PREEMPTING A PROBLEM: *MENSING*, *TEVA*, AND THE PROPER SCOPE OF CONFLICT PREEMPTION

Cameron J. Cook

State-law product liability claims provide a powerful incentive for companies to create safe products. Federal law, however, provides a defense for manufacturers: preemption of state-law claims when federal and state law conflict such that dual compliance is impossible. The Supreme Court recently addressed the scope of conflict preemption regarding state-law failure-to-warn claims against generic drug manufacturers in *PLIVA, Inc. v. Mensing*.[1] Questions, however, lingered regarding the scope of *Mensing* and the California judiciary adopted a narrow reading of *Mensing* in *Teva Pharmaceuticals USA, Inc. v. Superior Court*,[2] allowing a plaintiff to advance state-law failure-to-warn claims against a generic drug manufacturer. The defendants appealed to the Supreme Court, arguing that the claims were preempted based on a broad reading of *Mensing*. On January 20, 2015, the Supreme Court denied the petition for writ of certiorari. This Paper argues that the Supreme Court should have heard the case and affirmed the California appellate court's decision because precedent and public policy suggest that conflict preemption should be a demanding and limited defense to state-law tort claims.

I. Failure-to-Warn Claims, Conflict Preemption, and *Mensing*

Under state law, a manufacturer that sells a product with inadequate warnings may be liable to an injured consumer for any harm caused by that failure to warn.[3] But state law is not

[1] PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2012).

[2] Teva Pharmaceuticals USA, Inc. v. Superior Court of Orange County, 217 Cal. App. 4th 96 (2013).

[3] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1, 2(c) (1998).

alone in affecting product safety: the Federal Food, Drug and Cosmetic Act (FDCA) empowers the Food and Drug Administration (FDA) to ensure the safety and efficacy of drugs, which includes oversight over labeling in order to warn consumers of harmful side effects.[4] When state and federal law conflict, however, state law must be disregarded because the Supremacy Clause states that federal law "shall be the supreme law of the land."[5] State and federal law conflict when it is "impossible for a private party to comply with both state and federal requirements."[6] This doctrine is known as conflict preemption and it is a powerful defense that can insulate drug manufacturers from state-law tort claims insofar as they comply with the FDCA.

In order for a new drug to be sold, the FDCA requires that the manufacturer prove that the drug is safe and effective for its intended use and that the proposed label for the drug is accurate and adequate. There are regulatory differences, however, between name-brand and generic drugs. Name-brand drugs refer to pioneer products with original uses or chemical compositions and they must supply their own scientific data proving safety and efficacy. Generic drugs, however, have the same intended use and composition as drugs already on the market, and may reference the scientific data of an approved name-brand drug. As a condition on using the name-brand's data, the labeling for the generic must be identical to the reference drug's labeling.

---

[4] *See generally* 21 U.S.C. §§ 301–399f (2012). The FDA regulates "labeling," which means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* §321(m). A physical connection to the article is not necessary for material to count as "labeling." Kordel v. United States, 335 U.S. 345, 350 (1948).

[5] U.S. CONST. art. VI, cl. 2.

[6] Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995).

Name-brand manufacturers may strengthen their warning labels after FDA approval, but generic manufacturers may not unilaterally strengthen their warning labels. Generic labeling must always be the same as the labeling of the reference product, thus, "generic drug manufacturers have a federal duty of 'sameness.'"[7]

In *Mensing*, the Supreme Court held by a 5-4 vote that federal law preempted a state-law tort claim against a generic drug manufacturer for failing to update a warning label. The plaintiffs in *Mensing* took a generic drug, metoclopramide, and suffered tardive dyskinesia, a severe neurological disorder, as a side effect. The plaintiffs sued the manufacturer under state law, alleging a failure to provide adequate warning labels because even though there was evidence that long-term use of metoclopramide carried a greater risk than was indicated on the label, the defendants did not strengthen their warnings. The Court found that it was impossible for the generic manufacturers to unilaterally change their labels to provide an adequate warning. The only action that the manufacturers could have taken was to petition the FDA to require stronger warnings, which was sufficiently impossible to warrant preemption.[8] Hence, the Court found that the plaintiffs' state-law failure-to-warn claims against the generic manufacturer were preempted by the FDCA's duty of sameness.[9] Although, the scope of the majority's holding—that generic manufacturers cannot be sued for failing to warn given the name-brand manufacturer's failure to update the product's labeling—was not clearly defined.

II. *Teva* and the Disputed Scope of Conflict Preemption

[7] *Mensing*, 131 S. Ct. at 2575.

[8] The Court stated that the test for "impossibility" is "whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579.

[9] *Id.* at 2581.

The riddles of *Mensing* surfaced in *Teva Pharmaceuticals USA, Inc. v. Superior Court*. In *Teva*, the plaintiff suffered injuries from taking a brand-name drug, Fosamax, and its generic, alendronate sodium. Fosamax is meant to treat osteoporosis, but long-term use can cause femur fractures. In April 2011 the *Teva* plaintiff suffered a femur facture, allegedly due to her prolonged use of either Fosamax or alendronate sodium. The suit was pleaded under state law and filed against several manufacturers in the Orange County Superior Court in California. The trial court concluded that the plaintiff's failure-to-warn allegations were not preempted, but certified the question of preemption to the California Court of Appeal for the Fourth District, citing "substantial grounds for difference of opinion" due to the Supreme Court's decision in *Mensing*.[10] The appellate court applied *Mensing* to the state-law claims and found that it was possible for the defendants to comply with both federal and state duties. Specifically, the defendant could have communicated updated safety information to physicians, but did not. The allegedly tortuous conduct, thus, was a failure to disseminate FDA-approved warnings.

Standing in opposition to *Teva*, the Fifth Circuit in *Morris v. PLIVA, Inc.*[11] applied *Mensing* broadly. The plaintiff in that case took a generic drug, suffered tardive dyskinesia, and sued its manufacturers, alleging state-law tort claims. The plaintiff contended that the claims were not preempted because *Mensing* did not preempt claims alleging that a defendant failed to communicate approved warnings. But the Fifth Circuit rejected this, finding that *Mensing* preempted such claims because the duty of sameness extends "beyond just a label change."[12]

---

[10] Teva Pharmaceuticals USA, Inc. v. Superior Court of Orange County, 217 Cal. App. 4th 96, 102 (2013).

[11] Morris v. PLIVA, Inc., 713 F.3d 774 (5th Cir. 2013).

[12] *Id.* at 777.

Accordingly, the court found that the defendants could not unilaterally send out "Dear Doctor" letters[13] to health care professionals because that would violate the duty of sameness: "Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label."[14] Hence, the Fifth Circuit found the plaintiff's claims to be preempted since it was impossible for the generic manufacturers to comply with the state-law duty in light of the brand-name manufacturer's refusal to send out "Dear Doctor" letters, which was not impossible under federal law.

III. Preempting Further Error

Courts facing conflict preemption disputes should adopt the narrow understanding of *Mensing* found in *Teva*. The Fifth Circuit's holding in *Morris* should be ignored due to its feeble reading of precedent and the policy goal of incentivizing safe products.

A. Precedent Supports a Narrow, Substantive Approach to Conflict Preemption

The Fifth Circuit's reading of *Mensing* is illogically broad. As applied to "Dear Doctor" letters, *Morris* interpreted the *Mensing* test to be "whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contained information that is substantially similar to the label."[15] This interpretation likely comes from dicta in *Mensing* regarding Dear Doctor letters: "A Dear Doctor letter that contained *substantial new warning information* would not be consistent with the drug's approved labeling . . . if generic drug

[13] A "Dear Doctor" letter is a letter sent from a medical company to a physician, informing the medical professional of the uses and risks of the company's product.

[14] *Morris*, 713 F.3d at 777.

[15] *Id.*

manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference . . . and thus, could be impermissibly 'misleading.'"[16] The Fifth Circuit could have read this language two ways: dispersing Dear Doctor letters *without* substantial new warning information violate the duty of sameness or that dispersing such letters would not. The Fifth Circuit held that even without substantial new warning information, a claim against a generic manufacturer alleging a failure to warn by not sending "Dear Doctor" letters would still be preempted if the brand-name manufacturers had not sent such letters. Why would the Supreme Court mention "substantial new warning information" as part of the preemption-triggering example, if not to imply that letters *without* substantial new warning information would not violate the duty of sameness? The Fifth Circuit focused on the act of sending Dear Doctor letters instead of the information contained within those letters. While this is a possible reading of *Mensing*, it seems inimical to the plain meaning of the words.

The issue in *Mensing* was whether conflict preemption should take into account the possible actions by third parties. The Supreme Court held that possible actions by third parties were insufficient to show the possibility of compliance with both state and federal law. The relevant third-party inaction in *Mensing*, however, had to do with FDA approval of stronger warnings. But *Morris* found impossibility based on the inaction of brand-name companies to send out Dear Doctor letter containing information that already had FDA approval and that matched the generic labeling. While the Fifth Circuit may have thought the facts of *Morris* were nearly identical to *Mensing*, the two cases are meaningfully distinct. There is a difference between the content of a warning label and the act of disseminating the content of those labels; the former is a substantive requirement of the FDCA, while the latter is a procedural mechanism

[16] PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2012) (emphasis added).

for dispensing information. *Mensing* found preemption in the first scenario based on the inability of generic manufacturers to act independently, but *Morris* erred in applying *Mensing* to the latter scenario. In effect, *Morris* finds impossibility, and hence preemption, based on advertising efforts, which seems to be an improper extension of *Mensing*, which was focused on the product's warning, not that warning's audience.

B. Public Policy Demands a Limited Conflict Preemption Jurisprudence

The Supreme Court has stated that "the purpose of Congress is the ultimate touchstone in every pre-emption case."[17] It is noteworthy that the type of preemption at issue here is *implied* preemption, not express preemption. Express preemption is when Congress explicitly includes a statutory provision to preempt state law whereas implied preemption is determined by a conflict of law that render state and federal compliance impossible. Congress has never stated that the FDCA preempts all state law claims against generic-drug manufacturers. Indeed, state-law litigation against drug companies has become a fixture of the legal landscape. Hence, Congress has acquiesced to the vitality of state-law tort claims against drug manufacturers and courts should not needlessly expand conflict preemption doctrine against the implicit will of the Congress.

Product liability is an important means to ensure that consumers are well-informed about drug risks. Federal regulation is crucial for ensuring drug safety, but by eliminating state-law duties through an expansive conflict preemption jurisprudence, courts eviscerate a strong deterrence to corporate misconduct. Broadly construing conflict preemption is a misallocation of risk from sophisticated entities with marketplace agency to individual consumers that may be victimized by negligence. Given the importance of public health and the general population's

[17] Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

lack of medical knowledge, drug companies should be exposed to the highest potential of liability in order to ensure that consumers are informed about the health products in which they place their trust.

IV. Conclusion

State-law product liability claims play an important role in consumer protection. *Mensing* is best read as a route application of precedent, which is compatible with the vitality of state-law tort claims against generic drug manufacturers. The California appellate courts in the *Teva* saga were correct, but the Supreme Court should have affirmed that state court holding to fully repudiate the mistakes that some courts have made interpreting *Mensing*. Courts should continue to construe conflict preemption as a narrow defense, instead of extending *Mensing* to inappropriate situations. Conflict preemption doctrine in the FDCA context should be recognized as limited by its focus on the substance of warning information approved by federal law, and the policy goal of ensuring consumer safety should counsel against an interpretation of precedent that suggests otherwise.