

COMMENT

A First Amendment Approach to Generic Drug Manufacturer Tort Liability

In 2011, the landmark case *PLIVA, Inc. v. Mensing*¹ foreclosed many claims against generic drug manufacturers for harms caused by their products. In particular, *Mensing* held that because the Food, Drug, and Cosmetic Act (FDCA) requires generic manufacturers to use labels that are “the same as” the FDA-approved brand-name label,² the FDCA preempts state-law tort claims against these manufacturers for failing to communicate the potential risks of their products.

Mensing's outcome has been subject to widespread policy objections. Generic manufacturers, now immune from liability, are consequently also insulated from incentives to warn patients and physicians of known risks. Patients with grave injuries find themselves unable to recover for the harms they have suffered. And brand-name manufacturers increasingly are forced to defend themselves in court from dubious legal theories pressed by plaintiffs who were harmed by generic products.

This Comment identifies a never-before-raised legal problem with the FDA's current labeling regulations, which, if resolved by the courts, could address the policy concerns arising from *Mensing*. In *Mensing*, the FDA interpreted its regulations to prohibit generic drug manufacturers from communicating independently with physicians about pharmaceutical risks. The outcome in *Mensing* was reached without any party raising the First Amendment issues surrounding generic pharmaceutical manufacturer liability. Yet the Supreme Court has held that the First Amendment applies to speech by

1. 131 S. Ct. 2567 (2011).

2. 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G) (2012).

pharmaceutical manufacturers: regulatory burdens on such speech must be justified by narrow tailoring to advance sufficient government interests.³ A recent Second Circuit case applying these principles, *United States v. Caronia*,⁴ illustrates how plaintiffs could seek tort damages from generic manufacturers once more. If *Caronia*'s reasoning is applied in the context of tort suits against generic manufacturers, those manufacturers will no longer be able to take refuge behind the FDA labeling regulations that currently prevent them from warning consumers about risks. In consequence, plaintiffs injured by generic pharmaceuticals would be able to recover from generic manufacturers for failure to warn when those manufacturers failed to communicate warning information to physicians.

This argument is all the more relevant given the ongoing discussion about whether and how to reform the regulatory regime in the wake of *Mensing*. The constitutional infirmity of the status quo provides an essential starting point for any future reform. A recent Advance Notice of Proposed Rulemaking by the FDA suggests that the agency is considering new regulations that would liberate generic drug manufacturers to alert customers to health risks, potentially undoing the federal preemption of state tort law established in *Mensing*.⁵ This early proposal can find validation not only from the policy advantages of restoring state tort claims against generic manufacturers, but also from the recognition that it would resolve an important, albeit thus far overlooked, tension in constitutional law. But it remains to be seen whether and precisely how the FDA will ultimately address the problems *Mensing* created.

Part I explains the regulatory environment and the *Mensing* decision, which created the problem this Comment confronts. Part II turns to a different realm of pharmaceutical regulation: the uses for which manufacturers may market their products, as well as recent developments in speech jurisprudence declaring that pharmaceutical manufacturers have a right to communicate with physicians. Part III examines the contradiction of these divergent lines of cases and concludes that *Mensing*'s holding, based on an impermissible regulatory interpretation, must yield to the speech interests identified in Part II. Restoring the speech rights of manufacturers would vindicate First Amendment values,

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

4. 703 F.3d 149 (2d Cir. 2012).

5. *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, OFF. INFO. & REG. AFFAIRS, <http://www.reginfo.gov/public/servlet/ForwardServlet?SearchTarget=Agenda&textfield=0910-AG94> (last visited Sept. 23, 2013).

restore liability and the corresponding set of incentives for generic manufacturers to attend to their products' safety, and allow injured patients to recover for the harms done to them.

I. THE *MENSING* PROBLEM

This Part contextualizes the *Mensing* decision and explains why it is so objectionable. Brand-name and generic pharmaceutical manufacturers face sharply differing obligations under federal law and regulations. These divergent regulatory regimes resulted in the problematic *Mensing* holding, which immunized generic manufacturers from tort liability. *Mensing* created an array of urgent problems without good solutions. Courts are wrestling with fraught liability questions and sometimes rendering decisions dubiously consonant with principles of tort law. And while injured plaintiffs and brand-name manufacturers fight these battles in courts throughout the nation, the generic manufacturers whose products actually injure consumers remain immune from suit.

The availability of safe and inexpensive generic versions of brand-name drugs is a substantial public good.⁶ Accordingly, Congress has provided a simplified route for approval of generic formulations.⁷ The critical requirement for this streamlined application process is that the generic formulation must be actually “bioequivalent” or therapeutically identical to the brand drug.⁸ This minimizes entry costs for generic manufacturers, while ensuring that generic formulations have the same effectiveness and safety as clinically tested, FDA-approved, brand-name formulations.⁹ Correspondingly, unless a physician specifically prescribes one formulation or another, pharmacies may substitute a less expensive generic for a brand-name drug at their discretion.¹⁰

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6. See H.R. REP. NO. 98-857, pt. 2, at 9 (1984) (identifying the “policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent”).
 7. Drug Price Competition & Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2012)).
 8. 21 U.S.C. § 355(j)(2)(A)(iv) (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675 (1990).
 9. *But see* Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor’s Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 678 n.21 (2010) (collecting popular and professional discussion of the bioequivalence standard’s efficacy).
 10. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (“Currently, all States have some form of generic substitution law.”).

All manufacturers are required to submit annual reports containing information relating to the safety, effectiveness, and appropriate labeling of approved drugs.¹¹ Brand-name manufacturers, unlike generic manufacturers, are also responsible for the “accuracy and adequacy” of the label of a drug¹² and may modify its label to reflect new information. The FDA then approves or denies the manufacturer’s label modification through the “Changes Being Effectuated” (CBE) process.¹³ A generic manufacturer, in contrast, is responsible only for ensuring “that its warning label is *the same* as” the FDA-approved brand-name label.¹⁴ This reinforces the fact of actual chemical equivalence by ensuring that doctors and patients perceive the therapeutic identity between formulations.

State tort law often, as in the dispute which became *PLIVA v. Mensing*, holds drug manufacturers liable for failing to maintain reasonably safe warnings on labels, including failing to employ the CBE process to revise their labels.¹⁵ Under FDA regulations, however, generic manufacturers may not proactively revise their labels because of their duty to ensure that their labels are identical to brand-name manufacturers’ labels.¹⁶

In *Mensing*, the Court confronted the problem arising from these conflicting requirements. The plaintiffs were prescribed the brand-name drug Reglan and, after taking an approved generic formulation, developed a severe neurological disorder.¹⁷ They alleged that, despite evidence that the labeling didn’t adequately warn of the risk of this reaction, neither brand-name nor generic manufacturers had revised the drug label or advised the FDA.¹⁸ Had the plaintiffs taken brand-name Reglan, they would have been entitled to seek recovery under state-law failure-to-warn claims, assuming proof of their

11. 21 C.F.R. § 314.81 (2013) (brand-name manufacturers); *id.* § 314.98 (generic manufacturers).

12. *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(b)(1), (d) (2006)).

13. 21 C.F.R. § 314.70(c)(3), (c)(6)(iii)(A), (c)(7) (2013).

14. *Mensing*, 131 S. Ct. at 2574 (emphasis added) (citing 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G) (2006)); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7) (2013).

15. *Mensing*, 131 S. Ct. at 2573, 2575.

16. *Id.* at 2575.

17. *Id.* at 2572-73.

18. *Id.* at 2573.

allegations.¹⁹ As the plaintiffs took a generic formulation, however, they—properly—brought the same claim against the generic manufacturer.

The plaintiffs made three principal arguments supporting the claim that generic manufacturers, despite the duty of sameness, could have satisfied their duties under state tort law. First, the plaintiffs argued that generic manufacturers should have themselves requested that the FDA approve a revision to the label shared by both the brand and generic versions of the drug at issue.²⁰ The Court rejected this argument. As this option still required the FDA’s acquiescence to accomplish any change in warning, the manufacturer still could not have satisfied state-law duties on its own.²¹ Thus, the plaintiffs could only succeed on the basis of theories that afforded generic manufacturers an independent capacity to comply with the requirements of state tort law.

The plaintiffs also argued that the generic manufacturers could have employed the CBE process to revise their own label pending FDA approval.²² In support of this contention, the plaintiffs pressed an interpretation of the relevant FDA regulations which would permit generic labels to differ from the FDA-approved brand-name label when “important new safety information required a change to the labeling.”²³ The FDA disagreed, arguing that the “same as” requirement governing generic-drug labels was overriding,²⁴ and that another regulation upon which the plaintiffs relied was simply irrelevant.²⁵ Though there was a contest between dueling interpretations, the Court concluded that the FDA’s interpretation of its regulations was not “plainly

19. *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that the FDCA does not preempt state-law failure-to-warn claims and that brand-name manufacturers can be held liable for failures to warn).
20. *Mensing*, 131 S. Ct. at 2578; Brief for Respondents Gladys Mensing and Julie Demahy at 28-30, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501). The FDA put forward the same argument in support of the plaintiffs. Brief for the United States as Amicus Curiae Supporting Respondents at 15, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501).
21. *Mensing*, 131 S. Ct. at 2581 (“[W]hen a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.”).
22. *Id.* at 2575.
23. Brief for Respondents Gladys Mensing and Julie Demahy, *supra* note 20, at 34; *see also id.* at 33-35 (describing how the CBE process could “lead to a temporary difference in labeling”).
24. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 20, at 15-16.
25. *Id.* at 16 n.7.

erroneous or inconsistent with the regulation”²⁶ and thus were accorded dispositive *Auer* deference.²⁷

Finally, and critically for purposes of this Comment, the plaintiffs mounted a separate argument: that the generic manufacturers could have employed so-called Dear Doctor letters²⁸ to “send additional warnings to prescribing physicians.”²⁹ The FDA acknowledged that no statutory provision or agency regulation explicitly prohibited generic manufacturers from “unilaterally” sending such letters.³⁰ However, an existing FDA regulation did address “advertising” accompanying a drug, classifying it as “labeling” subject to the sameness requirement.³¹ The FDA interpreted this regulation to apply to Dear Doctor letters as well.³² This interpretation meant that generic manufacturers could not independently send Dear Doctor letters without violating regulatory obligations.³³

The plaintiffs made no argument contesting the interpretation the FDA provided in its amicus brief. Indeed, the plaintiffs’ merits brief did not once refer to the regulation that, in the FDA’s view, brought Dear Doctor letters under the “labeling” regulatory regime. The plaintiffs’ only attempt to contest the FDA’s interpretation focused on the interest adduced in support of classifying Dear Doctor letters as advertising: that such letters from generic manufacturers might pose a risk of misleading doctors and patients to believe that generic formulations were safer than brand formulations.³⁴ The plaintiffs characterized this FDA concern as “speculat[ive].”³⁵ No other effort to address the FDA interpretation appeared in the plaintiffs’ brief.³⁶ Nor did they dispute the applicability of *Auer* deference to the FDA’s interpretation; their brief did not once refer to the precedents regarding judicial deference to an agency’s

26. *Auer v. Robbins*, 519 U.S. 452, 461 (1997).

27. *Mensing*, 131 S. Ct. at 2575-76.

28. 21 C.F.R. § 200.5 (2013).

29. *Mensing*, 131 S. Ct. at 2576.

30. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 20, at 18.

31. 21 C.F.R. § 202.1(l)(2) (2010).

32. *Mensing*, 131 S. Ct. at 2576; Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 20, at 18.

33. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 20, at 19.

34. *Id.*

35. Brief for Respondents Gladys Mensing and Julie Demahy, *supra* note 20, at 37.

36. *Mensing*, 131 S. Ct. at 2576 (“Mensing and Demahy offer no argument that the FDA’s interpretation is plainly erroneous.”).

interpretation of its own regulations.³⁷ In the face of this silence, *Auer* deference followed almost as a matter of course. The Court accordingly deferred to the interpretation: generic manufacturers could not independently send Dear Doctor letters.³⁸

Having rejected all of the plaintiffs' arguments to the contrary, the Court held that the FDCA made it impossible for generic manufacturers to comply with, and so preempted, state tort law.³⁹ In the wake of *Mensing*, patients who experience profound medical harms from taking generic drugs may not bring failure to warn suits against the manufacturers of those drugs. As the *Mensing* Court acknowledged, that decision apparently foreclosed recovery for such plaintiffs.⁴⁰ Plaintiffs nonetheless seeking recovery have turned to widely rejected theories holding brand-name manufacturers liable for harm done by generic formulations of their products. Some plaintiffs have argued that brand-name manufacturers committed misrepresentation by failing to revise their own labels, knowing that generic manufacturers were bound to the letter of those labels.⁴¹ Others have relied on the learned-intermediary doctrine, arguing that brand manufacturers were obliged to keep physicians apprised of possible adverse reactions.⁴² An overwhelming majority of courts have rejected these theories, including every federal court of appeals to consider the question.⁴³ The Alabama Supreme Court, which in January 2013 joined the small minority of courts permitting plaintiffs to continue litigating on similar theories, has

37. Neither *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945), nor *Auer* appear in respondents' brief on the merits, nor does the word "deference."

38. *Mensing*, 131 S. Ct. at 2576.

39. *Id.* at 2580-81.

40. *Id.* at 2581 ("We acknowledge the unfortunate hand that federal drug regulation has dealt *Mensing* . . . and others similarly situated.").

41. See, e.g., *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340 (S.D. Ala. 2010).

42. See, e.g., *Wyeth, Inc. v. Weeks*, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013); see also Editorial, *Innovator Liability, Take Two*, WALL ST. J., Sept. 5, 2013, <http://online.wsj.com/article/SB10001424127887323324904579042850978337502.html>.

43. The weight of authority is astounding. See, e.g., *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 604 n.4 (N.D. Miss. 2013) (noting that "sixty-six decisions applying the law of twenty-three different jurisdictions [have held] that brand name manufacturers of a drug may not be held liable under any theory for injuries caused by the use of a generic manufacturer's product").

since granted the manufacturer's motion for reargument, leaving a rare plaintiff victory in danger of reversal.⁴⁴

Of course it is unsurprising that such theories are so widely condemned: as the Fourth Circuit put it almost two decades ago, "a name brand manufacturer's statements about its own product" lack a sufficient causal relationship to "injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control," to support imposing liability on the brand-name manufacturer.⁴⁵ Though always relying on the relevant state's tort law, courts have almost uniformly come to the conclusion—seemingly incontestable in the abstract—that the law only provides for liability when the injured party was harmed by a product manufactured by the defendant: "a name-brand manufacturer has no duty of care to consumers that are not using the manufacturer's product."⁴⁶ Alternative theories placing liability on brand manufacturers have attracted some support, but the courts approving such actions are likely motivated less by doctrinal persuasiveness and more by the tragic consequences of denying recovery in terrible circumstances. After *Mensing*, "[t]here is no good outcome in [such a] case."⁴⁷

Yet *Mensing* itself leaves open an alternative path to liability that the parties did not brief and the Court did not consider: the First Amendment's limits on regulation of manufacturers' speech. Part II surveys recent developments in speech jurisprudence and identifies the freedom of pharmaceutical manufacturers to communicate with physicians. If the First Amendment forbids the FDA's interpretation regarding Dear Doctor letters, a more principled route for recovery exists. When speech is free, failure to speak may create liability.

II. PHARMACEUTICAL FREEDOM OF SPEECH

This Part considers the recent developments in First Amendment analysis of regulations limiting the speech of pharmaceutical manufacturers. Part III argues that these principles forbid the FDA interpretation at issue in *Mensing*.

44. *Weeks*, 2013 WL 135753 (Ala. Jan. 11, 2013), *reh'g granted* (June 13, 2013); see Editorial, *supra* note 42.

45. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994).

46. *Demahy v. Schwarz Pharm., Inc.*, 702 F.3d 177, 184 (5th Cir. 2012).

47. *Weeks*, 2013 WL 135753, at *20 (Murdock, J., dissenting).

The Supreme Court examined the free-speech implications of pharmaceutical regulation in *Sorrell v. IMS Health, Inc.*⁴⁸ *Sorrell* concerned a Vermont law that prohibited brand-name manufacturers from accessing or using “prescriber-identifying information” to tailor marketing to individual physicians.⁴⁹ The Court held that “[s]peech in aid of pharmaceutical marketing” is a “form of expression protected by the” First Amendment.⁵⁰ It found that the regulation, by targeting only marketing, and only where it was conducted by pharmaceutical manufacturers, burdened certain disfavored content by disfavored speakers. This required that the regulation satisfy “heightened scrutiny” to survive.⁵¹ Finally, *Sorrell* considered whether the government had shown that the regulation was consistent with the First Amendment despite its speech costs. Vermont offered two primary justifications: decreasing healthcare costs; and improving public health by encouraging the use of cheaper, “safer” generics.⁵² The Court concluded that the regulation was not directly related to these interests and was inadequately tailored⁵³; in short, the fact that “the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.”⁵⁴ Because it imposed speaker- and content-based restrictions without a narrow, direct relationship to adequate justifications,⁵⁵ the Vermont statute was doomed.⁵⁶

48. 131 S. Ct. 2653 (2011).

49. *Id.* at 2659-60.

50. *Id.* at 2660.

51. *Id.* at 2667.

52. *Id.* at 2670. Vermont also sought to defend the law at issue in *Sorrell* on the ground that it protected physician confidentiality. *Id.* at 2668-70. The Court rejected this argument as largely specious, observing that the regulation simply “is not drawn to serve that interest.” *Id.* at 2668. Given that “pharmacies may share prescriber-identifying information with anyone for any reason” other than marketing, and given the existence of additional broad exceptions, the Court found that the regulation “d[id] not in itself advance privacy interests.” *Id.*

53. *Id.* at 2670-72.

54. *Id.* at 2671.

55. *Id.* at 2670-71.

56. *Sorrell* also concluded that the Vermont law failed the traditional *Central Hudson* standard for restrictions on commercial speech. *Id.* at 2667-68 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980)). For this reason, in part, the content of the *Sorrell* standard awaits elaboration by the lower courts and future cases at the Supreme Court itself to clarify how much more rigorous than *Central Hudson* the “heightened” scrutiny announced in *Sorrell* will be, and in what circumstances it will apply.

Sorrell fundamentally reframed the constitutional status of pharmaceutical marketing. The case says at a minimum that pharmaceutical manufacturer speech has First Amendment value; open communication between manufacturers and physicians is an important aspect of the free flow of ideas in society. Nor is *Sorrell's* holding limited to the question of manufacturers' access to and use of specific information about doctors. On the contrary, a recent Second Circuit case demonstrated that *Sorrell's* innovation extends through the broader regime governing the speech of pharmaceutical manufacturers. In *United States v. Caronia*,⁵⁷ the Second Circuit applied *Sorrell* in the context of off-label drug marketing, one area in which federal regulations have traditionally imposed extensive restraints on pharmaceutical manufacturers' speech. *Caronia* provides further weight to the *Sorrell* proposition: federal regulations of pharmaceutical speech must satisfy a heightened level of scrutiny. The Second Circuit concluded that off-label marketing regulations as currently written cannot do so. Careful analysis of *Caronia's* reasoning suggests that the FDA's regulations on generic pharmaceutical speech also offend the Constitution.

Current off-label marketing regulations are based on the rule that drug manufacturers must receive approval for each new proposed indication for a formulation,⁵⁸ requiring a demonstration through clinical trials of the application's safety.⁵⁹ Drug manufacturers may not "misbrand," or indicate that a drug's intended uses include anything other than those approved by the FDA.⁶⁰ FDA regulations identify several forms of evidence that can indicate a manufacturer intended to offer a drug for off-label uses, including "oral or written statements" by manufacturers or their representatives.⁶¹

Despite these marketing prohibitions, the FDCA expressly permits doctors to prescribe drugs for unapproved indications.⁶² Indeed, off-label prescriptions are "an accepted and necessary corollary" of the regulatory goal of achieving

57. 703 F.3d 149 (2d Cir. 2012).

58. 21 U.S.C. § 355(d) (2012).

59. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973).

60. 21 U.S.C. § 352(f) (2012).

61. 21 C.F.R. § 201.128 (2013).

62. 21 U.S.C. § 396 (2012) ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.").

patient safety without interfering with medical practice.⁶³ However, the decision regarding off-label uses is left to doctors, and manufacturers or their representatives may not advertise a drug for an unapproved “intended use.”⁶⁴

Caronia, a criminal prosecution for off-label marketing, concluded that this regime cannot survive in the post-*Sorrell* environment. Alfred Caronia, a pharmaceutical sales representative, made statements to doctors that a drug could be prescribed for a number of off-label uses.⁶⁵ The government charged Caronia with criminal violations of the FDCA misbranding provisions.⁶⁶ Caronia moved to dismiss on the ground that the misbranding provisions “unconstitutionally restricted his right to free speech” under the First Amendment.⁶⁷ The district court judge, ruling before *Sorrell* was decided, rejected this argument and concluded that the FDCA’s misbranding provisions were necessary to provide an adequate penal backstop to the FDA approval process.⁶⁸

The Second Circuit reversed the First Amendment holding, relying heavily on the intervening *Sorrell* decision.⁶⁹ The panel majority held that the misbranding provisions, like the Vermont law in *Sorrell*, discriminated both against content, forbidding only off-label marketing, and against speakers,

63. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001).

64. 21 C.F.R. §§ 201.5, 201.128 (2013) (including among “directions for use,” which constitute the total “intended uses” of the drug as offered on the market, items such as “oral, written, printed, or graphic advertising”).

65. *Id.* at 156.

66. *Id.* at 157.

67. *Id.* at 158.

68. *United States v. Caronia*, 576 F. Supp. 2d 385, 401-02 (E.D.N.Y. 2008), *vacated*, 703 F.3d 149 (2d Cir. 2012); *see also id.* at 401 (noting that misbranding prohibitions are “one of the ‘few mechanisms available’ to the FDA to ensure that manufacturers will not seek approval only for certain limited uses of drugs, then promote that same drug for off-label uses, effectively circumventing the FDA’s new drug requirements” (quoting *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 72 (D.D.C. 1998))).

69. *Caronia*, 703 F.3d at 152. Though *Sorrell* involved the speech rights of a corporation, the Second Circuit had no trouble applying the speech standard *Sorrell* established in an individual’s criminal prosecution. The relevant regulations apply equally to speech either by the manufacturer directly or its representatives, 21 C.F.R. § 201.128 (2013), and the Second Circuit treated the prosecution of Caronia individually as “criminaliz[ation of] the promotion of off-label drug use by pharmaceutical manufacturers,” *Caronia*, 703 F.3d at 164, presumably on the theory that off-label promotion is ultimately “by” the manufacturer whether conducted via corporate mailings or by individual sales representatives as agents of their corporate employer.

prohibiting only speech by pharmaceutical manufacturers.⁷⁰ Under *Sorrell*, these regulations received heightened scrutiny.⁷¹ The FDA presented two justifications: preserving the effectiveness of the FDA approval process and avoiding patient exposure to dangerous, unapproved indications.⁷² The panel concluded that the regulations did not directly advance these interests, as they permitted physicians to make such prescriptions but suppressed information that would allow them to do so safely,⁷³ and also found that narrower options existed that would accomplish these goals without First Amendment harms. To avoid the constitutional problems, the panel construed the FDA regulations not to prohibit manufacturers and their representatives from engaging in truthful off-label promotion.⁷⁴

The consequences of this holding are potentially significant. As Judge Livingston wrote in dissent, the holding “calls into question the very foundations of our century-old system of drug regulation.”⁷⁵ Nonetheless, the result in *Caronia* came as no surprise to commentators: almost every published article considering the interaction between *Sorrell* and the off-label regulations concluded that the regulations could not survive eventual review under the standard *Sorrell* had announced.⁷⁶ Development of these legal questions will

70. *Caronia*, 703 F.3d at 165. The panel majority also held in the alternative that the regulations failed the less-restrictive *Central Hudson* test for commercial speech, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980), because the regulations did not directly advance the government interest and narrower options existed. *Caronia*, 703 F.3d at 165-69.

71. *Caronia*, 703 F.3d at 165.

72. *Id.* at 166.

73. *Id.* at 167.

74. *Id.* at 168.

75. *Id.* at 169 (Livingston, J., dissenting).

76. See, e.g., John N. Joseph et al., *Is Sorrell the Death Knell for FDA's Off-Label Marketing Restrictions?*, J. HEALTH & LIFE SCI. L., Feb. 2012 at 1; Erin E. Bennett, Comment, *Central Hudson-Plus: Why Off-Label Pharmaceutical Speech Will Find Its Voice*, 49 HOUS. L. REV. 459, 461 (2012); Isabelle Bibet-Kalinyak, Note, *A Critical Analysis of Sorrell v. Ims Health, Inc.: Pandora's Box at Best*, 67 FOOD & DRUG L.J. 191, 240 (2012); Thea Cohen, Note, *The First Amendment and the Regulation of Pharmaceutical Marketing: Challenges to the Constitutionality of the FDA's Interpretation of the Food, Drug, and Cosmetics Act*, 49 AM. CRIM. L. REV. 1945, 1946-47 (2012); Gayland O. Hethcoat II, Note, *Regulating Pharmaceutical Marketing After Sorrell v. IMS Health Inc.*, 15 QUINNIPIAC HEALTH L.J. 187, 201-02 (2012).

have to wait, as the government sought neither en banc review in the Second Circuit nor certiorari from the Supreme Court.⁷⁷

Caronia is interesting in its own right as an illustration of how speech principles are altering the landscape in multiple regulatory contexts. It also demonstrates the vitality of the *Sorrell* standard and its relevance for the regulations the Court considered and accepted in *Mensing*. The First Amendment analysis announced in *Sorrell* and applied in *Caronia* offers a way to shift liability for pharmaceutical harms back to generic manufacturers. Relitigating *Mensing* based on *Sorrell*—this time bringing a meaningful attack against the validity of the FDA’s interpretation of its regulations regarding Dear Doctor letters—should invalidate that interpretation and afford generic manufacturers the freedom and duty to provide physicians with truthful warning information about potential harms. In turn, plaintiffs should be able to recover on tort claims against generic drug manufacturers who fail to do so. Part III explores this First Amendment approach to *Mensing*.

III. LIBERATING GENERIC MANUFACTURER SPEECH—AND RESTORING TORT LIABILITY

Caronia destabilizes one of the critical assumptions animating *Mensing*. The Court in *Mensing* accepted the FDA’s interpretation that generic manufacturers may not send Dear Doctor letters to inform physicians of possible risks.⁷⁸ This conclusion is unsurprising, as respondents failed to contest seriously the FDA’s interpretation of its regulations. Rendered without the benefit of briefing or argument on the merits of the underlying interpretation, the Dear Doctor section of *Mensing* amounts to nothing more than recognition of *Auer* deference in the absence of an argument to the contrary.⁷⁹ However, in light of *Sorrell* and *Caronia*, the Dear Doctor interpretation cannot endure, and the *Mensing* holding based on that interpretation should be reconsidered. Generic manufacturers should have the ability to send such letters, and, correspondingly, they should face liability for harms caused by their failure to do so.

77. See *Government Will Not Appeal 2nd Circuit’s Ruling in Caronia*, FDA ENFORCEMENT MANUAL NEWSL., Feb. 2013, at 1; Jose P. Sierra, *Government Takes a “Pass” on the First Amendment*, LEXOLOGY (Jan. 31, 2013), <http://www.lexology.com/library/detail.aspx?g=5818423f-2878-42d9-8bae-afc3342969cc>.

78. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011).

79. See *Auer v. Robbins*, 519 U.S. 452, 461 (1997).

Despite the deep tension between *Sorrell* and *Mensing*, which were decided by the Court on the same day,⁸⁰ the opinions did not directly contradict each other. The *Mensing* plaintiffs did not contest the FDA's interpretation regarding Dear Doctor letters in any meaningful way—and they could not have known that the Court in *Sorrell* would offer such a robust First Amendment ruling. The First Amendment's implications for the entire pharmaceutical regulatory regime have only emerged with elaboration of *Sorrell*'s analysis. Indeed, no reference to the First Amendment or speech analysis of any kind appears in the plaintiffs' brief or in the FDA's amicus brief in *Mensing*.⁸¹

Nonetheless, the Constitution should forbid the FDA's interpretation regarding Dear Doctor letters, in turn enabling those harmed by generic drugs to recover for their injuries. *Sorrell* and *Caronia* provide the analysis. First, under *Sorrell*, generic manufacturer "speech in aid of pharmaceutical marketing" is a form of protected expression.⁸² *Sorrell*—and *Caronia*—concluded that the implicated regulations imposed speaker- and content-based burdens and consequently required review under heightened scrutiny. Similarly, the FDA's Dear Doctor letter interpretation actively discriminates against speakers: brand-name manufacturers may independently send Dear Doctor letters, but generic manufacturers may not. The interpretation also burdens specific content: generic manufacturers may send approved advertising material to physicians, but they may not communicate unapproved information, even when truthful.⁸³

Admittedly, were the Court compelled to confront the contradiction between *Sorrell* and *Mensing* that this Comment identifies, it might avoid the confrontation by limiting *Sorrell* such that its apparently broad expansion of speech rights would not extend to cover speech designed to communicate risks to doctors. However, if *Sorrell* is to apply anywhere beyond its facts, this context seems appropriate. The Court's concerns in *Sorrell* regarding Vermont's speech regulation are squarely relevant. The FDA's interpretation

80. *Mensing* and *Sorrell* were announced on June 23, 2011.

81. Petitioners in *Mensing* made one reference to the First Amendment in their merits brief, but on an unrelated topic, referring to whether or not manufacturers may request that the FDA reconsider the warning information approved for a given drug. Brief of Petitioners PLIVA, Inc. et al. at 48, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501). This Petition Clause analysis was uncontested before the Court and is unrelated to the validity under the Free Speech Clause of the FDA's interpretation of its Dear Doctor letter regulations.

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

83. Such restrictions seem to run against the logic of *Sorrell*. See *id.* at 2670-72.

serves to bar one category of actor from engaging in speech available to all other actors, based solely on concerns regarding the potential effect of such speech when wielded inappropriately. *Sorrell's* declaration that “speech in aid of pharmaceutical marketing” is a form of protected expression was no mere flight of rhetoric: it was a recognition that the free flow of information “has great relevance in the fields of medicine and public health, where information can save lives.”⁸⁴ That observation is even more sharply true in the context of pharmaceutical risk than in the area of prescriber information that *Sorrell* examined. The freedom and obligation to send Dear Doctor letters—and the corresponding imposition of liability for the injuries of harmed plaintiffs attributable to manufacturers’ failure to send such letters—would lead to better-informed doctors and lower incidence of pharmaceutical harm. *Sorrell* should thus apply to Dear Doctor letters, and the FDA interpretation should receive heightened scrutiny.

Of course, the FDA’s interpretation would still survive First Amendment analysis if it were narrowly drawn to directly advance appropriate interests. After all, the speaker- and content-based analysis above could invalidate the entire generic labeling regime, in the absence of adequate justification. The interests behind the duty of sameness—safeguarding patient health by ensuring therapeutic equivalence and decreasing healthcare costs by increasing availability of cheap generic formulations—are of high moment. Fortunately, the sameness requirement directly advances these goals by simplifying the entry of generic manufacturers and guaranteeing that FDA-approved warnings are exactly reproduced. Nor are the regulations badly drawn. The burden on manufacturer speech, limited to the content of the label, goes no further than necessary to further the interests involved. In short, the generic labeling regime should withstand any First Amendment attack.

The FDA interpretation to which the Court deferred in *Mensing*, extending the sameness obligation to all communications from generic manufacturers, is another matter. The FDA justified this interpretation based on the risk that permitting generic manufacturers to send letters to doctors independently would create the perception that the generic formulation was not therapeutically identical to the brand-name version.⁸⁵ Ensuring therapeutic equivalence, both perceived and actual, is the heart of the generic regulatory regime and could justify speech burdens. For example, the FDA interpretation

84. *Id.* at 2664.

85. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 20, at 19.

would surely survive if it only barred misleading communications that created such a perception.⁸⁶ But a Dear Doctor letter providing truthful, impartial information about both brand and generic formulations would pose no risk of false or misleading communication.

The current interpretation does not advance the FDA's asserted justification. Brand-name manufacturers may send letters independently, risking the equally damaging perception that brand drugs are therapeutically advantageous; only after the FDA approved the letter could generic manufacturers follow suit.⁸⁷ Nor is the interpretation narrowly drawn. A different, narrower interpretation would better ensure perceived therapeutic identity at a lower speech cost: letters implying therapeutic advantage could still be construed as "advertising," in accordance with the existing FDA interpretation. False letters would remain actionable both for violating regulatory requirements and for fraud.⁸⁸

The FDA could alternatively defend its interpretation as seeking to advance its overall goal of ensuring patient safety. If so, the interpretation would fail constitutional muster more seriously. Content-based speech restrictions cannot be justified even by the "fear that people would make bad decisions if given truthful information."⁸⁹ The FDA interpretation, even worse, prevents physicians from making good decisions based on true information. Thus, the FDA interpretation violates the First Amendment rights of generic manufacturers and works to the detriment of public health.

For these reasons, the Dear Doctor interpretation cannot survive the analysis that *Sorrell* requires and *Caronia* applied. The Court should instead construe the regulations to avoid constitutional violations. Rather than accepting the FDA's broad reading, the Court could adopt the narrower interpretation identified above: only misleading letters implying an advantage to one class of drugs should be forbidden. Truthful, impartial letters simply

86. See *Sorrell*, 131 S. Ct. at 2672; *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012).

87. Cf. *Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150, 152-53 (Ct. App. 2013) (rejecting a generic manufacturer's *Mensing*-based preemption claim when "the brand-name drug label was updated but the generic drug manufacturers failed to update their products' labels accordingly"); *id.* at 162 (collecting comparable cases).

88. See, e.g., *United States v. Harkonen*, 510 F. App'x 633 (9th Cir. 2013) (unpublished) (upholding a fraud conviction for false pharmaceutical promotional materials).

89. *Sorrell*, 131 S. Ct. at 2670 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002)).

setting out health risks should be classed as communications protected by the Constitution.

Once no longer precluded by federal regulations from satisfying their duties under state tort law, generic manufacturers would then also face tort liability for neglecting to send such letters when they possessed sufficient evidence of adverse reactions. Patients who suffer harm from generic formulations should be able to recover on meritorious tort claims against generic manufacturers who fail to communicate warning information.

The benefits of this conclusion are numerous. It allows plaintiffs to recover for their injuries. It harmonizes tort law with respect to pharmaceutical injuries: patients will no longer confront the absurd prospect of suing brand-name manufacturers whose products they never purchased. Nor will courts face a decision between a principled application of causation requirements and the desire to see individuals compensated for preventable injuries. Generic manufacturers can exult in liberation from the First Amendment burdens of speech restraints. Far better, the manufacturers actually responsible for substantial injuries will be held to account, resting the costs of accidents on their most natural bearers. And the proper allocation of these costs will drive generic manufacturers to keep physicians informed of potential adverse reactions, decreasing the incidence of injuries as a whole.

CONCLUSION

This is a moment of great opportunity for solving the problems left by *Mensing*. A line of recent major cases continues to articulate and secure the First Amendment's protections in this area of the law. Simultaneously, the FDA is reconsidering the regulations that provided the basis for decision in *Mensing*, no doubt influenced by the roar of commentary deriding the policy consequences of the *Mensing* holding.

No policymaker or legal commentator, however, has yet appreciated *Mensing's* constitutional difficulties, independent of its undoubted negative policy consequences. This Comment has identified a contradiction between *Mensing* and free speech jurisprudence. The *Mensing* holding is unstable and should not endure: it assumed the validity of a regulatory interpretation that violates the Constitution. Whether through the courts or via regulatory reform, vindicating the speech interests at play here will also solve the conundrum of what to do with injured plaintiffs after *Mensing*.

Though resolving these problems may require bold lawyering, the argument stands on firm ground. First Amendment principles, as announced in *Sorrell* and applied in *Caronia*, cannot permit the FDA interpretation at issue

to survive. Generic manufacturers should face liability when they possess critical safety information and fail to communicate it.

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