative concerns about self-development and self-determination.”¹⁴³ It follows from this normative commitment to self-government that paternalism is highly problematic.

Unfortunately, neither conception of the role of liberty and individual autonomy seems entirely compelling. Post’s emphasis on the collective nature of democracy seems to beg the question of the normative value scheme that lies at the heart of the debate over commercial speech. Whether American democracy *should* privilege the autonomy of speakers conveying truthful information that is commercial in nature is precisely the question at issue. The statement that democracy “is about collective self-determination” rather than “individual self-government” seems little more than a conclusory restatement of the normative assumption that individual autonomy is not worthy of protection. The key question, as Redish correctly points out, is why Post’s notion of collective democracy should be preferred over the alternative of liberalism.¹⁴⁴

On the other hand, Redish’s view fails to persuade as well. Even if one assumes that private and collective self-government derive from a common commitment to self-determination, it does not follow that the legal protection given to both forms of speech should be identical or even that the ambit of the First Amendment encompass both. Numerous constitutional doctrines advance abstract normative principles of justice, equality, and freedom—but they do not receive identical doctrinal protection, nor do they all fall within the same constitutional provision. In that sense, Redish’s argument proves too much: interpreting the First

¹⁴² Robert C. Post, *Viewpoint Discrimination and Commercial Speech*, 41 LOY. L.A. L. REV. 169, 175–76 (2000).

¹⁴³ Martin H. Redish, *Commercial Speech, First Amendment Intuitionism, and the Twilight Zone of Viewpoint Discrimination*, 41 LOY. L.A. L. REV. 67, 81 (2007).

¹⁴⁴ *Id.* at 80–81 (“If one were to define ‘commercial speech’ as speech concerning commercial products or services, I suppose one starting from the premise that the First Amendment is primarily or exclusively designed to protect speech relevant to the political process would logically conclude that commercial speech is deserving of little or no First Amendment protection. I have attacked this view as flawed because *it fails to determine the normative reasons our system would choose democracy in the first place.*” (emphasis added)).

Amendment solely in light of a highly abstract normative commitment to self-government suggests that nearly any expressive human activity is entitled to its protection.

It seems that these views can be reconciled, however, by focusing more tightly on the distinction between paternalism and the provision of public goods. It is true that, at the most general level of abstraction, individual well-being is itself a public good, as suboptimal decisions by individuals reduce the overall level of welfare in society. But there is a distinction between regulating commercial speech *solely* for the sake of withholding information from consumers' cognitive processes and regulating in order to prevent a social externality that would inevitably result if the truthful—but socially harmful—information were to seep out into the marketplace and affect consumer behavior.

We discuss the application of this distinction in existing law in the following subsection, but consider the simple example of regulating disclosure in financial transactions. The recent financial crisis and ensuing recession demonstrated the tremendous cost to society that resulted, at least in part, from poor decisions by consumers regarding subprime mortgages.¹⁴⁵ It would be fundamentally inaccurate to characterize mandatory mortgage disclosure regulation as nothing more than a paternalistic effort to control the information available to homeowners. Disclosures that increase the likelihood individual decisions will be truly welfare-maximizing benefit society as a whole, not merely the homeowners who are the direct beneficiaries of the regulatory scheme. Mortgage disclosure is most accurately understood as regulation of commercial speech that supplies a public good, namely, more efficient pricing in housing and credit markets.

While helpful, this distinction is still rife with significant ambiguity. Any given policy is likely to benefit both the recipients of information *and* society as a whole. Of course, nothing in this discussion will yield a mechanical classification system for commercial speech—the contours of any legal doctrine ultimately reduce to difficult judgments in borderline cases. But the advantage of this definition is that it permits ascribing a predictable probability of heightened constitutional protection according to the degree to which the speech advances clearly defined public goods rather than the well-being of individual consumers.

¹⁴⁵ See generally FIN. CRISIS INQUIRY COMM'N, THE FINANCIAL CRISIS INQUIRY REPORT: FINAL REPORT OF THE NATIONAL COMMISSION ON THE CAUSES OF THE FINANCIAL AND ECONOMIC CRISIS IN THE UNITED STATES 67 (2011), available at <http://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf> (explaining the history of subprime mortgages and how consumers' poor decisions with them partially led to the recent financial crisis).

A good example of this predictive power is *Educational Media Co. v. Swecker*, discussed previously.¹⁴⁶ *Swecker* was decided several years after a very similar case in the Third Circuit, *Pitt News v. Pappert*.¹⁴⁷ In *Pitt News*, then-Circuit Judge Alito, writing for the majority, struck down a Pennsylvania law prohibiting advertisement of alcoholic beverages in media affiliated with educational institutions.¹⁴⁸ While the court technically found that the advertisement failed the third and fourth prongs of *Central Hudson*,¹⁴⁹ its rationale and justification are telling:

The suggestion that the elimination of alcoholic beverage ads from *The Pitt News* and other publications connected with the University will slacken the demand for alcohol by Pitt students is counterintuitive and unsupported by any evidence that the Commonwealth has called to our attention. Nor has the Commonwealth pointed to any evidence that the elimination of alcoholic beverage ads from *The Pitt News* will make it harder for would-be purchasers to locate places near campus where alcoholic beverages may be purchased.¹⁵⁰

Viewing this statement through a doctrinal lens might suggest Alito was merely applying a type of narrow tailoring test within the *Central Hudson* framework. But as we described previously, the *Central Hudson* framework is highly malleable, and what better proof of that than the Fourth Circuit's decision in *Swecker*? But the paternalism v. public goods distinction sheds great light on these two cases. The *Swecker* court was convinced that prohibiting the advertising would in fact improve public safety.¹⁵¹ The *Pitt News* court was not.¹⁵²

Accordingly, despite the Court's lip service in *Sorrell* to the content and speaker-based restriction, it is the probability of contributing to a public good that has consistently led courts to distinguish justified regulation from unwarranted paternalism. In *Sorrell*, the Court simply seemed unconvinced that the public interest was served by what amounted to little more than state-sanctioned favoring of generic drug manufacturers over their name-brand competitors.¹⁵³ Similarly, in *Caronia*, one way to understand the majority's decision was that it apparently did not believe that prohibition of truthful off-label marketing had a

¹⁴⁶ 602 F.3d 583 (4th Cir. 2010).

¹⁴⁷ 379 F.3d 96 (3d Cir. 2004).

¹⁴⁸ *Id.* at 101.

¹⁴⁹ *Id.* at 107–08.

¹⁵⁰ *Id.* at 107.

¹⁵¹ *Swecker*, 602 F.3d at 589.

¹⁵² *Pitt News*, 379 F.3d at 107.

¹⁵³ *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2658 (2011).

substantial benefit to society. In the following section, we discuss the benefits of regulating truthful commercial speech more generally, as this is one of the most hotly contested areas of First Amendment jurisprudence.

B. The Benefits of Regulating Truthful Commercial Speech

In the prior section, we discussed the theoretical justification for regulating commercial speech under the First Amendment and the implications for democracy and individual autonomy. In short, the promotion of the public good is a legitimate rationale whereas mere paternalism falls short. Here we discuss three instrumental benefits to society from restricting truthful commercial speech: (1) the difficulty of distinguishing truthful from false commercial speech, (2) the indirect benefit of prophylactically regulating truth to ameliorate evidentiary challenges with proving falsity, and (3) encouraging substantive compliance with a beneficial regulatory system. Applying strict scrutiny to the regulation of truthful speech would deprive society of these benefits, which are given concrete expression in numerous areas of law.

1. Difficulty of Distinguishing Truthful from Misleading Commercial Speech

A primary benefit of regulating truthful commercial speech is that it is often difficult to distinguish between truth and misleading falsehood. In Robert Post's words, "putting aside outright false communications, the difficulties of identifying misleading statements seem as formidable in the area of commercial speech as in the arena of public discourse."¹⁵⁴ He points to the Court's statement in *Zauderer v. Office of Disciplinary Counsel*, that "distinguishing deceptive from nondeceptive advertising in virtually any field of commerce may require resolution of exceedingly complex and technical factual issues and the consideration of nice questions of semantics."¹⁵⁵ In a classic article, Judge Alex Kozinski and Stuart Banner give a powerful illustration of the conceptual challenge of identifying misleading commercial speech:

What about a television commercial that shows a man using a particular brand of deodorant and, as an apparent result, leading a much more vigorous social life? How could we ascertain the truth of that commercial? Does it even have a truth? It is intended to plant the suggestion in the minds of consumers that this deodorant is a desirable product, but surely a purchaser cannot claim to have

¹⁵⁴ Post, *supra* note 134, at 37.

¹⁵⁵ 471 U.S. 626, 645 (1985).

been defrauded when he fails to acquire a new group of friends.¹⁵⁶

The problem is that the nature of the advertising message is not verifiable fact. However, the effectiveness of a pharmaceutical drug for treating a particular condition *is* a matter of fact. What is the barrier to holding such commercial speech to a standard of objective falsity?

We suggest that, while the uses of a drug are more factual than the example Kozinski and Banner give, the core problem is that the effectiveness and safety of such uses is not always empirically verified. Determining the truthfulness of a statement that “drug X is suitable for condition Y” requires conducting complex scientific studies and evaluating empirical evidence. The inability to instantly verify the *ex ante* accuracy of every claim regarding a drug’s usage justifies the regulation of (potentially) truthful statements.

In other words, we agree with the premise of Kozinski and Banner’s argument: it is often difficult to discern whether commercial speech is truthful. But while they argue that these expressive examples demonstrate the need for non-regulation akin to that of political speech,¹⁵⁷ we suggest that just the opposite is true with respect to pharmaceutical drug marketing. More generally, when the problem of regulating commercial speech lies not in the objectivity of the statements but rather in the practical capability to empirically verify their truthfulness, prophylactic regulation of potentially truthful statements is justified. This is because such regulation has a clear benefit—preventing the emergence of potentially misleading claims—rather than clamping down on expressive speech that has no factual nature as in Kozinski and Banner’s example.

Another way to see the factual nature and corresponding benefits of prophylactically regulating statements regarding drug effectiveness is to consider the injury that would result from the lack of regulation. With many examples of commercial speech—such as advertising common consumer products—the potential injury that would result, in expected value terms, from misleading communication is likely to be small. We could imagine a probability distribution of harm, which would reflect the amount of harm multiplied by its *ex ante* likelihood of occurring. With common consumer products, even if this curve had a long tail—i.e., there exists some extremely low probability that a consumer will suffer serious harm—it is reasonable to assume that the mean of the distribution would lie at a low level of expected injury.

¹⁵⁶ Alex Kozinski & Stuart Banner, *Who’s Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 635 (1990).

¹⁵⁷ *Id.* at 636–38.

With pharmaceutical drugs, however, this distribution would appear markedly different. The harm that could result from misusing a drug would be greater both in magnitude and probability. The magnitude of the injury would be much greater because of the potential powerful effects of pharmaceutical products on the physical body. Similarly, the probability of harm would also be greater because, unlike most consumer products, misuse of a pharmaceutical product is likely to harm the majority of users (even if it benefits some), whereas many ordinary products pose little to no risk of injury. We are not suggesting that regulators consider only the potential harms of pharmaceutical drugs—indeed, many have substantial net benefit to society—but rather that the costs of misleading marketing in this context are fundamentally different from those of the traditional consumer products that Kozinski and Banner identify.

Indeed, statements regarding the effectiveness and safety of drugs are deeply factual in nature rather than being matters of subjective opinion, such as whether using a particular deodorant will make one happy in life. Inaccuracy regarding drug effectiveness and safety has substantial costs, while inaccuracy regarding the benefits of deodorant exacts a comparatively small price. The challenge with regulating off-label marketing of pharmaceuticals lies in the inability to instantly verify the accuracy of factual claims regarding safety and effectiveness, not whether lack of regulation would exact a high price. Accordingly, the key question is whether the benefits of regulating truthful speech outweigh the costs of preventing drugs from reaching the market under these conditions of factual uncertainty. There might be situations in which the empirical safety or effectiveness of a pharmaceutical drug has been objectively verified by scientific research. Regulating truthful speech may still be justified under the theory that requiring regulatory preapproval ameliorates evidentiary challenges with proving false speech, as the next subsection explains.

2. Ameliorating Evidentiary Challenges with Proving Falsehood

Even if the truthful nature of the commercial speech is indisputable—e.g., established by reputable scientific research—there may still be societal benefits to prohibiting such speech if there is a high probability that it will be accompanied by false statements that are difficult to prove. With advertising in general, if the line between truthful puffery and misleading exaggeration is conceptually tenuous, it seems likely that many advertisers would cross this line in either direction. In the case of verifiable factual claims, such as the effectiveness of a pharmaceutical drug, the legitimate fear of crossing the line might manifest as reliance on questionable studies or other tainted data.

A second justification, therefore, for prohibiting truthful off-label marketing can be found in the concern that putatively truthful statements are accompanied by untrue exaggerations or inferences in practice. In *Caronia*, for example, Mr. Caronia claimed that while Xyrem was approved for narcolepsy, “because of the properties that . . . it has it’s going to insomnia, Fibromyalgia[,] periodic leg movement, restless leg, ahh also looking at ahh Parkinson’s and . . . other sleep disorders are under-way such as MS.”¹⁵⁸ Whether Xyrem is safe or effective for these uses is likely to be a mix of truth and falsehood. In 2010, the FDA rejected Xyrem’s request for approval as a treatment for fibromyalgia and insomnia, finding that it had no effect on sleep but did reduce pain, yet nonetheless concluding that the abuse and dependency risks of using it for fibromyalgia outweighed the benefit.¹⁵⁹ Accordingly, prohibiting Caronia’s truthful speech about fibromyalgia would prophylactically extend to the false speech about insomnia.

There are likely numerous instances of off-label marketing such as this, where the defining characteristic of the speech is not *whether* it can be proven truthful but rather the conveyance of falsity (by commission or omission) in a manner that is difficult to prove. Challenges of proof may result from intertwining truth and falsity, such that it is difficult to isolate and extract the false portion of the speech. Similarly, proof may be difficult when the underlying scientific studies are ambiguous or contradictory—an agent might be relying on one outlier study while the body of scientific evidence goes the other way. The government simply might not find it worth the expense to pursue prosecution in these types of situations. A regulatory prohibition on all forms of off-label marketing thus encompasses cases in which falsity is distributed in circumstances where *ex post* proof would be difficult.

Indeed, a similar rationale appears elsewhere in the law. As we discuss in Part II.C, securities regulation provides a useful analogical framework to guiding the development of FDA rules on off-label marketing. A classic challenge in the securities laws is how to address forward-looking or optimistic statements. As these types of statements concern the future, they lack a present state of truth or falsehood but will either be accurate or inaccurate at a future date. This is analogous to intertwining truth and falsehood in communication such as in *Caronia*, except that the mix is temporal in nature: speech will become true or false as time unfolds. In *Kowal v. MCI Communications Corp.*, the D.C. Circuit held that “projections and statements of optimism are false and misleading for

¹⁵⁸ U.S. v. Caronia, 703 F.3d 149, 156 (2d Cir. 2012).

¹⁵⁹ Matt McMillen, *FDA Panel Rejects Xyrem as Fibromyalgia Treatment*, WEBMD (Aug. 20, 2010), <http://www.webmd.com/fibromyalgia/news/20100820/fda-panel-rejects-xyrem-as-fibromyalgia-treatment>.

the purposes of the securities laws if they were issued without good faith or lacked a reasonable basis when made.”¹⁶⁰

The reasonable basis standard, therefore, serves to restrain putatively non-false speech when it is made in order to ameliorate the challenge of discerning which speech is likely to become false over time. Subjecting commercial speech that is not presently false to the reasonable basis restraint is justified under the rationale that determining which projections or optimistic statements are likely to be false is extraordinarily difficult. Such a justification applies with equal force to FDA regulation of off-label marketing: requiring preapproval for marketing for any uses would ameliorate the challenges (in the counterfactual universe of no preapproval) with demonstrating in *ex post* litigation that statements regarding certain uses are categorically false.

3. Encouraging Substantive Compliance with a Regulatory System

Finally, restricting truthful commercial speech can bring society the benefits of increased compliance with the substantive requirements of a regulatory system. Speech that encourages bypassing the protections provided by regulation may increase the prevalence of socially detrimental activities that the governmental scheme seeks to prevent. For example, off-label marketing facilitates the increased use of pharmaceutical drugs for purposes that have not undergone FDA testing and approval. As off-label uses are likely, on average, to be less safe than approved uses—despite providing additional treatment—the FDA prohibition on promoting off-label use brings society the benefits of increased safety as a result of greater compliance with the FDA approval process.

However, as this example demonstrates, increased substantive compliance with a regulatory regime does not necessarily imply an increased societal benefit. The safety benefits of requiring relatively more FDA approvals may be outweighed by the cost of depriving patients of potentially life-saving treatments. But even if *on average* the substantive costs of increased compliance exceed its benefits, a regulatory regime provides an independent benefit by reducing the *variance* of potential outcomes. As humans tend to be risk-averse, holding all else equal, society might prefer a state of affairs where the risk/reward spread is narrower. Without off-label uses, fewer patients might recover from life-threatening ill-

¹⁶⁰ 16 F.3d 1271, 1277 (D.C. Cir. 1994) (citing *Isquith v. Middle South Utils., Inc.*, 847 F.2d 186, 203–04 (5th Cir. 1988); *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, at 371 (3d Cir. 1993); *Roots P’ship v. Lands’ End, Inc.*, 965 F.2d 1411, 1417 (7th Cir. 1992); *Sinay v. Lamson & Sessions Co.*, 948 F.2d 1037, 1040 (6th Cir. 1991)); see also Bruce A. Hiler, *The SEC and the Courts’ Approach to Disclosure of Earnings Projections, Asset Appraisals, and Other Soft Information: Old Problems, Changing Views*, 46 MD. L. REV. 1114, 1123 (1987).

nesses, but it is also true that fewer will die from unexpected side effects of mislabeled drugs. An example of a social acceptance of this principle is found in the largely accepted ethical norm that affirmatively taking life is more morally blameworthy than failing to save life when one's own life might be at risk.¹⁶¹ Society recognizes the difference between obligating individuals not to *affirmatively* harm others—a matter of certainty—and intervening in conditions of uncertainty, even if, on average, such interventions would lead to a reduction in the loss of life. Preferring safety to risky reward by reducing the variance of outcomes is a legitimate social interest, even if the costs exceed the benefits on average.

In addition to reducing risky outcomes, other values are arguably worthy of substantive protection through a regulatory regime. As noted in the prior subsection, the definition of false and misleading commercial speech includes promoting outcomes for which one lacks a reasonable basis in fact.¹⁶² A prohibition on truthful commercial speech such as off-label marketing can go one step further and encourage a level of care beyond merely a reasonable basis. Indeed, even if reasonable basis is the desired substantive standard, a prohibition on speech lacking regulatory approval can reduce the subjectivity inherent in such a determination, giving speakers greater confidence that speech will not be found false *ex post*. This is related to the previous point on variance of outcomes: substantive compliance has independent value linked to the certainty and risk-reducing benefits of obtaining regulatory approval.

Regardless of the normative tradeoff of risk versus reward, it seems that increasing substantive compliance with a regulatory regime plausibly provides a benefit that is at least worthy of constitutional protection. If our democratically elected legislature has opted to subject market transactions to regulatory approval—either directly or by delegating authority to a regulatory body—incentivizing the substantive benefits that result from increasing compliance with this regime arguably justifies a restraint on truthful commercial speech, even if those benefits remain limited to reducing uncertain outcomes.

Indeed, one area in which the benefits of encouraging substantive compliance are particularly evident is compelled speech. As Jennifer Pomeranz points out in a recent article on the implications of *Sorrell*, numerous regulatory regimes impose mandatory disclosure requirements.¹⁶³ Specific examples include the securities laws, discussed at length in the next section, as well as nutrition labeling, allergen labeling,

¹⁶¹ This norm underlies the general rule that there is no duty to rescue at the common law. See, e.g., RESTATEMENT (SECOND) OF TORTS § 314 (1965).

¹⁶² *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1277 (D.C. Cir. 1994).

¹⁶³ Pomeranz, *supra* note 3, at 403.

and tobacco labeling.¹⁶⁴ Mandatory disclosure improves efficiency and fairness by reducing misallocation of resources and ensuring that consumers have access to essential information regarding products and services regardless of socioeconomic status or other private means of obtaining information. The compulsion of commercial speech, therefore, directly furthers these societal goals.

C. *The Securities Act of 1933 as an Analogous Regulatory Scheme*

The Securities Act of 1933 (the “Securities Act”) provides a useful analogy to FDA regulation of off-label marketing for two reasons. First, its constitutionality is suspect under a literal reading of *Caronia*, as its restriction on making offers of securities is both “content-based”—applying solely to securities transactions—and “speaker-based”—applying to certain types of issuers and not others. The Securities Act thus provides a useful *reductio ad absurdum* demonstration of the weakness of the majority’s reasoning in *Caronia*. Second, the Securities Act constitutes an informative example of how to balance the tension between paternalism and the public good in the context of speech regulation. The specific policies it employs can serve as useful analogies to reform the FDA’s policy regarding the off-label marketing of pharmaceutical drugs.

1. Regulating Speech Independent of Transactions: Section 5 and Exemptions to the Registration Requirement

A fundamental characteristic of the regulatory scheme established by the Securities Act is its regulation of speech regarding investment activity and not merely the transactions constituting such activity. Section 5(c) of the Securities Act provides:

It shall be unlawful for any person, directly or indirectly, to make use of any means or instruments of transportation or communication in interstate commerce or of the mails *to offer to sell or offer to buy* through the use or medium of any prospectus or otherwise any security, unless a registration statement has been filed as to such security, or while the registration statement is the subject of a refusal order or stop order or (prior to the effective date of the registration statement) any public proceeding or examination under section 77h of this title.¹⁶⁵

Section 5(c) therefore prohibits offers to buy or sell securities unless a registration statement has been filed in accordance with the statute. Two parallel provisions, section 5(a) and 5(b), prohibit the sale of a security

¹⁶⁴ *Id.* at 405–06.

¹⁶⁵ 15 U.S.C. § 77e(c) (2006) (emphasis added).

until a registration statement has been declared effective, as well as the sale of a security without an attached prospectus that conforms to the statutory requirement.¹⁶⁶

Section 7 of the Securities Act specifies the required contents of a registration statement,¹⁶⁷ which includes elements such as the names of beneficial owners, a list of material contracts, and financial statements.¹⁶⁸ Section 10 provides that a prospectus must contain a subset of the elements that are required to be filed with the registration statement.¹⁶⁹ To ensure compliance with these requirements, sections 11 and 12(a)(2) establish private causes of action for injured investors to sue for false or misleading statements in the registration statement or prospectus, respectfully.¹⁷⁰ Section 12(a)(1) also grants purchasers a right of rescission if the securities were sold in violation of section 5.¹⁷¹

The net effect of the section 5 regulatory scheme is to prohibit offers—communications regarding the sale of securities—until the statutory requirements for a valid registration statement and prospectus have been satisfied. Indeed, the term “offer” is defined very broadly by the statute as including “every attempt or offer to dispose of, or solicitation of an offer to buy, a security or interest in a security, for value,”¹⁷² and as such is plainly not restricted to the common-law definition of “offer.”¹⁷³ While the statute excludes “preliminary negotiations” and agreements between issuers and underwriters,¹⁷⁴ the prohibition on offers sweeps very broadly and encompasses “the publication of information and statements, and publicity efforts, generally, made in advance of a proposed financing” even if “not couched in terms of an express offer” as long as they “contribute to conditioning the public mind or arousing public interest in the issuer or in the securities of an issuer in a manner which raises a serious question whether the publicity is not in fact part of the selling effort.”¹⁷⁵

¹⁶⁶ *Id.* § 77e(a), 77e(b).

¹⁶⁷ *Id.* § 77g.

¹⁶⁸ *Id.* § 77aa sched. A.

¹⁶⁹ *Id.* § 77j.

¹⁷⁰ *Id.* § 77k, 77l(a)(2).

¹⁷¹ *See id.* § 77k.

¹⁷² *Id.* § 77b(3).

¹⁷³ *See, e.g.,* Diskin v. Lomasney & Co., 452 F.2d 871, 875 (2d. Cir. 1971); SEC v. Cavanagh, 1 F. Supp. 2d 337, 368 (S.D.N.Y. 1998).

¹⁷⁴ 15 U.S.C. § 77b(a)(3).

¹⁷⁵ Statement of Commission Relating to Publication of Information Prior to or After Effective Date of Registration Statement, Securities Act Release No. 33-3844, 22 Fed. Reg. 8359 (Oct. 8, 1957); *see also* Offers and Sales of Securities by Underwriters and Dealers, Securities Act Release No. 33-4697, 29 Fed. Reg. 7317 (May 28, 1964); Publication of Information Prior to or After Filing and Effective Date of Registration Statement, Securities Act Release No. 33-5009, 34 Fed. Reg. 16,870 (Oct. 7, 1969); Guidelines for Release of Informa-

However, the statute defines several exemptions to the registration requirement. As we explain in the following subsection, these serve to illuminate many of the underlying purposes of the Securities Act and reflect the fundamental distinction between paternalism and the provision of public goods. Analogies to these exemptions can guide the development of a more effective FDA regulatory policy with respect to off-label marketing.

The most commonly utilized exemptions involving securities are found in section 4(a)(2) and Regulation D of the Securities Act. Section 4(a)(2) provides that the provisions of section 5 do not apply to “transactions by an issuer not involving any public offering.”¹⁷⁶ While this is a highly fact-intensive inquiry, in Securities Act Release No. 4552 the SEC defined a series of factors which are used to determine whether a transaction does not involve a public offering, including the number of offerees, the size of the offering, public versus private advertising of the offering, whether the purchasers are acquiring the securities for investment purposes rather than resale, and the period of retention.¹⁷⁷ In 2010, the ABA Section of Business Law Committee on the Federal Regulation of Securities summarized the following four factors for the section 4(a)(2) exemption: (1) manner of offering, (2) eligibility of the purchasers, (3) information, and (4) resales.¹⁷⁸ In short, these various formulations of the private placement exemption under section 4(a)(2) reflect the notion that reduced disclosure is permitted for offerings made to a certain group of purchasers, one that is restricted and “non-public” in nature.

A similar policy underlies the exemptions under Regulation D. Regulation D contains three exemptions under Rules 504, 505, and 506.¹⁷⁹ The technical requirements for each are complex but, in short, Rule 504 applies to offerings by non-reporting companies with an aggregate offering price of \$1 million per year or less.¹⁸⁰ Rule 505 applies to offerings by any company with an aggregate offering price of \$5 million per year or less but, crucially, the offering may only be made to so-called “accredited investors” and up to thirty-five non-accredited investors.¹⁸¹ The definition of “accredited investor” is complex but includes corpora-

tion by Issuers Whose Securities Are in Registration, Securities Act Release No. 33-5180, 36 Fed. Reg. 16,506 (Aug. 16, 1971).

¹⁷⁶ 15 U.S.C. § 77d(2).

¹⁷⁷ Non-Public Offering Exemption, Securities Act Release No. 33-4552, 27 Fed. Reg. 11,316 (Nov. 6, 1962).

¹⁷⁸ Comm. on Fed. Regulation of Sec., ABA Section of Bus. Law, *Law of Private Placements (Non-Public Offerings) Not Entitled to Benefits of Safe Harbors—A Report*, 66 Bus. Law. 85, 93 (2010).

¹⁷⁹ 17 C.F.R. §§ 230.504–.506 (2013).

¹⁸⁰ *Id.* § 230.504.

¹⁸¹ *Id.* §§ 230.505, 230.501(a).

tions with assets exceeding \$5 million and individuals with a net worth exceeding \$1 million.¹⁸²

Rule 506 is not an independent exemption but provides a safe harbor under section 4(a)(2) for any size offering with accredited investor restrictions similar to Rule 505. However, the thirty-five non-accredited investors must be sophisticated investors, i.e., having “such knowledge and experience in financial and business matters that [the purchaser] is capable of evaluating the merits and risks of the prospective investment, or the issuer reasonably believes immediately prior to making any sale that such purchaser comes within this description.”¹⁸³ Accordingly, the exemptions and safe harbors provided by Regulation D seek to accomplish similar goals as section 4(a)(2), namely permitting non-restricted communications regarding investment transactions to a restricted audience of non-public, sophisticated, or “accredited” investors.

2. The Constitutionality of Regulating Offers Under the Securities Act of 1933

The only Supreme Court case in which certiorari was putatively granted to resolve the question of the constitutionality of restrictions on communications under the securities laws was *Lowe v. SEC*.¹⁸⁴ However, the *Lowe* Court found that the statute did not prohibit the communication at issue and thus elected not to opine on the First Amendment issue.¹⁸⁵ Indeed, lower courts have repeatedly rejected constitutional challenges to the securities laws on First Amendment grounds.¹⁸⁶ It seems that, as a matter of doctrinal law, the dominant view is that the restrictions on commercial speech regarding investment transactions found in the Securities Act and related statutes are constitutional.

Scholars have varying views on this issue. Some have argued that courts’ refusals to seriously consider the constitutional implications of restricting offers of securities plainly contradicts the commercial speech doctrine as developed in *Central Hudson* and subsequent case law.¹⁸⁷

¹⁸² *Id.* § 230.501(a).

¹⁸³ *Id.* § 230.506(b)(ii).

¹⁸⁴ 472 U.S. 181 (1985).

¹⁸⁵ *Id.* at 210.

¹⁸⁶ *E.g.*, *SEC v. Wall St. Publ’g Inst., Inc.*, 851 F.2d 365, 373 (D.C. Cir. 1988); *see also* *R & W Technical Servs. v. Commodity Futures Trading Comm’n*, 205 F.3d 165, 174–76 (5th Cir. 2000) (refusing to extend *Lowe* to apply to the Commodities Exchange Act).

¹⁸⁷ *E.g.*, Aleta G. Estreicher, *Securities Regulation and the First Amendment*, 24 GA. L. REV. 223, 225–26 (1990); Donald E. Lively, *Securities Regulation and Freedom of the Press: Toward a Marketplace of Ideas in the Marketplace of Investment*, 60 WASH. L. REV. 843, 847 (1985); Burt Neuborne, *The First Amendment and Government Regulation of Capital Markets*, 55 BROOK. L. REV. 5, 6–9 (1989); Michael E. Schoeman, *The First Amendment and Restrictions on Advertising of Securities Under the Securities Act of 1933*, 41 BUS. LAW. 377, 386 (1986). Some practitioners sounded a similar view in the wake of *Lowe*. *E.g.*, James C.

These scholars would likely point to *Caronia* and *Sorrell* as examples of courts properly engaging with the constitutional issues implicated by restricting commercial speech in the pharmaceutical contexts. Others have suggested that securities regulation—like antitrust and other areas of economic regulation—simply falls outside the scope of the First Amendment,¹⁸⁸ but these views are difficult to reconcile with these two recent cases.

Yet it is possible to take a more balanced approach that reflects the theory of the First Amendment developed above and does not contradict the underlying policy rationale in *Sorrell*. In the context of securities regulation, the paternalism versus public good distinction is particularly compelling: deceptive communication is likely to further the misallocation of capital, the prevention of which is not merely a paternalistic intervention to protect individuals from the adverse consequences of poor decision-making. Rather, promoting an efficient allocation of investment capital improves overall social welfare. Society as a whole benefits when firms are selected for investment based on true profitability, rather than false pretenses. The efficient flow of capital promotes employment and consumer and producer welfare by encouraging competitive market pricing. Society has a strong interest in preventing fraud, deception, and misleading statements from distorting the investment analysis.¹⁸⁹

The absence of a purely paternalistic motive—and the corresponding presence of a compelling public good—explains the general resistance to invalidating the securities laws under the commercial speech doctrine. But this theory can also shed light on the specific doctrines and exemptions articulated in the prior subsection. Take, for example, the “accredited investor” definition. The requirement of a minimum net worth functions as a proxy for access to investment advisors and the negotiating leverage to compel the necessary disclosure that would prevent a misallocation of capital.

This is another persuasive example of the absence of a paternalistic motive in the securities laws: misleading disclosure may just as easily harm high net-worth investors. Indeed, some have argued that the notion of an accredited investor is flawed for this very reason: highly intelligent recent graduates of finance programs are likely more capable of preventing harm to themselves than wealthy but ignorant individuals.¹⁹⁰ But

Goodale, *The First Amendment and the Securities Act: A Collision Course?*, N.Y. L.J., Apr. 8, 1983, at 1.

¹⁸⁸ E.g., Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 HARV. L. REV. 1765, 1768 (2004).

¹⁸⁹ This explanation, however, does not account for why, in the quest to promote allocative efficiency, government intervention is relatively superior to market self-discipline.

¹⁹⁰ E.g., Wallis K. Finger, *Unsophisticated Wealth: Reconsidering the SEC's “Accredited Investor” Definition Under the 1933 Act*, 86 WASH. U. L. REV. 733 (2009).

this paternalistic approach is precisely what the Court has resisted throughout the development of its First Amendment jurisprudence. When viewed through the lens of furthering the public good of allocative efficiency, negotiating leverage—not financial know-how—is much more likely to compel counterparty disclosure and ensure that resources are properly allocated throughout society. Negotiating leverage, of course, is largely determined by financial resources, suggesting that Regulation D’s accredited investor definition constitutionally reflects a public good rather than paternalistic motive.

The more general statutory exemption in section 4(a)(2) seems more problematic to justify under this rationale because of the Court’s statement in the seminal case interpreting section 4(a)(2), *SEC v. Ralston Purina Corp.*: “An offering to those who are shown to be able to fend for themselves is a transaction ‘not involving any public offering.’”¹⁹¹ Such a statement has a strong paternalistic ring, but the Court’s commercial speech jurisprudence has evolved over time. *Ralston Purina* was decided in 1953—over twenty years before *Virginia Pharmacy*,¹⁹² the first major commercial speech case that eventually led to *Central Hudson*. It is likely that justification seemed constitutional at that time, which was well before the courts rejected certain paternalistic regulation of commercial speech. Moreover, the notion of “fend[ing] for themselves” could refer not necessarily to a paternalistic self-protection rationale, but rather to the public benefit of informed investment which leads to greater allocative efficiency. The line between the two is razor-thin, but there is a fundamental difference between restricting speech to protect individuals for *their own sake* and protecting individuals for the *sake of others*. Ensuring that participants in a market are fully informed, even if they would prefer not to be, can be justified under the latter rationale without necessarily having a paternalistic nature.

3. Analogous Principles for FDA Regulation

The principles behind the restriction on offers and exemptions in the securities laws can inform the development of a more nuanced approach to regulating the off-label marketing of prescription drugs. In the next Part, we present detailed proposals for reforming the FDA regulations, but it is worth first examining how the aforementioned rules of securities regulation strike a careful balance between restricting speech to promote the public good and upholding autonomy and liberty by permitting the free flow of information.

¹⁹¹ 346 U.S. 119, 125 (1953) (emphasis added).

¹⁹² 425 U.S. 748 (1976).

As a starting point, there are many similarities between the section 5 prohibition on offers for the sale of securities and the FDCA's requirement of FDA approval prior to marketing pharmaceutical drugs. Both restrict *communication* regarding a transaction in addition to regulating the substantive transaction itself, and both give administrative agencies the discretion to permit such communication under certain conditions. In short, both regimes constitute powerful restraints on commercial speech.

The underlying rationales of the two regimes are similar as well. Section 5 seeks to protect unwary purchasers from buying securities based on inadequate information,¹⁹³ above and beyond the prohibition on fraud—i.e., false or misleading statements—that would apply under the Securities Exchange Act of 1934 or at the common law. Similarly, as described previously, FDA preapproval developed out of a similar recognition that *ex post* liability for misleading promotion of pharmaceuticals was insufficient to protect society from the harmful consequences of the proliferation of unsafe drugs.¹⁹⁴ The recognition of a need to restrain communication until regulatory approval may be obtained derived in both contexts from an understanding that courts and *ex post* litigation are insufficiently competent in institutional terms to provide an adequate level of protection for consumers and investors.

Despite these similarities, there is a crucial difference that is essential to understanding the limits of drawing analogies between the two regimes. The section 5 preapproval process is limited to ensuring adequate *disclosure*, which includes the list of required elements found in section 7 of the Securities Act.¹⁹⁵ A fundamental principle of federal securities regulation is the lack of substantive review by the SEC regarding the value of the investment opportunity.¹⁹⁶ On the other hand, FDA review is fundamentally *substantive* in nature: the agency is tasked with ensuring not only adequate disclosure—i.e., sufficiently detailed labeling—but also that the safety and effectiveness of a pharmaceutical drug justifies its marketing and sale to the public. Moreover, as we have discussed throughout this Article, this substantive review is conducted with regard to specific uses—the question of off-label marketing arises not with respect to drugs that have *never* received FDA approval for *any* use,

¹⁹³ See, e.g., *Pinter v. Dahl*, 486 U.S. 622, 638 (1988) (“The primary purpose of the Securities Act is to protect investors by requiring publication of material information thought necessary to allow them to make informed investment decisions concerning public offerings of securities in interstate commerce.” (citing *SEC v. Ralston Purina Co.*, 346 U.S. 119, 124 (1953))).

¹⁹⁴ See Janssen, *supra* note 72, at 429.

¹⁹⁵ 15 U.S.C. § 77g (2006).

¹⁹⁶ For a summary and critique of the disclosure-centric approach to U.S. securities regulation, see generally Susanna Kim Ripken, *The Dangers and Drawbacks of the Disclosure Antidote: Toward a More Substantive Approach to Securities Regulation*, 58 BAYLOR L. REV. 139 (2006).

but rather with respect to a particular use that has not (yet) been approved.

Because drugs are inherently dangerous products,¹⁹⁷ there is always the need to balance the risk of adverse effects with the benefits of treatment. That is why the FDA may approve a drug for one indication and not for another. In addition, a drug is deemed defective unless proper warnings are given. As a result, both the intended use and the labeling are integral to the product being sold. Thus, the mandatory labeling is distinguishable from both the liquor price advertising at issue in *44 Liquormart* and the advertising of compounded drugs at issue in *Western States Medical* (because the *Western States* pharmacist was mixing pre-approved active ingredients and not promoting unapproved uses). Instead, requiring the proper label on a drug is more akin to requiring that liquor bottles be labeled with the correct volume and proof.

The *substantive* nature of FDA review means that it is far more sweeping and restrictive than the SEC's check for adequacy of disclosure. It is only natural to conclude that there are likely to be constitutional implications to the differing degrees of the restraint on commercial speech between these two regimes. We are not suggesting that the FDA preapproval requirement is unconstitutional, but rather pointing out that the different degrees of severity of restraint on speech has First Amendment implications and should therefore inform the development of a more nuanced doctrine. In particular, it seems at least presumptively justified to construe exemptions to the FDA preapproval process more broadly than their Securities Act counterparts because the former play a more important role in protecting speech than the latter.

Indeed, the two exemptions to the SEC registration requirement provide useful guidance for construing a more balanced approach to FDA regulation of off-label marketing. As we emphasized in the prior subsection, both Regulation D and section 4(a)(2) are consistent with an underlying rationale of promoting allocative efficiency—the conditions for utilizing these exemptions reflect an assumption that investors in these circumstances will be capable of eliciting the truth necessary to make an informed and accurate investment decision. The analogy to FDA regulation lies in this truth-discovery function: if one were to consider exemptions to the prohibition on off-label marketing, just as with the Securities Act they should be justified under a theory that the specific conditions for obtaining such exemptions are likely to ensure that *truth* will be sufficiently *ascertained* to promote an efficient allocation of the benefits and risks of pharmaceutical products. The twin notions of truthful facts and

¹⁹⁷ Cf. RESTATEMENT (SECOND) OF TORTS § 519 (1977) (providing for strict liability for “carr[ying] on an abnormally dangerous activity”).

the ability to properly ascertain those facts are highly analogous to the policies underlying Regulation D and section 4(a)(2).

In particular, consider the accredited and sophisticated investor requirements for utilizing the Rule 504, 505, or 506 exemptions under Regulation D. The underlying theory is that investors with these financial resources are capable of compelling disclosure through bilateral bargaining because of the strength of their balance sheets. Put differently, economic resources serve as a proxy for the probability of obtaining and ascertaining the truth in a bilateral manner, i.e., without compulsory disclosure. In the FDA context, one might analogously point to the *scientific knowledge* that medical professionals hold as an effective proxy for the probability that the truthful content of information regarding the off-label effectiveness of a drug will accurately be ascertained. The existence of preexisting scientific knowledge can be thought of as rendering a doctor an “accredited consumer of information” who is capable of distinguishing between truthful data regarding the effectiveness of a particular drug from the mere puffery that would lead unsophisticated consumers astray. We return to this point in Part III when discussing our proposal to permit the distribution of independent scientific studies to physicians.

In a similar manner, the Security Act’s more general section 4(a)(2) private placement doctrine can be understood as recognizing the danger of widespread public disclosure of potentially misleading information, even if it contains partial truth. This goes beyond the sophistication of individual consumers of information to the size of the audience to which the speech is directed. The conditions for qualifying for the section 4(a)(2) exemption reflect an understanding that the social cost of *widespread* marketing of potentially misleading information is likely to exceed the benefits of the dissemination of truth. Applying this rationale to FDA regulation suggests that a more nuanced framework might distinguish between different forms of off-label marketing according to the size of the audience. Marketing directly to the public might be more worthy of an absolute prohibition than off-label usage information “privately placed” among a smaller group. In short, a comprehensive reform to FDA regulation of off-label marketing should consider both the informational competency of the audience as well as its size—both of these factors contribute to the likelihood that a commercial speech is likely to impose a cost on society, justifying a restraint under a public good theory rather than mere paternalism.

III. REFORMING THE FDA RULES ON OFF-LABEL MARKETING OF PRESCRIPTION DRUGS

A. *The Food and Drug Administration's 2011 Draft Guidance for Responding to Unsolicited Requests for Off-Label Information*

In December 2011, the FDA published the *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* draft (“2011 Draft Guidance”)¹⁹⁸ in response to a citizen petition filed in July of 2011 seeking clarification on permissible off-label promotions.¹⁹⁹ The FDA defined an “unsolicited request” as one “initiated by persons or entities that are completely independent of the relevant firm.”²⁰⁰ Responses to these unsolicited requests comprise two categories—“requests made directly and privately to firms and requests made in public forums, including through emerging electronic media.”²⁰¹

In introducing the subject, the FDA explained the rationale for loosening the absolute prohibition on distributing off-label information by manufacturers to the general public:

FDA recognizes that firms are capable of responding to requests about their own named products in a truthful, non-misleading, and accurate manner. Furthermore, as these firms are regulated by FDA and have robust and current information about their products, FDA recognizes that it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm’s products that are addressed to a public forum, as other participants in the forum who offer responses may not provide or have access to the most accurate and up-to-date information about the firm’s products.²⁰²

The *2011 Draft Guidance* reassures firms that if they respond to unsolicited requests for off-label drug information as outlined within the document, the “FDA does not intend to use such responses as evidence of the

¹⁹⁸ 2011 DRAFT GUIDANCE, *supra* note 16.

¹⁹⁹ Allergan, Inc., et al., Citizen Petition, Docket No. FDA-2011-P-0512 (July 5, 2011), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0512-0001> (submitted on behalf of certain member companies of the Medical Information Working Group (MIWG), a working group comprising major manufacturers of prescription drugs and medical devices); see also “FDA Pressed to Clarify Permissible Formulary, Clinical Guideline Communications,” *The Pink Sheet Daily* (July 5, 2011), <http://www.biopharmatoday.com/2011/07/fda-pressed-to-clarify-permissible-formulary-clinical-guideline-communications.html>.

²⁰⁰ 2011 DRAFT GUIDANCE, *supra* note 16, at 4.

²⁰¹ *Id.* at 3.

²⁰² *Id.*

firm's intent that the product be used for an unapproved or uncleared use."²⁰³ Although this reassurance applies only to the FDA, not necessarily to the Department of Justice, one would expect the Justice Department to give considerable deference to the FDA on this issue. The *2011 Draft Guidance* provides no protection for solicited requests, a point to which we return in Part III.B.

In order to enjoy the benefit of the FDA's proposed safe harbor for responses to *nonpublic*, unsolicited requests for off-label information, the information provided by the pharmaceutical company must be (a) provided directly in a private, one-on-one communication with the individual making the request, (b) tailored to answer only the specific questions asked; (c) truthful, non-misleading, accurate, and balanced, (d) scientific in nature, and (e) generated by medical or scientific personnel independent from sales or marketing departments.²⁰⁴

Information distributed in response to an unsolicited request should be accompanied by: (a) a copy of the FDA-required labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling), (b) a prominent statement that (i) notifies the recipient that the FDA has not approved or cleared the product for the off-label use and discloses the indications for which FDA has approved or cleared the product and (ii) provides all important safety information including, if applicable, any boxed warning for the product, and (c) a complete list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts).²⁰⁵ Additionally, a firm should maintain records of (a) the nature of the request for information, including the name, address, and affiliation of the re-

²⁰³ *Id.* at 9. However, the distinction between disseminating off-label information in a promotional versus educational capacity is not always clear. See VANESSA K. BURROWS & KATHLEEN ANN RUANE, CONG. RESEARCH SERV., R40458, FDA GUIDANCE REGARDING THE PROMOTION OF OFF-LABEL USES OF DRUGS: LEGAL ISSUES (2009). Also note that, unlike the tack taken by the prosecution in the closing arguments to the jury in *Caronia*, which equated mere speech with the crime of intending to sell drugs for non-approved uses, the 2011 Draft Guidance makes clear that mere speech is not illegal per se, but only problematic when it can be construed as evidence of intent to introduce misbranded and unapproved drugs into interstate commerce. This may be one reason why the government did not seek an en banc review of the Second Circuit panel's decision in *Caronia*, preferring to defend its stance in a case where both the jury instructions and the government's arguments made this distinction more clear.

²⁰⁴ 2011 DRAFT GUIDANCE, *supra* note 16, at 7–8. The material in this and the following paragraphs is excerpted from the FDA's guidelines without quotations because of the presence of numerous technical terms of art.

²⁰⁵ *Id.* at 9.

questor, (b) records regarding the information provided to the requestor, and (c) any follow-up inquiries or questions from the requestor.²⁰⁶

To fall within the FDA's proposed safe harbor for responses to *public*, unsolicited requests for off-label information, the pharmaceutical firm must meet several requirements. First, the firm should respond only when the request pertains specifically to its own named product (and is not solely about a competitor's product). Second, a firm's public response to public unsolicited requests for off-label information about its named product should be limited to providing the firm's contact information and should *not* include any off-label information.²⁰⁷ Instead, the firm's public response should (1) indicate that the question pertains to an unapproved or uncleared use of the product, (2) state that individuals can contact the medical/scientific representative or medical affairs department with the specific unsolicited request to obtain more information, and (3) provide specific contact information for the medical or scientific personnel or department (e.g., e-mail address, telephone number, facsimile) so that individuals can follow up independently with the firm to obtain specific information about the off-label use of the product through a non-public, one-on-one communication. Third, representatives who provide public responses to unsolicited requests for off-label information should clearly disclose their involvement with a particular firm. Fourth, responses to public unsolicited requests for off-label information should not be promotional in nature or tone.²⁰⁸

In our view, there are aspects of the FDA's proposed safe harbor that provide a good starting point for beneficial reform of the off-label marketing rules, but they are woefully incomplete. Most pointedly, the rationale behind the public/nonpublic dichotomy seems questionable. The central underlying public policy concern is balancing the societal benefit of the dissemination of truthful information into the marketplace with or without the benefits of FDA indication preapproval, not whether a request for information on off-label use made to a pharmaceutical company was publicly disclosed or not. Put differently, the costs and benefits of off-label information dissemination seem to have less connection to the public nature of the request as to the truth versus falsehood of the information.

Indeed, inasmuch as the public distinction matters, it seems to raise more questions than it answers. Specifically, the potential impact on

²⁰⁶ *Id.*

²⁰⁷ Essentially, all this does is turn a public request into a non-public conversation. There seems to be no mechanism for a company to direct members of the public to otherwise publicly available information, which is strange in light of the public interest in the free flow of information. This is particularly concerning in light of the fact that a patient/consumer cannot "buy" the drug in question without first getting a physician to prescribe it.

²⁰⁸ 2011 DRAFT GUIDANCE, *supra* note 16, at 8.

prescribers and consumers could vary extensively between different “public” forums. The *2011 Draft Guidance* lumps together questions at live presentations,²⁰⁹ posted questions on web sites,²¹⁰ and responses by a firm on its own web site²¹¹ as “public.” But the potential audience of the information in each of these can vary widely. For example, attendees at a conference may constitute a particular subset of the public as a whole—i.e., medical doctors—and as such, may interpret responses by the firm in a very different manner than ordinary consumers.

Viewed in light of the public interest justification of benefitting society from having prior regulatory approval, truthful information made available to the general public by a firm—e.g., on its web site—should be treated differently from statements spoken in a public atmosphere where the audience is composed of specialists. This is all the more important when information is communicated *orally* rather than in writing. Written communications—which might include oral presentations that are recorded and made available publicly—have the potential to influence a much wider audience than those made solely in oral presentations. As we explain in the following section, the distinction between written and oral communication should play a role in the development of more fundamental reforms to the regulation of information about off-label uses of prescription drugs.

B. Principles for Reforming Regulation of Off-Label Marketing of Prescription Drugs

1. Truthfulness and Transparency

Given the dangers of criminal prosecution of pharmaceutical companies and their representatives for misbranding, off-label prescription drug use remains a proverbial “third rail” within the halls of drug companies and a “dirty little secret” within the overall healthcare marketplace. As a result, companies often do not attempt to quantify or even acknowledge the off-label use in their business dealings and forecasts. In the pharmaceutical industry, off-label use is sometimes euphemistically referred to as “spontaneous use,” but the reality is that off-label decisions by physicians are anything but spontaneous and are subject to malpractice liability if made inappropriately. A 2006 study of 150 drugs revealed that off-label use ranged from 1% to 46% within therapeutic classes.²¹² Only 7% to 54% of off-label use was supported by what the

²⁰⁹ *Id.* at 4.

²¹⁰ *Id.*

²¹¹ *Id.* at 4–5.

²¹² David C. Radley, Stan N. Finkelstein, & Randall S. Stafford, *Off-label Prescribing Among Office-Based Physicians*, 66 ARCHIVES INTERNAL MED. 1021 (2006).

authors would consider “strong scientific support.”²¹³ Put another way, 21% of the 725 million prescriptions studied were for off-label uses.²¹⁴ Fully 73% of the off-label uses lacked any “firm scientific” evidence.²¹⁵ As off-label prescriptions are often well-thought-out medical decisions, Congress and the FDA have been reluctant to prevent the practice of prescribing a drug for uses that have not been approved by the FDA.

We agree with the FDA that all written and oral off-label information must be truthful, non-misleading, accurate and balanced. As discussed in Part III.B.3, we suggest that any off-label oral discussion must be always preceded by, and based on the distribution of, the appropriate printed documentation. The liability for disseminating false or misleading information should squarely fall on the company and its agents. The learned intermediary doctrine²¹⁶ should not be available to protect drug companies from product liability claims based on off-label uses promoted in response to solicited or unsolicited requests for off-label information.

But there remains a significant gap in the marketplace of information. Companies, investors, and the public have a vested interest in knowing how drugs are used. We propose that the FDA adopt regulations requiring pharmaceutical manufacturers to measure and deliver a statistically validated report of drug usage by indication that quantifies the amount of off-label use for its product. If total off-label use represents more than say 5% of new or total prescriptions, the company should be required to break out the off-label use into its sub-uses. If an individual off-label use exceeds a specified percentage of overall use or a specified dollar threshold, then the company should be required to submit a supplemental New Drug Application. The FDA should impose fines that penalize any drug company for significant and persistent off-label use of its product without providing sufficient, accurate, and balanced information to the marketplace.

This proposal builds on the suggestion in *Western States Medical* that one alternative to a complete ban on advertising compounding drugs is to limit the total amount of compounding.²¹⁷ It also parallels the Securities Exchange Act requirement that once an issuer has more than 2,000 holders of record or 500 non-accredited holders of record and as-

²¹³ *Id.* at 1024

²¹⁴ *Id.* at 1023.

²¹⁵ *Id.*

²¹⁶ See generally, e.g., Robert J. Friedman, *Take Two of These and Sue Me in the Morning: Efficacy of the Learned Intermediary Doctrine in Prescription Drug Failure to Warn Cases*, 22 ST. THOMAS L. REV. 278 (2009) (discussing the learned intermediary doctrine in the context of prescription drug failure-to-warn cases).

²¹⁷ *Thompson v. Western States Medical Center*, 535 U.S. 357, 372 (2002).

sets in excess of \$10 million, it must register that class of securities under the Securities Exchange Act and provide periodic reports.²¹⁸

2. Differentiate Based on the Sophistication of the Listener, the Speaker and the Type of Information

The FDA's current approach to off-label promotion is over-inclusive because it bans the dissemination of truthful scientific and medical information to sophisticated listeners who are not only capable of making informed treatment choices but who actually make the final decision to prescribe medication to patients. It also minimizes the benefits a broader audience would gain from easier access to truthful information upon request and fails to reflect the training of the speaker and the different types of off-label information provided. Our approach strongly affirms a company's right to distribute truthful and non-misleading off-label information to the marketplace when the benefits of that information for a given class of listener outweighs the risk of harm to the patient. As a general rule, the greater the sophistication of the listener and the speaker and the more independently reliable the information, the less restrictive the FDA limits on dissemination should be.

The *2011 Draft Guidance* offers no protection when a drug representative solicits a request for off-label information when meeting one-on-one with a physician. This encourages an artificial context in which the sales representative and physician "dance around" the topic of off-label information. Yet why should it matter whether the physician or the representative initiates the discussion as long as the information provided is *scientific* and not unduly promotional in nature? It is difficult to see how any public interest is harmed by the accurate disclosure of truthful scientific information. The pursuit of knowledge that has undergone validation, testing, and acceptance by the scientific community arguably constitutes the type of commercial speech that is most worthy of protection under the First Amendment.

As the Supreme Court recognized in *Sorrell*, physicians are sophisticated consumers of medical and scientific information who are better able to evaluate such information and to weigh the costs and benefits of unapproved uses than untrained recipients of that information. For that reason, the FDA should permit drug sales representatives to offer solicited or unsolicited off-label *scientific* information (which we classify further in the following Subsection) to a *Tier I recipient*, which we define as a medical professional with a medical degree (i.e., M.D. or D.O.) from an accredited medical school with a state medical license in good standing. The Tier I medical professional is akin to the sophisticated investor

²¹⁸ 15 U.S.C. § 781(g)(1)(A) (2006).

who is able to fend for himself or herself and is eligible to receive offers of unregistered securities in a private placement under section 4(a)(2) of the Securities Act without the need for a prospectus.²¹⁹

There are significant discrepancies in the training of the various medical audiences that influence an individual listener's ability to comprehend and safely interpret the information provided. For that reason, we would *prohibit* the unsolicited dissemination of off-label Class 2 or 3 promotional information (see discussion of classes of information *infra* Part III.B.3) to (1) *Tier II medical practitioners*, which we define as professional medical care providers who are not Tier I medical professionals, such as a physician assistant or nurse practitioner, who have legal authority to prescribe medications and a license in good standing, or (2) *Tier III healthcare workers*, non-Tier I or II individuals whose main responsibilities are directly interacting with patients or working within an institution primarily in direct contact with patients (e.g., those working in medical offices, hospitals, clinics, physical therapy departments, and long term care facilities).

The justification for distinguishing between Tier I and Tier II/III providers is that medical doctors have sufficient education and experience to understand the *mechanisms* by which prescription drugs operate. Medical doctors have a more in-depth understanding of pathophysiology, i.e., how a patient's body will respond to medication in scenarios other than those for which the drug has received approval. Nurse practitioners, physicians' assistants, and similarly situated healthcare providers typically lack this level of knowledge and understanding.

We would, however, permit *Tier IV medical stakeholders*, which we define as healthcare payers or other industry stakeholders with direct knowledge and interest in the healthcare business, including health insurance issuers, pharmacy benefit managers, group health plans, and federal or state governmental agencies, to receive solicited and unsolicited off-label information. The key difference between Tier II/III and Tier IV is that payers cannot prescribe any medication, whereas nurse practitioners and physician assistants have the ability to prescribe. Payers should have access to information regarding off-label use in order to facilitate payments and the provision of funding, but since they are unable to prescribe, there is no harm in giving them full exposure to this information.

A key aspect of our proposal is that we would prohibit the distribution of *any* off-label information at the initiative of pharmaceutical companies to *Tier V consumers*, that is, unsophisticated individuals, such as a lay patient, a caregiver, or a legal guardian for the patient. However, we agree with the proposal in the *2011 Draft Guidance* to permit the distri-

²¹⁹ 15 U.S.C. § 77d(a)(2).

bution of information that is otherwise publicly available in response to a Tier V consumer request. All written information provided, as per the *2011 Draft Guidance*, however, will be greatly restricted in its appearance and provided with appropriate contact information for a learned/sophisticated intermediary if follow-up questions exist from them or any medical professional they enlist. The responsibility of either intermediary is to ensure that the less sophisticated listener is protected from harm and educated appropriately to balance the information given. As will be done for all protected off-label information shared in the marketplace, copies should be numbered and trackable to ensure that any attendant liability can be traced. Similar to the status quo, companies will be strictly prohibited from dissemination of non-publicly available off-label information to Tier V consumers.

3. Types of Protected Disclosures and Prescribed Formats

Although the FDA has provided some guidance about the appearance and disclosures required for off-label information, we believe that stronger and clearer guidance is needed. Drawing analogies from regulation of the financial markets, we propose that the FDA classify the various types of information and restrict dissemination based on the prospective listener's needs and ability to easily identify and assess both the risks and benefits of the content. We also suggest varying formats for dissemination depending on where the information is situated on the spectrum from pure science to pure commercial promotion.

We suggest the FDA define a series of *classes* of information. *Class 1* information would consist of promotional materials regarding labeled indications. The existing legal regime applies to this type of information. *Class 2* information would consist of *peer-reviewed* publications regarding off-label use. The definition of a peer-reviewed publication may be taken from section 401 of the now-expired Food and Drug Administration Modernization Act of 1997, which permits the distribution of medical information regarding new uses as long as it includes, among other requirements, a list of articles from "a scientific reference publication or scientific or medical journal."²²⁰ The distribution of such articles must maintain a non-adulterated appearance (i.e., the information should not be tailored or changed in any way), and all funding or potential conflicts must be clearly acknowledged. We also propose that, similar to SEC-guided financial reports, each document be numbered and printed using a color-coded border identifying the document as discussing an off-label use and that such document be available only for Tier I medical professionals. These documents will be required

²²⁰ 21 U.S.C. § 360aaa(b)(6)(B) (2006).

to be filed with the FDA and must use only an FDA-approved border scheme. Distribution records of the recipients and the time and place of distribution should be kept by the manufacturer and possibly submitted to the FDA upon request.²²¹

Class 3 information would consist of *non-peer reviewed* medical articles or publication of clinical results intended to inform medical professionals. To qualify as permissible disclosure, all information should be narrowly tailored to address the specific issue or clinical result the company would like to disseminate. Such documents should be granted FDA approval prior to sharing in the marketplace, akin to an offering circular pursuant to a Regulation A offering.²²² Similar to *Class 2*, these non-peer-reviewed articles must be printed on paper identifying this material as discussing off-label indications and be available for use only by Tier 1 medical professionals. The FDA might also consider further formatting requirements to minimize the promotional appearance of *Class 3* information. For instance, *Class 3* documents might be required to use only black and white text and charts, similar to the requirements for a tombstone advertisement under the securities laws.²²³

4. Additional Responsibilities for Firms Disseminating Off-Label Information

Because drug companies are the most significant financial beneficiaries of off-label product use, they should bear the responsibility for assuring that accurate and appropriately crafted information is delivered to the market. We suggest that the FDA subject any pharmaceutical company pursuing an off-label information dissemination strategy to four ongoing requirements: training, monitoring, reporting, and auditing.

As for training, we suggest that firms be required to supply documented training of all speakers²²⁴ on the printed material and the regulations for oral discussion. To that end, we suggest developing a formal registration accreditation program for sales representatives similar to the

²²¹ The 2011 Draft Guidance provides a helpful list of recordkeeping requirements. See 2011 DRAFT GUIDANCE, *supra* note 16, at 9.

²²² See 17 C.F.R. § 230.252(g) (2013) (providing for SEC approval of offering statements, including the offering circular, by rendering them qualified after 20 days unless the SEC intervenes); *id.* § 230.253 (specifying the required contents of an offering circular under Regulation A, the conditional small issues exemption).

²²³ See *id.* § 230.134 (providing that an advertisement containing only the most basic factual information about an issuer and an offering does not constitute a prospectus). The 2011 Draft Guidance supplies a list of requirements for the transmission of unbiased information which can provide inspiration in this context. See 2011 DRAFT GUIDANCE, *supra* note 16, at 8–9.

²²⁴ The speakers will primarily be registered sales representatives who ultimately are responsible for the majority of the interactions, but all other paid representatives/agents of the company should also be included.

Series 7 exam. All company training materials should be on record with the FDA for discretionary review but should not necessarily require FDA approval for use. Training does not necessarily need to be done in person but can be performed via technological means. Currently, many sales representatives go through training for peer-reviewed studies for approved indications, during which they are told how to respond to certain types of questions and to whom to refer questions they cannot answer. The purpose of the training requirement is to ensure that a representative is adequately prepared regarding the off-label information he or she is presenting to a doctor.

Second, the activities of speakers should be regularly reviewed and monitored by company sales training personnel and management with written documentation of results. It is essential to ensure that the representatives are *accurately* conveying the information regarding off-label use. Such monitoring is particularly justified in the context of off-label marketing because patient safety is at issue. This reflects the fundamental principle of transparency—ensuring that a company can demonstrate to the FDA that it is tracking the activities of its representatives and making an effort to ensure compliance with the rules regarding the dissemination of off-label information under the tier and classification system we previously articulated.

Third, reports tracking the dissemination of Class 2 and Class 3 protected information, as well as exception reports, should be submitted to the FDA.²²⁵ We anticipate there will be circumstances where a registered sales representative may orally divulge off-label information without the appropriate written documents because dissemination of written material was impractical (e.g., a sales representative in an operating room suggests off-label use of a specific product based on specific evidence). Furthermore, we anticipate other conversations where an unsolicited question may raise an issue beyond the scope of the printed material or a representative may become concerned that a specific conversation might have the appearance of violating the above requirements. In such cases, the drug firm should be required to file an exception report with the FDA. This resembles the filing required by Regulation FD when an issuer realizes it has impermissibly selectively disclosed material nonpublic information to institutional investors.²²⁶ Exception reports

²²⁵ This is akin to the Form D that issuers must file when selling securities pursuant to the exemptions from registration set forth in Regulation D. Form D is a brief notice that includes basic information about the company and the offering, such as the names and addresses of the company's executive officers, the size of the offering and the date of first sale. *See* 17 C.F.R. § 230.503 (requiring the filing of Form D when an issuer relies on Rule 504, 505, or 506 under Regulation D); *id.* § 239.500 (specifying the contents of Form D).

²²⁶ *See id.* § 243.100 (mandating disclosure to the public upon the disclosure of any "material nonpublic information regarding that issuer or its securities" to broker-dealers, invest-

will provide the company with an important closed loop that it may audit. The reports will also provide the FDA with a trackable source of what additional written information the market needs, thereby providing important guidance about what should be changed or added to existing protected material. Sales representatives should be accountable to their employers to file this paperwork or face disciplinary action, thus giving employers some enforceability and control to manage the speech of their representatives that otherwise might have been encouraged by the *Caronia* decision.

This reflects the importance of transparency and meeting the market's need for information. This also benefits pharmaceutical firms because it gives them the ability to identify the issues and questions raised by their customers and to find a way to answer such questions appropriately. *Caronia* is likely to have a negative impact on pharmaceutical firms from a compliance perspective because it may encourage representatives to speak freely, beyond what the pharmaceutical company itself would prefer its representatives say. If representatives are not submitting reports as required, the company has a legitimate reason to discipline or terminate them. The thrust of our approach gives representatives the freedom to speak regarding off-label use under certain conditions in order to promote the public interest in the dissemination of truth, but mandates that they also *divulge* such speech to the pharmaceutical company and FDA.

Finally, we recommend that the FDA require companies to undertake a third party audit of some of the conversations with medical professionals. (Of course, there would also be a requirement to act on the information received.) This audit should cover both the recipients and non-recipients of off-label information. The importance of a third-party audit derives from the need to make sure that the reports are adequate, that representatives are in fact talking to doctors, and that doctors are getting accurate information from the interaction, rather than receiving misleading or otherwise inaccurate information. This four-part framework makes it more likely that the benefits to society from the limited disclosure of truthful off-label usage information by pharmaceutical companies and their representatives will outweigh the potential costs, and would give such firms a safe harbor to train sales representatives and develop predictable norms of corporate compliance.²²⁷

ment advisers, investment companies, and current shareholders who may trade on such information).

²²⁷ Finally, it is worth mentioning that a 1935 Michigan Supreme Court decision permitted experimentation (i.e., off-label use) without malpractice liability, setting a standard for appropriate experimentation without liability as long as the patient consented and the use did not "vary too radically" from accepted methods of procedure. *Fortner v. Koch*, 261 N.W. 762

CONCLUSION

In this Article we have discussed both the dangerous implications of the majority's approach in *Caronia* for efficient economic regulation in general and have charted a path forward by articulating a new standard for regulating the dissemination of information about the off-label use of pharmaceutical drugs that would withstand constitutional scrutiny. By anchoring this regulatory regime in promoting the public good, rather than paternalism, and subjecting these restraints to intermediate scrutiny under *Central Hudson* as long as they do not discriminate between industry participants, our approach comports with the theoretical justification for restricting truthful commercial speech under the First Amendment and reflects the underlying considerations motivating the Supreme Court in *Sorrell*.

Indeed, as we discussed in Part II, securities regulation can serve as a useful analogous framework for articulating a more nuanced approach to regulating off-label marketing. Many of the challenges faced by the two regimes are similar and reflect the fundamental tension between permitting the distribution of information that facilitates welfare-enhancing transactions while promoting the public good by reducing the variance of outcomes among market participants. Specific exemptions to restrictions on offers for the sale of securities, such as the accredited and sophisticated investor categories under Regulation D, can serve as an example for formulating similar exemptions to restrictions on the distribution of truthful information regarding the efficacy and safety of off-label use of prescription drugs. In Part III, we articulated a concrete proposal for reforming the FDA's rules on off-label marketing based on these general principles and analogous lessons from the securities laws. Distinguishing between types of information and the intended audience is essential to ensuring that the distribution of facts regarding off-label uses of prescription drugs furthers legitimate public interests rather than unconstitutional paternalism.

At the heart of our argument lies the fundamental point that the majority's approach in *Caronia* reflects a false dilemma. It is unnecessary to take a binary, either/or approach to regulating truthful commercial speech. Promoting the free flow of truthful information is a worthy goal in a liberal democracy. But the potential harm to the public from risky pharmaceutical drugs is real. Just as with the capital markets, it takes only a few catastrophes to undermine the trust and confidence essential to the proper functioning of the pharmaceutical and healthcare industries. Advancing a public interest such as this justifies limited re-

(Mich. 1935). We see this as a matter for state law and the appropriate licensing authorities rather than as something that should be addressed through FDA regulation.

strictions on truthful commercial speech, provided that the government has a rational basis for doing so and the restraint itself satisfies the *Central Hudson* framework.

In short, as important as the free flow of information is, our society already made the decision to reject the anti-regulatory ideology of the *Lochner* era—and for good reason. As the recent financial crisis vividly demonstrated, the absence of adequate regulation can lead to market inefficiencies and unnecessary suffering among the weakest in society. Restricting speech is often inextricably tied to regulating underlying transactions. The solution to the danger of excessive paternalism is to prohibit this specific ill, not to render the regulation of advertising, marketing, and offers to transact outside the ambit of government regulation. The purpose of the First Amendment is to facilitate political liberty and individual autonomy, not a laissez-faire false utopia of unrestricted commercial promotion.

