SUPREME COURT
STATE OF CONNECTICUT

S.C. 20409

Eugene Roberto,

Plaintiff-Appellant

v.

Boehringer Ingelheim Pharm., Inc.

Defendant-Appellee

AMICUS CURIAE BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE

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TABLE OF CONTENTS

STATEMENT OF ISSUE OF AMICUS CURIAE

Whether the trial court erred by refusing to apply a presumption against preemption in assessing whether the newly acquired information proffered by plaintiff was sufficiently conclusive and reliable to establish a causal association between risk of bleeding and use of Pradaxa by at-risk subgroups.

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

INTEREST OF AMICUS CURIAE

The American Association for Justice ("AAJ") is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiff trial bar. AAJ's members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions, including cases dealing with preemption. Throughout its more than 70-year history, AAJ has served as a leading advocate for the right of all Americans to seek legal recourse for negligence or wrongful conduct.[1]

[1] No counsel for a party wrote any part of this brief, and no party or counsel other than AAJ, its members, and its counsel contributed to the cost of the preparation or submission of this brief.

ARGUMENT

THE TRIAL COURT ERRED IN REFUSING TO APPLY A PRESUMPTION AGAINST PREEMPTION WHEN ASSESSING THE RELIABILITY OF PLAINTIFF'S NEWLY ACQUIRED EVIDENCE OF A CAUSAL ASSOCIATION BETWEEN PRADAXA AND EXCESSIVE RISK OF BLEEDING IN AT-RISK SUBGROUPS.

In assessing the weight of the Plaintiff's initial burden to proffer newly acquired evidence justifying a CBE label update, the trial court reasoned that "[i]t is unclear whether the presumption [against preemption] applies" to federal laws that preempt state common-law doctrines as opposed to a "state statute or section thereof." Roberto v. Boehringer Ingelheim Pharmaceuticals, Inc., Docket No. HHD CV16-6068484, 2019 WL 5068452 (Conn. Sept. 11, 2019) at 31. The trial court also reasoned that, because "the FDA contemplated that the FDA's 'Changes Being Effected' (CBE) regulation, 21 C.F.R. §314.70(c)(6), would be used 'sparingly,'" skepticism about the likelihood that the FDA would approve a unilateral label change "tend[s] to neutralize" any presumption against preemption. *Id*.

These two rulings contravene a longstanding canon of statutory construction commonly known as the "presumption against preemption." Specifically, the presumption against preemption requires the manufacturer seeking to preempt state law to identify some actual decision by the FDA carrying the force of law that rejects the type of label change sought by the plaintiffs, just so long as the plaintiffs have proffered newly acquired information sufficient to allow the FDA to approve a CBE label supplement that the defendant could have, but did not, attempt.

By speculating about the FDA's willingness to allow manufacturers to use the CBE process to update labels, the court below engaged in judicial guesswork about how the

FDA *might* treat some hypothetical risks that the FDA has never *actually* considered. The presumption against preemption avoids such judicial guesswork, thereby ensuring that federal agencies, not courts, make the decisions about whether and to what extent federal law requires state law to be set aside.

I. The Trial Court Erred in Refusing to Apply the Presumption Against Preemption to Protect Connecticut's Common-Law Doctrine of Negligent Labeling from Preemption.

Contrary to the trial court below, it is well-established that the presumption against preemption protects states' common-law doctrines as well as state statutes. The U.S. Supreme Court has repeatedly applied this presumption to protect the state tort claims of negligent labeling strikingly similar to the claims alleged by Plaintiff in this case. In Wyeth v. Levine, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), for instance, the Court applied the presumption to protect Diana Levine's common-law claim of negligent labeling against the manufacturer of an anti-allergy drug from implied preemption under the Food Drug and Cosmetic Act, 21 U.S.C. ch. 9 §301 *et seq*. ("FDCA") -- precisely the same sort of common-law negligent labeling claim alleged in this case. The Wyeth Court made it plain that "[i]n *all* pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" Wyeth, 555 U.S. at 565 (emphasis added). See also Altria Group, Inc. v. Good, 555 U.S. 70, 77, 129 S. Ct. 538, 172 L.Ed.2d 398 (2008) (explaining that the Court "begin[s its] analysis" with a presumption against preemption "[w]hen addressing questions of express or implied pre-emption" in case involving cigarette manufacturer's defense that claim seeking damages for

fraudulent labeling of cigarettes was preempted by the Cigarette Labelling Act). Cf. Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 449, 125 S. Ct. 1788; 161 L. Ed. 2d 687 (2005) ("Even if [the defendant] had offered us a plausible alternative reading of [the relevant preemption clause]—indeed, even if its alternative were just as plausible as our reading of the text—we would nevertheless have a duty to accept the reading that disfavors preemption.")

None of the considerations limiting the application of the presumption against preemption apply here. Like any other canon of statutory construction, the presumption against preemption does not apply where the statutory text unambiguously sets aside state law. See, e.g., Puerto Rico v. Franklin Cal. Tax-Free Trust,136 S. Ct. 1938, 1946, 195 L. Ed. 2d 298 (2016) (explaining that, where the text of a preemption clause is unambiguous, the Court "do[es] not invoke any presumption against pre-emption but instead focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent"). The FDCA, however, contains no such preemption clause, so its preemptive effect must be inferred from some unwritten federal purpose allegedly frustrated by state law. Likewise, the Court has stated that the presumption might not apply to fields that states have not traditionally regulated such as claims of fraud against a federal agency. Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-48, 121 S. Ct. 1012; 148 L. Ed. 2d 854 (2001). There is no doubt, however, that providing remedies for common-law torts is quintessentially a traditional state function. See, e.g., Desiano v. Warner-Lambert & Co., 467 F.3d 85, 95 (2d Cir. 2006)(holding that presumption against preemption applied to state tort law defining "traditional state law duties between pharmaceutical companies and their consumers").

In short, there is nothing "unclear" about whether the presumption against preemption applies to a preemption defense asserted against a state common-law negligent labeling claim. The trial court erred in ignoring this presumption.

II. The Trial Court Erred in Judicially Presuming that the FDA Would Not Permit Unilateral Labeling Changes on the Ground that the FDA Contemplated that CBE Changes Would Be "Sparingly" Used.

The trial court also erred in ruling that any presumption against preemption was "neutralize[d]" by the FDA's supposed policy of wanting the CBE process to be used "sparingly." This error led the trial court erroneously to dismiss plaintiff's newly acquired information about bleeding risks in subgroups of patients as "preliminary discussions" or "uncorroborated trial balloons" that did not "provide reliable evidence of new risks," Roberto v. Boehringer Ingelheim Pharmaceuticals, Inc., Docket No. HHD CV16-6068484S, 2019 WL 5068452 (Conn. Sept. 11, 2019) at 39.

This standard of reliability ignores the presumption against preemption. The essence of this presumption is that federal agencies are presumed to allow that which state law requires. In the context of drug labelling, the U.S. Supreme Court has recently held that, because "the CBE regulation permits changes [to labels]… a drug manufacturer will not *ordinarily* be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." Merck, Sharp, & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679, 203 L. Ed. 2d 822 (2019)(emphasis added). The trial court instead flipped Albrecht's presumption on its head by presuming that CBE supplements are "sparingly" rather than "ordinarily" granted.

This presumption that CBE changes are "ordinarily" allowed is amply justified by the FDA's CBE regulation, which provides that the plaintiff did not have to provide evidence

that "definitely established" a connection between inadequate warnings and excessive bleeding in subgroups of patients. Instead, that regulation requires only "reasonable evidence of a causal association" between a labeled use and a risk. 21 C.F.R. § 201.57(c)(6). While "reasonable evidence" excludes mere "theoretical possibilities," 21 C.F.R. § 201.57(c)(6), plaintiff's post-approval analyses indisputably went beyond mere theoretical speculation, as the trial court itself conceded when it found that plaintiff's information had "sufficient reliability or substance" to qualify as newly acquired information. Roberto v. Boehringer Ingelheim Pharmaceuticals, Inc., Docket No. HHD CV16-6068484S, 2019 WL 5068452 (Conn. Sept. 11, 2019) at 38.

It is, therefore, beyond dispute that the FDA had policy-making discretion to approve a CBE supplement based on plaintiff's admittedly preliminary but nevertheless reliable and substantive information. As the U.S. Supreme Court has noted, "[t]here are some propositions for which scant empirical evidence can be marshaled," such that agencies have to rely on their expert judgment rather than any "unobtainable" proof of causation. F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 519, 129 S. Ct. 1800, 173 L. Ed. 2d 738 (2009). That the FDA properly approves labels based on incomplete and preliminary information is illustrated by the FDA's approval of Pradaxa's label in this case. Dr. Ellis Unger, the Deputy Director of the Center for Drug Evaluation and Research, acknowledging that the decision was "a difficult one," concluded that the label should not suggest a lower dose of 110 mg, based on speculation that "educat[ing] doctors not to prescribe lower than optimal dosages "may not prove very effective," because "[m]any physicians tend to 'play it safe' with anticoagulants and anti-platelet agents." Trial Exhibit 5827 (Deputy Office Dir. Decisional Memo, Application No. 22-512, Summary Review, October 19th, 2010), at 14-

15). Dr. Unger cited no empirical research for these observations, and indeed the FDA's own Scientific Advisory Committee did not endorse them.

By reversing the presumption required by Albrecht that CBE supplements are "ordinarily" approved, the trial judge engaged in guesswork about what exactly the FDA would approve, a prediction that the judiciary is ill-equipped to make. In effect, the trial court put words in the mouth of a silent FDA by speculating about how the FDA would have responded to a CBE supplement that was never offered by the defendant. Such judicial speculation violates the foundational principle of administrative law that, with respect to "a determination of policy or judgment which the agency alone is authorized to make and which it has not made, a judicial judgment cannot be made to do service for an administrative judgment." See Securities & Exchange Comm'n v. Chenery, 318 U.S. 80, 87, 63 S. Ct. 454, 87 L. Ed. 626 (1943).

The presumption against preemption requires a different approach. Once the plaintiff has proffered scientifically reliable albeit preliminary information suggesting (but not definitively establishing) a new risk, the trial court must shift the burden to the defendant to identify some decision by the FDA carrying the force of law that actually rejects the extra precautions required by state law. As the U.S. Supreme Court has recently stated, "the answer to the pre-emption question" requires some "agency action carrying the force of law" such as the FDA's "formally rejecting a warning label that would have been adequate under state law." Merck, 139 S. Ct. at 1679. Because the trial court rested its finding of preemption on judicial speculation about what the agency might do rather than identification of any specific "agency action carrying the force of law," the trial court erred in inferring preemption.

CONCLUSION

For the forgoing reasons, amicus curiae urges the Court to reverse the trial court's conclusion that the Plaintiff's newly acquired information of bleeding risks in patient subsets was insufficient to shift the burden to the Defendant to show by clear evidence that the FDA would preclude additional labeling.

RESPECTFULLY SUBMITTED,

AMERICAN ASSOCIATION FOR JUSTICE,
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CERTIFICATION OF SERVICE AND COMPLIANCE

I hereby certify, on this 4th day of March, 2020, the following:

1. The Brief complies with the format requirements of Rule of Appellate Procedure § 67-2;

2. The printed Brief was mailed postage prepaid to:

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3. The Brief does not contain any names or other personal identifying information that is prohibited from disclosure.

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