UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

In re: Genentech, Inc., Herceptin (Trastuzumab) Marketing and Sales Practices Litigation	)))))	Case No. 19-5035 On appeal from MDL No. 16-MD-2700 (N.D. Okla.) Hon. Terence C. Kern, Judge Presiding

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION AND OKLAHOMA STATE MEDICAL ASSOCIATION IN SUPPORT OF REVERSAL

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The American Medical Association and the Oklahoma State Medical Association have no parent companies, and no publicly held company has a 10% or greater ownership interest in the American Medical Association or the Oklahoma State Medical Association.

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IDENTITY AND INTEREST OF AMICI

Founded in 1847, the American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Its mission is to promote the science and art of medicine and the betterment of public health. Substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates. AMA members practice and reside in all states and in all areas of medical specialization.

Founded in 1906, the Oklahoma State Medical Association (OSMA), a constituent medical association of the AMA, is the largest professional association of physicians, residents, and medical students in Oklahoma. Its purpose is to advance the science and art of medicine for the betterment of Oklahoma physicians and their patients. OSMA members practice in all areas of medical specialization.

The AMA and OSMA submit this brief on their own behalf and as representatives of the AMA's Litigation Center (a coalition among the AMA and the medical societies of each state and the District of Columbia), whose purpose is to represent the viewpoint of organized medicine in the courts.

The AMA and OSMA are committed to advancing the goal of providing quality, fairly priced health care to all Americans. Overstating the amount of a

critically important pharmaceutical in a package is directly contrary to this commitment. Accordingly, we respectfully submit this brief to offer our perspective on the important issues raised by this case.

Amici file this brief with the parties' consent. No one other than Amici and their counsel funded the preparation and submission of this amicus brief.

ARGUMENT

The plaintiffs in these consolidated MDL proceedings are medical providers who claim that the manufacturer of the cancer drug Herceptin violated state law (regarding express and implied warranties and unjust enrichment) by providing a smaller amount of the drug than stated on the package—conduct economically harmful to medical providers who had to buy more packages to provide proper therapeutic doses to their patients. The issue before this Court is whether federal law preempts these state-law claims.

As this Court has recognized,

> There are three types of preemption: "(1) express preemption, which occurs when the language of the federal statute reveals an express congressional intent to preempt state law . . . ; (2) field preemption, which occurs when the federal scheme of regulation is so pervasive that Congress must have intended to leave no room for a State to supplement it; and (3) conflict preemption, which occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Cerveny v. Aventis, Inc., 855 F.3d 1091, 1097-98 (10th Cir. 2017), *quoting Mount*

Olivet Cemetery Ass'n v. Salt Lake City, 164 F.3d 480, 486 (10th Cir. 1998). This Court's summary of the three types of preemption is firmly rooted in Supreme Court teaching. *See, e.g., Hillsborough Cty. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 712-13 (1985); *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516 (1992); *Arizona v. United States*, 567 U.S. 387, 399-400 (2012).

None of these three types of preemption applies here. As discussed below, (1) Congress has not expressly preempted state-law warranty and unjust enrichment claims in the context of drug labeling; (2) federal regulation is not so pervasive as to leave no room for the operation of state law that furthers federal policy; and (3) it is not only easy to comply with both federal and state law, but enforcement of state law in this case would advance the congressional objective, as set forth in the Food, Drug and Cosmetics Act (FDCA), of avoiding mislabeling of pharmaceutical products. The district court should not have barred the medical providers' state-law claims at the threshold, but should have allowed them to be developed and evaluated on their merits.

I. Preemption Principles: The Presumption Against Preemption Is Overcome Only by Manifest Congressional Purpose.

As Justice Stevens noted in *Wyeth v. Levine*, 555 U.S. 555, 565 (2008), in any preemption case, a court must "'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'" (quoting *Medtronic, Inc. v. Lohr*, 518

U.S. 470, 485 (1996)). This is so particularly when Congress has legislated in a field that "the States have traditionally occupied." *Id.* And protection of patients and other consumers from unlawful practices by manufacturers and distributors of drugs is a field that the States have traditionally occupied. *Id. Cf. Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 144 (1963) (Brennan, J.) (regulation of food labeling is a traditional function of the States). In these circumstances, there is a presumption against preemption. *Wyeth*, 555 U.S. at 565 & n.3; *Arizona*, 567 U.S. at 400 ("In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress.") (internal quotation marks and citations omitted).

Here, as we discuss below, there is no explicit preemption of state law. There is no other indication that Congress intended the FDCA, 21 U.S.C. §§ 101 et seq., to displace the power of the States to bar deceptive labeling of drugs. And far from being impossible or standing as an obstacle to the purposes of Congress in preventing deceptive labeling of drugs, enforcement of the state law invoked by plaintiffs in this case would further those objectives.

II. "Express Preemption" Does Not Apply.

It is established that "both the National and State Governments have elements of sovereignty the other is bound to respect," but "Congress may withdraw specified powers from the States by enacting a statute containing an express preemption

provision." *Arizona*, 567 U.S. at 399.

Congress knows how to expressly preempt state law when it so intends. *See, e.g., Gobeille v. Liberty Mut. Ins. Co.,* 136 S. Ct. 936, 943 (2016) (ERISA's "terse but comprehensive" preemption clause—preempting "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan"—expressly preempts state plan requirements); *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 316, 321 (2008) (Medical Device Amendments of 1976 expressly preempted state safety regulations of medical devices different from device-specific federal rules, by stating: "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device") (though even this express preemption clause did not completely preempt state law, *see Medtronic v. Lohr,* 518 U.S. at 475-76).

If Congress had intended the FDCA to bar state law requirements that are "different from, or in addition to" any provision of the Act regarding pharmaceutical labeling, it could have done so—as it did in the Medical Device Amendments with respect to the labeling of devices. *See* 21 U.S.C. § 360k(a)(1). That it did not do so is a strong indication that plaintiffs' claims under state law in this case are not preempted.

III. "Field Preemption" Does Not Apply.

"Field preemption" exists when federal law has completely occupied the field, demonstrating that Congress intended to leave no room for any state-law claims. *See, e.g., Arizona,* 567 U.S. at 399 (Congress's "intent to displace state law altogether can be inferred from a framework of regulation so pervasive that Congress left no room for the States to supplement it or where there is a federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject") (internal quotation marks, ellipses, and citations omitted).

The Supreme Court has repeatedly made clear that the FDCA was not intended to preclude enforcement of state laws that affect products regulated by that Act. Quite to the contrary, the Court has made it clear that it regards regulation of such products as being within the historic police powers of the States—and therefore not preempted absent explicit preemption or a compelling indication that Congress intended preemption in a particular area. *See* pp. 3-4 above. Here, there is absolutely no indication that Congress intended to bar States from prohibiting deceptive statements of net quantity of contents by pharmaceutical manufacturers.

To be sure, there may be a compelling need for preemption where the effect of state regulation might be to require different labels in different states. But there is no such uniformity issue here. Plaintiffs are not invoking state law in order to impose a requirement in one State that is different from labeling requirements in other

States. Rather, if they are successful, the statement of contents of Herceptin packages that is at issue here would be accurate—and would be the same in every State. This fact distinguishes this case from *Jones v. Roth Packing Co.*, 430 U.S. 519 (1977), a case on which the district court heavily relied, and makes it much more like *Hillsborough Cty. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 716-20 (1985), where state law was found not to be preempted by the FDCA.

Just because a federal statute addresses an activity, that does not mean it has occupied the field regarding all possible related activity. For example, in *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1601 (2015), the Court held that the Natural Gas Act, under which FERC has authority to determine whether interstate natural gas sale prices are reasonable, did not preempt purchasers' state antitrust claims that pipelines had engaged in anticompetitive behavior affecting wholesale and retail natural gas prices. The Court rejected the claim of field preemption because of the "broad applicability of state antitrust law," which is "not aimed at natural-gas companies in particular, but rather all businesses in the marketplace." *Id.* The same is true of state warranty and unjust enrichment law.

IV. "Conflict Preemption" Does Not Apply.

Nor is state law preempted on a "conflict" rationale. "Conflict preemption" applies "either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and

execution of the full purposes and objectives of Congress." *Cerveny,* 855 F.3d at 1098. Neither of these types of conflict exists here.

A. Complying with Both Federal and State Law Is Not Impossible.

"Impossibility pre-emption is a demanding defense," requiring the defendant "to demonstrate that it was impossible for it to comply with both federal and state requirements." *Wyeth v. Levine*, 555 U.S. at 573.

The "impossibility" question asks whether doing what state law requires is forbidden by federal law. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013) (impossibility preemption exists "[w]hen federal law forbids an action that state law requires"); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (impossibility exists when it is "not lawful under federal law for the Manufacturers to do what state law require[s] of them"). Here, the impossibility question is whether satisfying the asserted state law—by delivering a minimum of 440 mg of Herceptin in a vial so labeled[1]—would have violated federal law.

Nothing in federal law forbade Genentech from delivering a minimum of 440 mg of Herceptin in a vial so labeled. Even if federal law is more lenient (allowing downward variation in the amount for federal purposes), it does not forbid a more

[1] We must assume that state law so requires. The district court did not reach the merits of this issue before holding at the threshold that state-law claims are preempted. *See* DE 388 at 17 n.9 (declining to address issues that "go to the merits of Plaintiffs' claims rather than the issue of preemption").

demanding state-law requirement.

State law is not preempted just because it is more demanding than federal law. Many cases so recognize. For example, in *Wyeth v. Levine* (involving a drug whose administration by "push-IV" rather than intravenous drip or intramuscular injection injured the patient), the fact that the drug's label complied with federal law did not preclude the patient from asserting that state law required an additional, stronger warning, because it was not "impossible for Wyeth to comply with both federal and state requirements." 555 U.S. at 571. The Court rejected Wyeth's argument that changing its packaging to add a stronger warning would violate federal law unless it first got FDA approval, because Wyeth could strengthen its warnings while seeking FDA approval under the federal "changes being effected" (CBE) regulation. *Id.* at 568-71. The present case is simpler, because the claim is that state law required Genentech to provide at least the 440 mg that its Herceptin package stated—not that it change the label. Nothing in federal law forbade Genentech from doing so.

Many other cases recognize that compliance with both federal and state law is not impossible simply because state law demands more. *See, e.g., Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668, 1678 (2019) ("we have refused to find clear evidence of such impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit"; whether federal law forbade a stronger state-law-required warning was for the court, not jury);

Williamson v. Mazda Motor of Am., Inc., 562 U.S. 323, 332-36 (2011) (federal motor vehicle law permitting either lap or shoulder belts did not preempt state law that restricted the choice by requiring shoulder belts: "the fact that DOT [decided to allow either lap or shoulder belts] cannot by itself show that DOT sought to forbid common-law tort suits in which a judge or jury might reach a different conclusion"; "a standard giving manufacturers 'multiple options for the design of' a device would not pre-empt a [state-law] suit claiming that a manufacturer should have chosen one particular option"); *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 257 (1984) (no preemption of punitive damages when "[p]aying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible"). *See also Pom Wonderful LLC v. Coca-Cola Co.,* 573 U.S. 102, 113-21 (2014) (holding, in the similar context of whether one federal law precludes another, that compliance with FDCA labeling rules for juice content did not preempt a claim that the label was deceptive under Lanham Act requirements; each body of law can be enforced in its own sphere, and the FDCA is not "a ceiling on the regulation of food and beverage labeling").

B. State Law Is Not an Obstacle to Congress's Purposes and Objectives.

The district court concluded that "obstacle preemption" applies because the federal FDA statute and regulations concerning pharmaceutical net quantity labels allow variation (at least for "solid drugs") above and below the stated amount. DE

388 at 14-17. While describing how Genentech satisfied these federal rules, the court did not explain why compliance with additional state-law rules would be "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Cerveny,* 855 F.3d at 1098. The district court discussed only *Jones v. Roth Packing Co.*, 430 U.S. 519 (1977), which disallowed state-law challenges (demanding different labels from state to state) when bags of flour were properly labeled under the FDCA with the correct weight at milling, but were prone to subsequent weight variation depending on atmospheric humidity. But as noted above (at p. 7), that case is readily distinguishable because, absent preemption, manufacturers would have had to use different labels in different states. Here, by contrast, all that plaintiffs are seeking is for Genentech to state the minimum net quantity of contents of Herceptin packages uniformly, but accurately.

The district court did not focus on the more analogous decision in *Wyeth v. Levine*, which held that FDA rules regarding labeling of a pharmaceutical did not preempt additional requirements arising under state law, rejecting the drug manufacturer's argument "that requiring it to comply with a state-law duty . . . would obstruct the purposes and objectives of federal drug labeling regulation." 555 U.S. at 573. The label at issue in *Wyeth* concerned proper administration of the drug—the federally approved label lacking a specific warning about the risk of "IV-push" administration, and state law assertedly requiring a stronger warning. The Court

"f[ou]nd no merit" in the argument that the asserted additional state-law obligations would "interfere with Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives," because that argument "relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* The Court rejected the argument that federal law "establishes both a floor and a ceiling for drug regulation" and that "[o]nce the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate." *Id.* at 573-74. As the Court explained:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . ., Congress has not enacted such a provision for prescription drugs. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574-75. The Court held that "Congress did not regard state tort litigation as an obstacle to achieving its purposes," and rejected the argument that the FDA "must be presumed to have performed a precise balancing of risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments." *Id.* at 575. The same analysis applies here.

Indeed, it is noteworthy that § 502(b)(2) of the FDCA, 21 U.S.C. § 352(b), explicitly provides that a drug in package form is misbranded "unless it bears a label

containing . . . an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count." That is precisely what the plaintiffs in this case allege that Genentech has not done. In short, rather than frustrating the purposes of Congress, permitting this case to proceed would advance those purposes as set forth in § 502(b). As the Court stated in analogous circumstances in *Pom Wonderful*, when "Congress did not enact a provision addressing the preclusion of other . . . laws that might bear on . . . labeling . . . [t]his is 'powerful evidence that Congress did not intend FDA oversight to be the exclusive means' of ensuring proper . . . labeling.'" *Pom Wonderful*, 573 U.S. at 114 (quoting *Wyeth*, 555 U.S. at 575).

CONCLUSION

For the reasons set forth above, the plaintiffs' claims are not preempted. The decision of the district court should therefore be reversed.

Respectfully submitted,

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August 6, 2019

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CERTIFICATE OF COMPLIANCE

The undersigned counsel for Amici certifies that:

1. No privacy redactions were required in this brief.
2. The hard copies of this brief are exact copies of the ECF filing of August 7, 2019.
3. The ECF submission was scanned for viruses with the most recent version of McAfee VirusScan Enterprise v8.0.012000 (updated 08/05/19), and, according to the program, is free of viruses.
4. This brief complies with the word limits of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), it contains 3191 words.
5. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Baskerville Old Face font.

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CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2019 I electronically filed the foregoing BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION AND OKLAHOMA STATE MEDICAL ASSOCIATION IN SUPPORT OF REVERSAL using the court's CM/ECF system, which will send notification of such filing to all counsel of record.

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