No. 19-5035

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

IN RE MDL 2700 GENENTECH, INC. HERCEPTIN (TRAZTUZUMAB) MARKETING AND SALES LITIGATION

Appeal from the United States District Court
for the Northern District of Oklahoma
Case No. 16-MD-2700

Brief of *Amicus Curiae* Chamber of Commerce of the United States of America in Support of Appellees and Affirmance

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *amicus curiae* Chamber of Commerce of the United States of America states that it has no parent corporations and no publicly held company owns 10% or more of its stock.

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INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million businesses and professional organizations of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of concern to the nation's business community, including preemption cases. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 2018 WL 4562162 (2019); *Mutual Pharmaceutical Company, Inc. v. Bartlett*, 570 U.S. 472, 2013 WL 314461 (2013); *Wyeth v. Levine*, 555 U.S. 555, 2008 WL 2322235 (2009).

This is such a case. The Chamber's members include not only pharmaceutical companies, which depend on the doctrine of implied preemption as protection against state and local mandates that conflict with requirements imposed by federal law, but also many other businesses that are subject to preemptive federal statutes and

regulations. The Supremacy Clause serves a vital structural role by protecting federal law and programs against encroachment and interference. It also helps to create unified and rational markets for nationally distributed goods and services by ensuring that uniform federal regulation is not undermined by state and local law, including state tort law. Accordingly, the Chamber has a strong interest in the proper resolution of the important issues raised in this case.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

The Chamber files this brief with the consent of all parties pursuant to Federal Rule of Appellate Procedure 29(a)(2). No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party, or person other than *amicus*, its members, or counsel made any monetary contribution intended to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents important issues of preemption that arise in the distinctive setting of the federal government's longstanding and strict regulation of prescription drugs pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. That Act prohibits the marketing of biologic drugs under labels that are "false or misleading in any particular." 21 U.S.C. § 355(d)(1), (7). The Food and Drug Administration enforces that prohibition in several ways, including through a pre-market approval regime that scrutinizes a drug's manufacturing process and proposed label to ensure safety, efficacy, and transparency. *See In re Genentech*, 367 F. Supp. 3d 1274, 1277–78 (N.D. Okla. 2019).

In this case, FDA approved Genentech's cancer drug, Herceptin®, for manufacturing and marketing. That included approving both the label's statement that a vial of the drug nominally contained 440 milligrams of the medicine and the drug application's specification that the manufacturing process could yield vials containing anywhere between 405 and 475 milligrams. *Id.* at 1279–80. "The term 'nominal' in

prescription drug labeling refers to a 'theoretical' amount, signaling the actual amount in each vial will vary." *Id.*

FDA thus determined that stating a nominal weight of 440 milligrams was appropriate so long as the actual amount of medicine in each vial remained within the 405–475 milligram range. This is exactly the kind of determination that Congress directed FDA to make. In declaring that a drug's label must bear "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count," Congress expressly provided that "reasonable variations shall be permitted ... by regulations prescribed by the Secretary." 21 U.S.C. § 352(b)(2).

FDA complied with Congress's directive by promulgating 21 C.F.R. § 201.51(g). That regulation provides that "[t]he declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package," *id.*, and then it specifies the "reasonable variations" (21 U.S.C. § 352(b)(2)) that Congress directed it to permit: "In the case of a solid drug in ampules or vials, the declaration shall be considered to express the accurate net weight" so long as "[v]ariations ...

comply with the limitations provided in the U.S. Pharmacopeia or the National Formulary." 21 C.F.R. § 201.51(a), (g).

It is undisputed that every vial of Herceptin® that Genentech sold complied with the applicable limitations regarding fill weight, both under this regulation and under the specifications governing FDA's approval of the drug. Every vial, in other words, fell within what Congress declared "shall be permitted." Plaintiffs can defend bringing this case only by pretending that this dispositive statutory language does not exist: their brief manages, through nearly 13,000 words, never to quote these three. *Cf.* Pl. Br. 7 (stating only that "FDA may further define what constitutes misbranding under the FDCA by adopting regulations permitting 'reasonable variations' in the quantity of package contents," without acknowledging that Congress declared that such reasonable variations "shall be permitted").

According to Plaintiffs, the laws of various states required every vial of Herceptin to contain at least 440 milligrams of the medicine. As a matter of state law, that proposition is highly dubious. Where the weight stated on the package is expressly described as "nominal" and purchasers know that FDA permits vials to vary within a given range, it

is unclear how anyone could be deceived into thinking that the nominal weight means the exact or minimum weight. But even assuming (charitably) that Plaintiffs have accurately described state law, their claim runs headlong into federal law. Although the Supreme Court has referred to "impossibility," "obstacle," and ordinary "conflict" preemption, these "terminological" distinctions cannot obscure the fundamental principle that the Supremacy Clause reaches *all* cases where there is an *actual* or *direct* conflict between state and federal requirements. *Geier v. Am. Honda Motor Co.,* 529 U.S. 861, 873–74 (2000); *see also Hines v. Davidowitz,* 312 U.S. 52, 67 (1941).

No doctrinal refinements are needed to know that where Congress has legislated that certain conduct "shall be permitted," a state cannot prohibit that conduct. In "impossibility" preemption terms, the (alleged) state laws at issue here are preempted because the same conduct cannot simultaneously be permitted and prohibited. In "obstacle" preemption terms, Plaintiffs' claims pose (to understate matters) an obstacle to the accomplishment of Congress's purposes, because Congress declared that conduct like Genentech's shall be permitted—but allowing Plaintiffs' claims to proceed will prevent drug manufacturers from engaging in that

conduct. Or, in simple "conflict" preemption terms, Plaintiffs' claim that state law prohibits Genentech's conduct conflicts, in the ordinary sense of the word, with Congress's and FDA's affirmative approval of that conduct.

As the above makes clear, the reasons for holding Plaintiffs' claims preempted are myriad. *Amicus* submits this brief to highlight two points of law that warrant the Court's attention if the Court chooses to resolve this case on "impossibility" grounds.

First, the Court should not lose sight of the central "impossibility" question in this case: whether Genentech could have complied with the state-law duties Plaintiffs sought to saddle it with sans "the Federal Government's special permission and assistance." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623–24 (2011). The Supreme Court has made that question clear and paramount through *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA, Inc. v. Mensing*, 564 U.S. 604, (2011), and it did not waver from that course in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). Moreover, as explained in Genentech's brief and in the District Court's opinion, the answer to the bedrock "impossibility" question is no: the changes state law supposedly mandated would have

required Genentech to obtain prior approval from FDA. Plaintiffs' claims are thus preempted.

Second, one of Plaintiffs' proposed solutions for how Genentech could solve the conflict and avoid liability—pull from the market any Herceptin® vial that contained less than 440 milligrams of the drug—"is no solution" at all. *Bartlett*, 570 U.S. at 475. The fact that *some* Herceptin® vials contained at least 440 milligrams of the drug does not change the "incoherence" of Plaintiffs' "stop-selling" theory. *Id.* at 488. The Supreme Court has recognized that "the stop-selling" theory would "render impossibility pre-emption a dead letter." *Id.* The Court should reject Plaintiffs' reliance on that invalid theory.

ARGUMENT

I. The FDCA Preempts Plaintiffs' Claims Because Genentech Could Not Have Made the Changes Plaintiffs Say Were Required Without FDA's Approval.

The District Court correctly held that the FDCA preempts Plaintiffs' claims. That is because Plaintiffs contend that *state* law required Genentech to make significant changes to the vial-fill specifications, manufacturing process, and labeling of its FDA-approved

drug, but *federal* law prohibited Genentech from making those changes without FDA's prior approval.

The Supremacy Clause bars a state-law claim where it is "impossible for a private party to comply with both state and federal requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *see also Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286 (10th Cir. 2013). The Supreme Court has specifically addressed what "impossibility" means in the context of claims that state law requires changes to an FDA-approved drug product, holding that the "question for 'impossibility' analysis is whether the private party could *independently* do under federal law what state law [supposedly] requires." *Mensing*, 564 U.S. at 620 (emphasis added). In other words, the manufacturer must have been able to make the change at issue "unilaterally," without prior FDA approval. *Id.*; *see also Bartlett*, 570 U.S. at 483–84; *Wyeth*, 555 U.S. at 573.

The Supreme Court has confirmed that this is the correct way to analyze conflict preemption. In *Wyeth*, the Court considered whether Vermont could impose liability on a brand-name drug manufacturer (Wyeth) for using an FDA-approved label that—in the *state's* judgment—failed to adequately warn users of the drug's potential side effects. *Id.* at

558. Federal law, the Court explained, does not preempt such claims if applicable federal regulations would have allowed the manufacturer *unilaterally* to alter its previously approved labeling in the way state law required, unless the manufacturer can show that FDA ultimately would have rejected the change. *Id*. at 568, 570–71. FDA's past approval of the drug's warning label was not a "complete" answer to the plaintiff's Vermont failure-to-warn claim, because FDA's "changes being effected" regulation "permitted Wyeth to unilaterally strengthen its warning." *Id.* at 559, 573. Stated differently, it was *possible* for Wyeth to comply with both the state and federal labeling standards on its own, without needing FDA's help, because FDA had promulgated a regulation allowing Wyeth to do what state law allegedly required.

Mensing complements *Wyeth* by confirming that the FDCA preempts state claims where, as here, it is *not* possible for a manufacturer to comply with both state and federal requirements without FDA's approval. *Mensing* presented similar failure-to-warn claims as *Wyeth*, but this time against makers of *generic* drugs. *See* 564 U.S. at 609–10. That distinction proved dispositive, as the Court concluded that federal law did not grant generic drug makers the same autonomy as brand-

name drug makers. *See id.* at 618. Specifically, federal law requires generics to have the same labels as their brand-name counterparts, and the "changes being effected" regulation is not available to them. *See id.* Nor did any other avenue under federal law allow the generic manufacturers to exercise control over their labels in the way the Court had found was true for Wyeth. The Court acknowledged that the generic manufacturers could have tried to engage with FDA in a way that could potentially have led to the label change allegedly required by state law, but that did not matter: Because the generic manufacturers could not strengthen their labels "of [their] own volition," the Court held that the claims were preempted. *Id.* at 624. In short, *Mensing* makes clear that the defense of impossibility preemption turns on whether it was possible for the defendant to make the changes supposedly required by state law *on its own* in conformity with federal law.

The Court's most recent preemption opinion in *Merck Sharp & Dohme Corp. v. Albrecht* did not alter this analysis. *Merck* did not concern the question of drug-maker autonomy under federal law to make a change allegedly required by state law. Instead, the *Merck* Court considered a question related to *Wyeth*'s subsidiary holding that a brand-

name manufacturer *could* establish an impossibility preemption defense by offering clear evidence that FDA would have rejected the state-law-required label change *after the fact*. *See* 139 S. Ct. at 1669, 1679. The Court held that whether FDA would have done so poses a question of law, rather than fact. *Id.* at 1680. That question does not arise in this case, because Genentech—like PLIVA and unlike Wyeth—had no right under federal law in the first place to unilaterally make the changes that Plaintiffs say were required by state law.

Given this precedent, Plaintiffs sensibly refrain from directly challenging the District Court's determination that their claims are preempted *if* Genentech "cannot comply with state law without first obtaining the approval of a federal regulatory agency." *Genentech*, 367 F. Supp. 3d at 1282 (citing *Mensing*, 564 U.S. at 620). It makes no difference whether Genentech might have been able to obtain FDA's "permission" to redesign its product, manufacturing process, or label, because any such permission would have been "dependent on the exercise of judgment by [the] federal agency." *Mensing*, 564 U.S. at 623–24.

Plaintiffs ostensibly accept this principle, which is why they insist that the changes they say were required did not necessitate prior

approval by FDA. Pl. Br. 41–49, 52–56. As Genentech explains, Plaintiffs are incorrect. Genentech Br. 36–47.

To do what Plaintiffs say state law required, Genentech would have needed *either* to ensure that every vial contained at least 440 milligrams of Herceptin® and, as a result, to change the description of the reconstituted solution concentration itself, *or* to change the descriptions on the product labeling of the product weight. *In re Genentech, Inc.*, 367 F. Supp. 3d at 1288. Plaintiffs suggest that Genentech could have made these changes unilaterally because they would not have adversely affected Herceptin®'s safety. *See* Pl. Br. 41–49. But, as the District Court correctly explained, neither the "changes being effected" regulation nor any other avenue under federal law allowed Genentech to make any of these changes without FDA's prior approval. 367 F. Supp. 3d at 1288–89. Changing the target fill weight is a "major change" requiring prior FDA approval because it is a change to the specifications provided in Herceptin®'s approved biologic license application. *Id*. (relying on, *inter alia,* 21 C.F.R. §§ 601.12(b)(2)(i), 211.110(a)(1), 211.110(b)). Changes to the sterile filling process or labeling are also "major changes" that require the agency's prior approval. *Id*. at 1289 (relying on 21 C.F.R.

§§ 601.12(b)(2)(vi), 601.12(f)(1)). Genentech's brief (at 36–47) shows why the governing regulations did not allow Genentech to unilaterally make the changes that Plaintiffs contend it should have made. That should be the end of the matter, and this Court should affirm.

II. Plaintiffs' "Stop Selling" Argument Fails.

Plaintiffs also argue that, even if federal law prevented Genentech from changing Herceptin®'s label or manufacturing process unilaterally, it was still not *impossible* for Genentech to avoid liability under state law. This is because, according to Plaintiffs, Genentech could simply have refrained from selling Herceptin® vials containing less than 440 milligrams of the drug. Pl. Br. 49–51.

As the District Court easily concluded, *see* 367 F. Supp. 3d at 1289–90, this is "no solution" at all, as the Supreme Court and this Court have soundly rejected a similar "stop selling" theory. *See Bartlett*, 570 U.S. at 475; *see also Schrock*, 727 F.3d at 1290 (applying *Bartlett*). In *Bartlett*, the defendant drug manufacturer faced liability under New Hampshire law for the allegedly dangerous design of its generic drug. *See* 570 U.S. at 479. Because the manufacturer could not redesign the drug consistent with its FDA approval in an effort to avoid its purported dangers, New

Hampshire law required a stronger warning label than the one FDA had approved. *Id.* at 484. As in *Mensing*, however, federal law prevented the manufacturer from changing the warning label unilaterally. *See id.* at 480.

Nonetheless, the First Circuit held that the FDCA did not preempt the state-law claims because the manufacturer could avoid liability by *not selling* the drug. *See Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30, 37 (1st Cir. 2012). The Supreme Court squarely rejected this theory and reversed. Such an out, it reasoned, would be "incompatible with [the Court's] pre-emption jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Bartlett*, 570 U.S. at 488.

The "incoherence of the stop-selling theory," the Court reasoned, "becomes plain when viewed through the lens of [its] previous cases." *Id.* "In every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting." *Id.* Lending credence to that theory would thus eviscerate impossibility

preemption. *Id*. at 489. The Court pointed specifically to *Mensing* as an example, noting that it had reached its preemption holding in that case "undeterred by the prospect that PLIVA could have complied with both state and federal requirements by simply leaving the market." *Id.* This was so even though the Court of Appeals had endorsed that rationale and Mensing had raised it in an unsuccessful petition for rehearing. *Id.* The Court thus held that the "stop selling" notion was "incompatible with [its] pre-emption jurisprudence." *Id.* at 488.

Plaintiffs' attempts to distinguish *Bartlett* from this case are unpersuasive. Their principal argument is that Genentech—unlike the defendant in *Bartlett*—would not have had to cease acting "*altogether*" in order to avoid the claimed state-law liability. Pl. Br. 50 (quoting *Bartlett*, 570 U.S. at 488) (emphasis added by Plaintiffs). Instead, Plaintiffs reassure the Court, Genentech "*merely* would have" had to "limit [Herceptin®'s] domestic sales to those lots … containing at least 440 [milligrams] of the drug." *Id*. at 51 (emphasis added).

Plaintiffs' reading of *Bartlett* is much too narrow; there is nothing in the opinion to suggest that its reasoning applies *only* where a manufacturer must halt operations *completely*. In fact, the manufacturer

in *Bartlett* did not need to literally cease acting altogether in order to avoid liability under New Hampshire law; it needed only to stop selling its drug *in New Hampshire*. The dissent seized on this point to argue that New Hampshire's law was not preempted. *See* 570 U.S. at 496 (Breyer, J., dissenting). But the Court disagreed, and correctly so: It is *always* true in the preemption context that the defendant could avoid liability under a given state's law by *not acting in circumstances where the laws of that state would apply*. By definition, after all, preemption involves the question of whether overarching federal law ousts the inherently more-limited application of a given state's law. PLIVA likewise could have avoided liability by avoiding selling its drug in Minnesota and Louisiana, but that was no answer to the conflict question in *Mensing*. *See* 564 U.S. at 618–19. So too in *Schrock*. *See* 727 F.3d at 1286 (Oklahoma law); *see also Jones v. Rath Packing Co.*, 430 U.S. 519 (1977) (California law). *Bartlett* thus correctly rejected the "stop selling" theory as "incoheren[t]," *see Bartlett*, 570 U.S. at 488, and it forecloses Plaintiffs' argument here.

The District Court's rejection of Plaintiffs' "stop selling" argument certainly does not prevent states from "ever forc[ing] defendants to

conform their conduct to more stringent standards than what federal law requires," as Plaintiffs hyperbolically contend. Pl. Br. 51. States remain free to impose higher regulatory standards than federal law in myriad contexts—*Wyeth* is but one example. And Plaintiffs are simply wrong that the District Court's application of *Bartlett* stands in "square[] conflict[] with *Wyeth*." Pl. Br. 51. As discussed, in *Wyeth*, a branded drug maker's right under federal law to make *unilateral* changes to its warning label was critical to the Court's holding that the manufacturer could simultaneously comply with federal law and state law. *See* 555 U.S. at 573. But *Wyeth* is inapplicable here, because Genentech cannot take unilateral action to simultaneously comply with federal law and state law. And *Wyeth* in no way suggests that, where it is impossible to comply with both state and federal law, state law prevails and the manufacturer must stop selling a product that complies with federal law. That result would be particularly troubling in this case, given that Congress expressly provided that reasonable variations in weight "shall be permitted." 21 U.S.C. § 352(b).

Plaintiffs' failure to grapple with the logic of *Bartlett* leads to a second flaw in their "stop selling" theory. Accepting their theory would

put one state in the position of regulating Herceptin®'s distribution *nationwide*. This is because a product like Herceptin® is distributed nationally through multiple distribution entities and layers—e.g., wholesalers, warehouses, and pharmacy chains. Stopping sales in a single state is a complex problem and, as a practical matter, keeping Herceptin® vials containing less than 440 milligrams of the drug out of one state could require ceasing to distribute such vials more broadly or even at all. Plaintiffs appear to understand this practical reality, as they admit that their "stop selling" theory would require Genentech to ensure that all "*domestic sales* … contain[] at least 440 [milligrams] of the drug" per vial. Pl. Br. 51 (emphasis added). This leads Plaintiffs back into the teeth of *obstacle* preemption, *cf. Bartlett*, 570 U.S. at 493–94 (Breyer, J., dissenting) (explaining that the need to stop selling in *one* state may frustrate Congress's *interstate* regulatory objectives), and it creates additional constitutional problems.

The spillover of one state's law into other states raises Commerce Clause concerns. In our federal union, states must limit their regulatory initiatives to their own territory; the Supreme Court has not hesitated to strike down state laws that effectively constrain activities that are lawful

in sister states—including as recently as this year. *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2464 (2019) (explaining that "the Commerce Clause prevent[s] States from passing facially neutral laws that place[] an impermissible burden on interstate commerce" and striking down Tennessee's durational-residency requirement for retail liquor store license applicants); *Healy v. Beer Institute,* 491 U.S. 324, 335–36 (1989) (observing that the Constitution has a "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres" and invalidating a state price-posting statute based on its extraterritorial effects).

Manufacturers distributing in interstate commerce and consumers in other states should not be foreclosed from accessing a life-saving drug by a state's idiosyncratic disagreement with FDA's reasoned judgment, in accordance with congressionally delegated authority, that the challenged labels on Herceptin® were accurate. *Cf. Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 673 (4th Cir. 2018) (holding invalid on Commerce Clause grounds a state law that "require[d] manufacturers

and wholesale distributors to … alter their distribution channels … in a way that 'interfere[s] with the natural function of the interstate market'" (citing *McBurney v. Young*, 569 U.S. 221, 235 (2013)).

CONCLUSION

This Court should affirm the District Court's judgment.

Respectfully submitted,

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October 11, 2019

CERTIFICATE OF COMPLIANCE

The undersigned counsel for *amicus* certifies that:

1. No privacy redactions were required in this brief.

2. Any required hard copies of this brief are exact copies of the ECF filing of October 11, 2019.

3. The ECF submission was scanned for viruses with the most recent version of McAfee Endpoint Security, 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 3560 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 Century Schoolbook font.

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2019, I electronically filed the foregoing brief using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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