No. 24-977

IN THE

# Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

*Petitioner,*

v.

DORIS ALBRECHT, et al.,

*Respondents.*

**On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit**

**BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING PETITIONER**

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## QUESTION PRESENTED

Does the Federal Food, Drug, and Cosmetic Act preempt a state-law claim against a drug manufacturer for failure to warn of a potential risk when the FDA has formally rejected the manufacturer's request (accompanied by all relevant scientific data) to update the drug's label to warn of that very risk?

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## INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as an amicus in important preemption cases, urging the Court to ensure that federal law operates efficiently and uniformly—as Congress intended. *See*, *e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019) (*Albrecht I*); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Wyeth v. Levine*, 555 U.S. 555 (2009).

WLF believes that individual freedom, the American economy, and public health all suffer when state law, including state tort law, interferes or conflicts with federal regulatory regimes, including the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. Conflicting federal and state duties are not merely inefficient; they make it impossible for regulated parties to comply with both state and federal law without incurring enormous liability.

The Supremacy Clause prevents state and federal courts from imposing that Hobson's choice on anyone. But if the Third Circuit's denial of federal preemption in the face of clear impossibility stands, it would erode the uniformity of federal law and visit chaos on the pharmaceutical industry.

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*No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, helped pay for the preparation or submission of this brief. All parties received timely notice of WLF's intent to file this brief.

## INTRODUCTION

In 2008, the Judicial Panel on Multidistrict Litigation consolidated several suits against Merck, all alleging that its Fosamax label failed to warn of an increased risk of atypical femoral fracture. Plaintiffs insisted that New Jersey tort law required Merck to supply a stronger warning label. Seventeen years later, that dispute has come to resemble the notorious *Jarndyce v. Jarndyce* of Dickens's *Bleak House*. It has wound its way through multiple MDL judges overseeing 1,200 claims, one bellwether trial, two appeals before six Third Circuit judges, and now returns to this Court following *Albrecht I* in 2019.

Merck's position has been consistent from day one: In May 2008, it proposed a stronger Fosamax warning label to the FDA, supported by all available data from 1995 to 2007. The FDA rejected that request in 2009 and offered no alternative. The Supremacy Clause, enshrined in Article VI, resolves such conflicts—federal law prevails whenever state law imposes a duty that is impossible to meet under federal law. *Albrecht I* set forth the standard: preemption is a question for judges, which is satisfied when a manufacturer fully informs the FDA and the agency denies the warning. On the record here, Merck easily meets that test. Yet 17 years on, this litigation stands less as a testament to justice than a monument to confusion, ensnaring the parties in uncertainty and upending the federal judiciary's goal of finality.

The Third Circuit has seemingly lost its way, prolonging this saga beyond all reason. In 2017, it demanded a "smoking gun"—proof by clear and convincing evidence that Merck could not secure FDA

approval—a standard this Court unanimously rejected. *Albrecht I*, 587 U.S. at 315–18. On remand, the district court followed this Court's guidance: Merck asked for a label that disclosed the risk; the FDA said no; so preemption follows. But in 2024, the Third Circuit took yet another detour, insisting that a "heavy presumption" defeats preemption unless the FDA's firm denial is the sole possible reading of the record. That approach strays from *Albrecht I*'s clear path and the Supremacy Clause's mandate. It mires Merck in escalating fees and costs, denies the plaintiffs much-needed closure, and burdens the courts with more than a decade of MDL proceedings. No other circuit has followed this course; the Third Circuit stands alone, ill-serving the parties and the law.

This Court does not lightly revisit a circuit's work for a second time in the same case. But nearly two decades of *Jarndyce*-like drift—marked by untold billable hours, financial tolls, and wasted judicial resources—compels review here. Merck has borne the weight of endless litigation for merely adhering to federal law; the plaintiffs, seeking redress, remain in limbo; and the judiciary expends scarce time on a dispute that should have ended long ago. The Third Circuit's detour has exacted a high price—a 17-year-long legal odyssey that warrants resolution.

Only this Court can cut through this doctrinal quagmire, restore order, and conclude a saga that has lingered far too long. Merck informed the FDA; the FDA refused; and preemption governs. The Court should grant the petition, affirm federal supremacy, and bring this protracted chapter to its rightful end.

## SUMMARY OF ARGUMENT

Complying with both federal and state law is "impossible" for drug manufacturers when "[i]t was not lawful under federal law for [them] to do what state law required of them." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). That is this case.

The only way Merck could have avoided liability under New Jersey tort law would have been to strengthen Fosamax's label to warn of an increased risk of atypical femoral fractures. But only the FDA can authorize a revised label, and Merck has shown decisively and repeatedly that the FDA rejected that very warning.

A starker showing of impossibility preemption is hard to imagine. If the Third Circuit's view of conflict preemption is left in place, it would invite great confusion and render the Supremacy Clause "all but meaningless." *Bartlett*, 570 U.S. at 488.

**I.** The Third Circuit's holding lives and dies by the presumption against preemption. While espousing "respect for the thorough and thoughtful work the District Court did in this complex case," the appeals court "conclude[d] that it erred in its pre-emption analysis by giving too little weight to the required presumption against pre-emption." Pet. App. 5a. But that presumption has no bearing here. In fact, as shown below, *no* presumption attaches when it is impossible to honor federal law without also defying state law.

**A.** The Constitution provides no textual basis for a presumption against preemption. The

Supremacy Clause declares federal law "the supreme Law of the Land," a command reinforced by its instruction that state laws to the contrary must give way. U.S. Const. art. VI, cl. 2. This Court has long recognized, as in *Gibbons v. Ogden*, 9 Wheat. 1 (1824), that the question is simply whether state law conflicts with federal law—no presumption required. The Clause's *non obstante* language, a familiar tool of eighteenth-century drafting, underscores that federal law's ordinary meaning governs—not some judicially imposed preference for state authority. The Tenth Amendment, meanwhile, confirms that Congress's delegated powers leave no room for state interference, suggesting that preemption flows naturally from the Constitution's design, not from a contrived barrier against it.

**B.** History gives no support to a presumption. The Framers crafted the Supremacy Clause to address a core weakness of the Articles of Confederation, ensuring federal law's primacy over conflicting state measures. Early preemption decisions reflected a judicial tendency to find preemption readily when federal and state laws conflicted, often prioritizing national uniformity. While mid-twentieth-century cases like *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), introduced a focus on congressional intent, this shift was neither consistent nor rooted in the Founding era. More recent rulings, including *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. 115 (2016), have clarified that express preemption requires no such presumption, aligning with a historical pattern that favors federal authority when the two sovereigns collide.

**C.** In cases of impossibility preemption, a presumption against preemption lacks both legal and logical grounding. When simultaneously complying with state and federal law is impossible, the Supremacy Clause resolves this tension without the need for artificial hurdles. This Court has questioned the presumption's relevance in such contexts, noting in *Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000), that its role remains unsettled, and in *Franklin*, 579 U.S. at 125, dispensing with it entirely for express preemption. Where compliance with both laws is impossible, preemption is not a policy choice but a constitutional necessity—state tort law included. Requiring Congress to incant specific words to trigger this result would elevate form over substance, a step the Clause's plain text neither demands nor supports.

**D.** This petition presents an ideal opportunity to resolve the confusion surrounding the presumption against preemption. The Third Circuit's reliance on it dictated the outcome, yet this Court's own application has been uneven. Such inconsistency risks undermining the predictability essential to our federal system. This case, unclouded by extraneous issues, allows the Court to clarify whether and when the presumption applies, ensuring that lower courts apply the Supremacy Clause with fidelity to its text and purpose. Resolving this question now serves not just the parties, but the broader goal of a coherent preemption jurisprudence.

**II.** Finally, there are major risks in allowing the Third Circuit's decision to stand. It would upend the predictability and uniformity of federal law on prescription-drug labeling. This could discourage

pharmaceutical companies from developing and marketing lifesaving drugs because of the risks of outsized verdicts in similar cases. Review is thus critical to ensure continued innovation in the vital pharmaceutical sector.

## ARGUMENT

### I. THE COURT SHOULD GRANT REVIEW TO ABOLISH ANY PRESUMPTION AGAINST PREEMPTION IN IMPOSSIBILITY-PREEMPTION CASES.

#### A. The Presumption Finds No Footing In The Constitution's Text Or Structure.

No constitutional justification exists for applying a presumption against preemption when it is impossible to simultaneously comply with state and federal law. As long ago as *Gibbons,* 9 Wheat. at 210, the Court asked whether a state law "interfer[ed] with," was "contrary to," or "c[a]me into collision with" federal law—and it did so without invoking a "presumption."

As "a matter of constitutional structure, there should be no systematic presumption against or in favor of preemption." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 Geo. L.J. 2085, 2092 (2000). The Supremacy Clause makes Congress's lawful enactments "the supreme Law of the Land[,] * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Consistent with that command," this Court has "long recognized that state laws that conflict with

federal law are without effect." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (cleaned up).

The Supremacy Clause's concluding phrase—"any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"—is a classic *non obstante* provision. Eighteenth-century legal drafters used *non obstante* clauses "to specify that they did not want courts distorting the new law to accommodate the old." *Mensing*, 564 U.S. at 622 (plurality opinion).

The Supremacy Clause's *non obstante* provision "indicates that a court need look no further than 'the ordinary meanin[g]' of federal law, and should not distort federal law to accommodate conflicting state law." *Id.* at 623 (plurality opinion) (quoting *Wyeth*, 555 U.S. at 588) (Thomas, J., concurring in judgment). By going beyond the "ordinary meaning," the presumption against preemption distorts federal law and the Supremacy Clause. *See* Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 304 (2000).

Nor is any such presumption required "to defend state interests from undue infringement." *Geier v. Am. Honda Motor. Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting). After all, "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York v. United States*, 505 U.S. 144, 156 (1992). Put differently, the Constitution itself resolves the inherent tension between federal and state power with a straightforward, self-executing rule: Federal law trumps conflicting state law. Because Congress enacts federal law against the backdrop of the

Supremacy Clause, we already know that Congress would desire preemption in cases of impossibility.

In sum, the "constitutional structure of federalism does not admit to a general presumption against federal preemption of state law." Dinh, 88 Geo. L.J. at 2087. Rather, "proper preemption analysis" requires carefully determining "whether state laws are displaced" by "Congressional enactments." *Id.* The Third Circuit's blanket presumption against preemption finds no purchase in the Constitution's text or structure.

### B. The Presumption Finds No Support In History.

There is "no significant support in constitutional history for the conclusion that the [F]ramers intended any such presumption to be read into Article VI, clause 2." Martin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. Davis L. Rev. 1, 30 (2001). On the contrary, the Framers adopted the Supremacy Clause precisely "to remedy one of the chief defects in the Articles of Confederation, by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 Iowa L. Rev. 355, 402 (2004). By design, the Supremacy Clause "invalidates" any "interfer[ing]" or "contrary" state law. *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (cleaned up).

The notion of a presumption against preemption—as a bulwark of state sovereignty against the Supremacy Clause—lacks any historical

foundation in this Court's early cases. *See, e.g.*, Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967, 974 (2002) (showing that the Court's earlier preemption cases "resulted in almost automatic preemption of concurrent state regulation"). In the early twentieth century, the Court's preemption doctrine operated under a framework of "latent exclusivity," whereby federal legislation was broadly construed to "occupy the field" despite little evidence of congressional intent. *Id.*

Early cases like *Southern Railway Co. v. Reid*, 222 U.S. 424 (1912), and *New York Central Railroad Co. v. Winfield*, 244 U.S. 147 (1917), show the Court readily finding preemption when state and federal laws overlapped, favoring national uniformity over state authority. This early trend undercuts claims that a presumption against preemption is a deeply embedded, foundational principle. Davis, 53 S.C. L. Rev. at 975–76.

Far from embedding a presumption against preemption, this Court's historical approach often presumed federal dominance, particularly when Congress legislated under an enumerated power like the Commerce Clause. Emphasizing the federal need for uniformity, these early cases confirm that the Court viewed Congress's silence on unregulated areas to be just "as expressive of what its intention is as the direct provisions made by it." *Id.* at 976. This broad approach shows that the Court has historically used the Supremacy Clause as a tool to affirm federal law's primacy.

The mid-twentieth-century shift toward discerning congressional clear intent, as seen in cases

like *Rice*, 331 U.S. at 218, is often cited as evidence of a presumption against preemption. But this was more a temporary deviation than a historical norm. *See* Davis, 53 S.C. L. Rev. at 979. While *Rice* suggested that "the historic police powers of the States were not to be superseded by Federal Act unless that was the clear and manifest purpose of Congress," the Court's application of this principle was inconsistent and easily overridden by a focus on national uniformity. *Id.*

Above all, the federal courts' invocation of a "presumption against preemption" is a recent phenomenon. It wasn't until the 1980s that the presumption first appeared in field preemption cases "as a possible reaction to the [federal government's] significant and ever-widening control over so many aspects of our daily lives." *Id.* at 1013. If anything, the presumption arose to combat *not* impossibility preemption, which is always legitimate, but a different, less popular species of conflict preemption. The historical trajectory thus reveals a judicial preference for federal supremacy over conflicting state laws, not a protective shield for state autonomy.

Indeed, this Court has abolished any "presumption against preemption" in express-preemption cases. In *Franklin*, the Court held that when a "statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption." 579 U.S. at 125 (quoting *Chamber of Com. of the United States v. Whiting*, 563 U.S. 582, 594 (2011)). Instead, the Court simply "'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Id.*

In short, for most of its long history, the Court has consistently applied the implied preemption doctrine broadly to override conflicting state laws. From the early railroad cases to modern products liability disputes, the Court has often presumed preemption, driven by a quest for uniformity and certainty rather than a deference to state police powers. The occasional invocation of a presumption against preemption represents an anomaly within a broader narrative of federal dominance. Confirming this history, as Mary Davis's scholarship does, clarifies that the Supremacy Clause's traditional application favors preemption.

### C. Nothing In Law Or Logic Supports Applying The Presumption Here.

In cases like this one, where preemption hinges on the existence of an immovable conflict between state and federal law, a presumption against preemption makes no sense. Rather, every reason supports the view that Congress always wishes to preempt state law whenever it genuinely conflicts with federal law. "Why," after all, "would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake?" *Geier*, 529 U.S. at 870. If courts must presume otherwise, "state law could impose legal duties that would conflict directly with federal regulatory mandates." *Id.* That can't be right.

Some courts, including the Third Circuit here, defend the presumption against preemption as a safeguard for state sovereignty, particularly in areas like tort law traditionally reserved to the States under their police powers. See Pet. App. 5a (emphasizing

"the required presumption against pre-emption"). They argue that state failure-to-warn claims, such as those under New Jersey law, serve as a vital complement to federal regulation, incentivizing drug manufacturers to disclose risks the FDA might overlook and thereby protecting public health. This view posits that without a presumption, federal law might unduly stifle state efforts to address local health concerns.

This argument, while perhaps intuitively appealing, collapses under scrutiny in impossibility-preemption cases like this one. When compliance with both state and federal law is truly impossible—as when the FDA rejects a warning that state law demands—the Supremacy Clause admits no compromise. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 ("[P]reemption is inescapable" in cases of direct conflict). Put differently, conflict preemption is the quintessential example of the Supremacy Clause at work. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("[S]tate law is nullified to the extent that it actually conflicts with federal law."). Under the Supremacy Clause, "the relative importance to the State of its own law is not material when there is a conflict with a valid federal law." *Id.* (cleaned up). And because the scope of the conflict itself delineates the scope of preemption, "a narrow focus on Congress's intent to supersede state law is misdirected." *City of New York v. FCC*, 486 U.S. 57, 64 (1988).

Here, Merck proposed to the FDA a stronger warning, supported by all relevant data, only to have it denied. Pet. App. 2a–3a. State tort law cannot override that federal decision without nullifying the

FDCA's regulatory framework, which Congress designed to ensure uniform national standards for drug labeling. Far from supplementing federal oversight, imposing liability in such circumstances penalizes manufacturers for adhering to federal law—a result that undermines, rather than advances, public health by sowing confusion and deterring innovation (*see infra* Section II).

Moreover, the presumption's federalism rationale assumes a harmony between state and federal goals that simply does not exist in true conflict cases. When state law demands a party to do what federal law forbids, deference to state police powers does not preserve federalism—it erodes the constitutional balance the Framers struck. *See Felder v. Casey*, 487 U.S. 131, 138 (1988) ("[A]ny state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."). The Third Circuit's heavy reliance on the presumption thus misapplies a tool meant for ambiguous cases to one where the conflict is stark and unavoidable. To elevate federalism here would be to defy the Supremacy Clause itself.

Again, this Court has already abolished any "presumption against preemption" in express-preemption cases. *Franklin*, 579 U.S. at 125. But a presumption against preemption makes even *less* sense in a conflict-preemption context. Perhaps that is why the Court has openly questioned whether the presumption should ever apply in conflict-preemption cases. *See, e.g., Crosby*, 530 U.S. at 374 n.8 ("We leave for another day a consideration in this [implied preemption] context of a presumption against preemption."); *United States v. Locke*, 529 U.S. 89,

108 (2000) ("No artificial presumption [against preemption] aids us."). And at least four Justices on the Court have already answered "no." *See, e.g.*, *Mensing*, 564 U.S. at 622 (plurality opinion) (explaining that, if anything, "federal law should be understood to impliedly repeal conflicting state law").

As the Eleventh Circuit has noted, "it is difficult to understand what a presumption in conflict-preemption cases amounts to, as we are surely not requiring Congress to state expressly that a given state law is preempted using some formula or magic words." *Fla. State Conf. of the NAACP v. Browning*, 522 F.3d 1153, 1168 (11th Cir. 2008). Nor is federal law "obliged to bend over backward to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction." *Id.*

### D. The Petition Offers An Ideal Vehicle For Clearing Up Widespread Confusion About The Presumption.

The Third Circuit's holding stands entirely on the presumption against preemption. Pet. App. 5a ("Applying that presumption, and considering the record here, we conclude that Plaintiffs' state-law claims are not preempted."). Without that critical thumb on the scale, this case easily would have been resolved in Merck's favor. When federal appellate courts differ in their interpretations or misread this Court's precedents, this Court's supervisory role demands intervention—not merely to resolve theoretical "percolation," but to enforce a coherent and consistent legal framework. Failure to do so

undermines the integrity and uniformity of the federal judicial system.

Some of this confusion must fall at the feet of this Court, where the presumption "is only inconsistently invoked and applied." Mark D. Rosen, *Contextualizing Preemption*, 102 Nw. U. L. Rev. 781, 785 (2008). That is, the presumption against preemption has been honored as much in the breach as in the observance, suggesting that it operates more as a tiebreaker in close cases—or a makeweight in cases where the Court wishes to preserve state authority—than as a consistent legal doctrine.

True, in many cases when the Court finds no preemption, its majority will invoke the presumption. *See, e.g., Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005) (finding that federal law regulating pesticides doesn't preempt state statutory and common-law claims); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (finding that the FDCA's manufacturing and labeling requirements for medical devices don't preempt state common-law claims).

But just as often, when the Court finds state law preempted, the presumption vanishes without a trace. *See, e.g., Arizona v. United States*, 567 U.S. 387 (2012) (preempting Arizona's efforts at cooperative enforcement of federal immigration law); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (preempting New York's common-law claims under the FDCA); *Geier*, 529 U.S. at 906-07 (Stevens, J., dissenting) ("[T]he Court simply ignores the presumption [against preemption].").

In other words, the Court "continues to simultaneously repeat and ignore the presumption against preemption." Calvin R. Massey, *Joltin' Joe Has Left and Gone Away: The Vanishing Presumption Against Preemption*, 66 Alb. L. Rev. 759, 764 (2003). But a legal presumption that courts can wield as they please and withhold as they please is little more than a crude thumb on the scale of justice. Above all, "the maintenance of a presumption against preemption" forces a court "to treat essentially similar cases in very different manners." Scordato, 35 U.C. Davis L. Rev. at 30–31. That way madness lies.

Armed with so pliable a presumption, federal courts can't help but act capriciously. And whenever a court "systematically favor[s] one result over another" when analyzing state and federal conflicts, it "risk[s] an illegitimate expansion of the judicial function." Dinh, 88 Geo. L.J. at 2092.

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The Supremacy Clause speaks for itself. The Court "should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Mensing*, 564 U.S. at 622 (plurality opinion). The petitioner deserves to have its preemption defense evaluated on the best available evidence of an unavoidable conflict rather than on a presumption that bears no apparent relation to that question.

As it has done many times before, this Court should grant review and apply ordinary, longstanding, and time-tested principles of conflict preemption. As in *Albrecht I*, that analysis should be based on the substantive requirements of state and

federal law—*not* on the expedient of some *a priori* rule of decision.

## II. LEFT TO STAND, THE DECISION BELOW INVITES DISASTROUS CONSEQUENCES FAR BEYOND THIS CASE.

This case is no less important and deserving of this Court's review than it was six years ago. If anything, the stakes are even higher now. If the Court declines to hear this appeal, immense consequences will follow. Those negative downstream effects will reach well beyond the parties and facts of this case.

So long as pharmaceutical manufacturers believe they can recover more than their research and development costs when creating lifesaving and life-improving drugs, they will devote their finite resources to developing new drugs. A recent study shows just how expensive it is to bring new drugs to market. "Between 2009 and 2018, the FDA approved 355 new drugs and biologics." Oliver J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 J. Am. Med. Ass'n 844, 848 (2020). The average cost of bringing each drug to market was $1.56 billion. *See id.* That number, however, may underreport the cost of pre-clinical trials. Factoring in that potential underreporting, the average cost of bringing a single drug to market is between $1.78 billion and $2.19 billion *See id.* at 850.

Despite the enormous cost of bringing drugs to market, the number of new drugs becoming available has increased over the past decade. *See* CBO, *Research & Development in the Pharmaceutical*

*Industry* 1 (Apr. 2021), https://perma.cc/D8L4-3XUQ. That is because the amount that pharmaceutical manufacturers spend on research and development today "is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation." *Id.* The percentage of revenues spent on research and development has also doubled over the past two decades. *See id.* In other words, pharmaceutical manufacturers see a reason to innovate in the current market.

No doubt one reason why pharmaceutical companies are willing to devote more and more limited resources to researching, developing, and distributing drugs is that they are protected under the Supremacy Clause from conflicting state-law claims. They understand that, under the FDCA and this Court's preemption precedents, federal law fully preempts state-law tort claims arising from following federal law or adhering to FDA regulations. *See, e.g., Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 814–15 (7th Circ. 2018). But if the Third Circuit's decision stands, this assurance will vanish. Pharmaceutical companies will face an untenable binary choice: either comply with federal law or risk hundreds of billions of dollars in state-law liability.

Rather than innovate and release new drugs that can save lives, some pharmaceutical companies may choose not to release any drug with a serious adverse side effect. This means that drug manufacturers, when faced with potential liability that dwarfs possible profits, will produce only drugs with few or negligible side effects. That also means fewer lifesaving and life-improving drugs. *See, e.g., Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal,*

*Inc.,* 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) (observing that "the threat of * * * enormous awards" has convinced prescription-drug manufacturers "that it is better to avoid uncertain liability than to introduce a new pill"); *Carlin v. Superior Court*, 920 P.2d 1347, 1361 (Cal. 1996) ("[T]he imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs.").

True enough, companies faced with arbitrary and unpredictable liability might just "continue making and selling their wares, offering 'tort insurance' to those who are injured." *Carroll v. Otis Elevator Co.,* 896 F.2d 210, 217 (7th Cir. 1990) (Easterbrook, J., concurring). But if "the judgment bill becomes too high," they are more likely to throw up their hands and leave the market. *Id.* "Products liability law as insurance is frightfully expensive." *Id.* As seen with the withdrawal of Bendectin—a popular drug once used to treat morning sickness—following unpredictable tort liability despite FDA approval, this possibility cannot be casually dismissed. *See* Louis Lasagna & Sheila R. Shulman, "Bendectin and the Language of Causation," in *Phantom Risk: Scientific Inference and the Law* 101 (Kenneth R. Foster et al. eds., 1993).

The stakes are high. The linchpin to our nation's pharmaceutical industry is the predictability and uniformity of federal law in a nationwide marketplace. If a single circuit can go off the rails and inflict tens of billions of dollars in costs, then every drug company must factor that into its cost-benefit

analysis. Many may decide that intolerable risk is not worth taking.

Pharmaceutical companies must weigh this risk carefully because they are subject to general jurisdiction in Pennsylvania, which sits in the Third Circuit. *See Mallory v. Norfolk S. Ry.*, 600 U.S. 122, 135 (2023) (upholding Pennsylvania law requiring out-of-state firms to consent to personal jurisdiction in Pennsylvania courts as a condition of registering to do business in the Commonwealth). Of course, federal district courts enjoy the same personal jurisdiction as "a[ny] court of general jurisdiction in the state where the district court is located." Fed. R. Civ. P. 4(k)(1)(A). And the American Tort Reform Foundation recently recognized the Pennsylvania state courts as among the most plaintiff-friendly jurisdictions in the nation. *See* Am. Tort Reform Found., Judicial Hellholes, *The Pennsylvania Supreme Court and Philadelphia Court of Common Pleas*, https://perma.cc/ZAW3-XYXN. Plaintiffs' attorneys thus flock there to file suits that would be laughed out of court in most jurisdictions.

In short, correcting the Third Circuit's egregious preemption holding is not the only reason to grant review here. This case has serious implications for the wider pharmaceutical industry and for federal preemption in general. Blessing—through acquiescence—the Third Circuit's latest botching of this case will sow confusion and discourage pharmaceutical innovation. This Court should not take that risk. Rather, it should hear this case and reaffirm the supremacy of federal law.

## CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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