No. 20-1069

In The

Supreme Court of the United States

JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC,

Petitioners,

v.

A.Y. AND BILLIE ANN YOUNT,

Respondents.

On Petition for a Writ of Certiorari to the Superior Court of Pennsylvania

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

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QUESTION PRESENTED

Whether federal law preempts state-law failure-to-warn claims for the off-label use of prescription drugs when federal law bars the manufacturer from unilaterally altering labels to provide such warnings.

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INTRODUCTION AND INTEREST OF *AMICUS CURIAE*[1]

A state court orders a company to release information about a ballistic-missile submarine's location to help bring about service of process. Because that information is classified, the company declines and the court imposes a billion dollar fine. The state appellate courts affirm that order. Would this Court intervene and reverse the contempt finding?

This Court would most likely prevent this interference with federal law. That, of course, is why the Founders included the Supremacy Clause in the Constitution. They did not want rogue States preventing the federal government from exercising its enumerated powers—including the power to regulate interstate commerce.

The decision of the Court of Common Pleas is a similar afront to the Supremacy Clause. It ordered Petitioners to pay tens of millions of dollars because they complied with federal law. And because this is just one of many similar cases, Petitioners face a potential bill in the billions.

Rather than meaningfully review the trial court's order, the Superior Court gave short shrift to Petitioners' preemption arguments. Most of the opinion is just block quotes followed by perfunctory

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[1] No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, paid for the brief's preparation or submission. After timely notice, all parties consented to WLF's filing this brief.

analysis. Some preemption arguments were mentioned only when describing Petitioners' position. The Superior Court failed to explain how Respondents' claims are not preempted by federal law.

The Supreme Court of Pennsylvania then denied allocatur. This Court is now the only one that can ensure that Petitioners do not suffer for following federal law. It should therefore intervene and reaffirm the Supremacy Clause's command.

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 *amicus* in important preemption cases to urge the federal courts to prevent contrary state law from undermining the predictability and uniformity of federal law. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013).

The decision below upends the predictability and uniformity of federal law. Allowing the Superior Court's decision to stand would stifle pharmaceutical innovation. Granting review to reaffirm the supremacy of federal law will ensure that pharmaceutical companies can continue to engage in life-saving research and development. Denying review makes the Supremacy Clause surplusage.

STATEMENT

I. STATUTORY AND REGULATORY FRAMEWORK

The FDA must approve any prescription drug that crosses state or international borders. 21 U.S.C. § 355(a).[2] When seeking approval, a manufacturer must include "the labeling proposed to be used for such drug." *Id.* § 355(b)(1)(F). The labeling must include "[i]ndications and [u]sage," "[w]arnings and [p]recautions" and "[a]dverse [r]eactions." 21 C.F.R. § 201.56(d)(1).

The indications and usage section "must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition." 21 C.F.R. § 201.57(c)(2). This is the origin of the term on-label use. When a drug is being used for one of the listed indications and uses, it is being used on-label. When it is being used for another purpose, it is being used off-label.

About one-third of prescriptions are for off-label uses. Pet. 36 (citation omitted). For some drugs, more than 99% of prescriptions involve off-label uses. *See, e.g.*, Sumathi Reddy, *Risk of Off-Label Uses for Prescription Drugs*, Wall St. J., Nov. 23, 2015, https://on.wsj.com/39Ogrux.

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[2] Unless otherwise indicated, all statutory and regulatory citations are to the current versions. There are no substantive differences between the cited provisions and the comparable 2003 provisions.

The warnings and precautions and adverse reactions sections are limited to information for those taking the approved dosage for the indications and uses included on the label. 21 C.F.R. §§ 201.57(a)(6), (7), (10), and (11). The only exception to this rule is that "FDA may require" warnings if "there is a lack of evidence that the drug is effective or safe for" an off-label use. *Id.* § 201.57(c)(2)(ii).

Risperdal is an anti-psychotic medicine that rebalances dopamine and serotonin in the brain to improve mood. Between 1993 and 2006, Risperdal was not approved to treat psychotic disorders in minors. Because it was not approved for children, the indications and uses section of the label described use by only adults. *Cf.* 21 U.S.C. §§ 331(a) (barring misbranding of drugs), 352(f) (a drug is misbranded if it includes unapproved indications and uses). So the warnings and precautions and adverse reactions sections could not describe risks for children taking Risperdal.

II. FACTS AND PROCEDURAL HISTORY

Risperdal can cause elevated prolactin levels. Most people with increased prolactin levels suffer no adverse effects. One in forty boys, however, sees unusual breast tissue growth. So once the FDA approved Risperdal for children in 2006, Petitioners added a warning to the label describing this risk.

In 2003, a doctor prescribed four-year-old A.Y. Risperdal for oppositional defiant disorder. As described above, this was an off-label use. When A.Y. saw unusual breast tissue growth, he stopped taking Risperdal. But his mother later requested that he

resume taking the medication because the benefits outweighed the side effects.

A.Y. and his mother then sued Petitioners arguing that A.Y. would not have taken Risperdal had they known the risk of breast tissue growth. The Court of Common Pleas held that federal law did not preempt Respondents' failure-to-warn claim. After refusing to engage with Petitioners' preemption arguments, the Superior Court applied a non-existent presumption against preemption and affirmed. This Court's review is needed because the Supreme Court of Pennsylvania refused to hear the appeal.

SUMMARY OF ARGUMENT

I.A. There is no evidence that the Framers envisioned a presumption against federal preemption of state laws. Rather, the evidence suggests that the Founders tried to solve the Articles of Confederation's problems by barring a patchwork of state laws on some matters. The Superior Court, however, applied a broad presumption against preemption that is unsupported by history.

B. This history explains why federal courts have traditionally not applied a presumption against preemption. A recent preemption decision from this Court in the prescription-drug sphere rejected applying a presumption against preemption in conflict-preemption cases. But the Superior Court did not cite that decision—much less explain why its reasoning does not apply here.

C. This Court has rejected a presumption against express preemption. But a presumption

against impossibility preemption—a subset of conflict preemption—makes even less sense. In essence, such a presumption makes federal law yield to state law—the opposite of the Supremacy Clause's command.

II.A. Federal courts have held that any claim a drug lacks a warning about an off-label use is preempted because the FDA alone can require such a warning. As it did not do so for pediatric use of Risperdal, federal law barred Petitioners from adding a warning to Risperdal's label. The Superior Court's decision ignores these precedents.

B. As with prescription drugs, the FDA must approve labeling for class III medical devices. Because the device manufacturers cannot change the label—including warnings—without FDA approval, this Court has held that failure-to-warn claims are preempted by federal law. The same rationale applies here.

III. There are major risks in letting the Superior Court's decision stand. It would upend the predictability and uniformity of federal law on prescription-drug labeling. This could cause pharmaceutical companies to release fewer life-saving drugs because of the risks of outsized verdicts in similar cases. Review is thus necessary to ensure continued pharmaceutical innovation.

ARGUMENT

I. THE SUPERIOR COURT IMPROPERLY APPLIED A PRESUMPTION AGAINST PREEMPTION.

No basis exists in the Constitution for applying a presumption against preemption—in this or any other case. 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).

Yet with a single block quote, the Superior Court applied a presumption against preemption. Pet. App. 16-17 (quoting *Hassett v. Dafoe*, 74 A.3d 202, 210 (Pa. Super. 2013)). This presumption against preemption ignores the Constitution's history, this Court's precedent, and logic.

A. History Does Not Support A Presumption Against Preemption.

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).

There is "no significant support in constitutional history for the conclusion that the [F]ramers intended" for a presumption against preemption. Martin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. Davis L. Rev. 1, 30

(2001) (citations omitted). Rather, 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 Supremacy Clause's phrase—"any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"—is a *non obstante* provision. In the 18th century, legal drafters used *non obstante* provisions "to specify that they did not want courts distorting the new law to accommodate the old." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 622 (2011) (plurality) (citations omitted).

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." *Mensing*, 564 U.S. at 623 (quoting *Wyeth v. Levine*, 555 U.S. 555, 588 (2009) (Thomas, J., concurring)). By going beyond the ordinary meaning, the presumption against preemption distorts federal law. *See* Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 304 (2000). The Superior Court's blanket presumption against preemption is thus ahistorical.

B. Case Law Does Not Support A Presumption Against Preemption.

Courts' invocation of a presumption against preemption is a new phenomenon. *See, e.g.*, Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967, 974 (2002) (the Court's earlier preemption cases "resulted in almost automatic preemption of concurrent state regulation" (citation omitted)). It wasn't until the 1980s that the presumption first arose 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. But for most of its history, "the Court has consistently applied implied preemption doctrine broadly to support a finding of preemption." *Id.*

A presumption against preemption is unnecessary "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.

This Court's recent decision on federal preemption of state attempts at regulating drug labels shows the straightforward nature of federal preemption. In *Mensing*, the Court considered whether a failure-to-warn claim against a generic

drug manufacturer was preempted by federal law. In concluding that the claim was preempted by federal law, the plurality soundly rejected applying a presumption against preemption. *Mensing*, 564 U.S. at 621-23. As Justice Thomas explained for the plurality, the history discussed above shows there is no presumption against conflict preemption. *Id.*

The Superior Court did not cite *Mensing* once. This shows that the panel failed to read a recent preemption decision from this Court. This failure to conduct even the most basic task of an appellate court—reading relevant precedent—shows the short shrift it gave Petitioners' preemption argument. It also helps explain why the Superior Court failed to follow this Court's case law disclaiming any presumption against preemption.

C. Logic Does Not Support A Presumption Against Preemption.

Common sense also weighs against a presumption against preemption here. It is rational to presume that Congress always wishes to preempt a state law when complying with that law would make compliance with federal law impossible. "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 871. If courts must presume otherwise, "state law could impose legal duties that would conflict directly with federal regulatory mandates." *Id.* That cannot be right.

This Court has recently abolished any presumption against preemption in express-

preemption cases. In *Puerto Rico v. Franklin-California-Tax-Free Trust*, the Court held that when a "statute 'contains an express pre-emption clause,'" there is no "presumption against pre-emption." 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Com. of the U.S. v. Whiting*, 563 U.S. 582, 594 (2011)). Rather, the Court simply "focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.* (cleaned up).

But a presumption against preemption makes even less sense in conflict-preemption cases. That is why four justices in *Mensing* rejected a presumption against preemption in conflict-preemption cases. *Mensing*, 564 U.S. at 622 (plurality). Conflict preemption "requires no inquiry into congressional design." *Fla. Lime & Avacado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (citations omitted). That is because state law automatically falls when it conflicts with federal law. *Felder v. Casey,* 487 U.S. 131, 138 (1988); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

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." *Free v. Bland*, 369 U.S. 663, 666 (1962). And because an actual conflict is determinative, "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) (cleaned up).

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 Conference of the NAACP v. Browning*, 522 F.3d 1153, 1168 (11th Cir. 2008) (citation omitted). Because "the Framers of our Constitution provided that the federal law must prevail" over state law, *Free*, 369 U.S. at 666, federal law is not "obliged to bend over backwards to accommodate contradictory state laws." *Fla. State Conference of the NAACP*, 522 F.3d at 1168.

* * *

The Superior Court thus erred by reflexively reaching to a non-existent presumption against preemption. This fundamental error at the outset infected the rest of the preemption "analysis." This case presents the perfect opportunity to definitively reject the presumption against preemption in a case that cries out for federal court intervention.

II. THE SUPERIOR COURT'S DECISION SPLITS FROM FEDERAL COURT DECISIONS.

Petitioners explain why this case is exceptionally important and deserves this Court's review. Pet. 34-37. But there is another reason to grant review in this case: The Superior Court's decision conflicts with federal court decisions.

Plaintiffs' attorneys try hard to ensure that cases like this one remain in state court. They understand that their liability theories do not fit this Court's preemption jurisprudence. But sometimes plaintiffs must litigate in federal court. When that happens, the federal courts swiftly reject their claims as preempted by federal law. These decisions involve

prescription drugs and analogous class III medical devices.

A. Federal Courts Have Held That Pharmaceutical Companies Cannot Unilaterally Add Warnings For Off-Label Uses.

The Eastern District of New York has explained a key difference between federal preemption of failure-to-warn claims for on-label uses and off-label uses. A failure-to-warn claim is preempted if (1) federal law prohibits a drug company "from unilaterally modifying the FDA-approved labeling or" (2) "the FDA would not have approved a change to the drug's label." *McGrath v. Bayer HealthCare Pharm. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (cleaned up).

In 2003, FDA's "changes being effected" (CBE) regulation allowed drug companies to unilaterally alter warnings for on-label uses. *See* 21 C.F.R. § 314.70(c)(2)(i) (2003). But "the FDA retain[ed] authority to reject labeling changes" made under this regulation. *Merck*, 139 S. Ct. at 1677 (quotation omitted). Thus, if pediatric use of Risperdal were an on-label use, the failure-to-warn claim would be preempted only if FDA would have rejected any change to the label. *Wyeth*, 555 U.S. at 571.

But A.Y. used Risperdal off-label. So Petitioners were barred from using the CBE regulation to alter the label. As such, the claims here are preempted if FDA regulations barred unilaterally changing Risperdal's label. As described above, FDA regulations were crystal clear: Petitioners could not

unilaterally change the label. *See* 21 C.F.R. §§ 201.57(a)(6), (a)(7), (a)(10), (a)(11), and (c)(2)(ii). Respondents' claims are therefore preempted by federal law.

Other federal courts have applied this rule when rejecting claims almost identical to Respondents' claims. One case, *Byrd v. Janssen Pharm., Inc.*, 333 F. Supp. 3d 111 (N.D.N.Y. 2018), is illustrative. There, the plaintiff, like A.Y., took Risperdal when he was a child and saw abnormal breast tissue growth. Like A.Y., the plaintiff used Risperdal before 2006. Still, he sued for failure to warn.

The case proceeded to trial where the jury awarded the plaintiff $1,000,000—far less than the jury awarded Respondents. After the trial, Janssen moved for judgment as a matter of law.

The trial court granted the motion. It held that the plaintiff's failure-to-warn claims were preempted by federal law. *Byrd*, 333 F. Supp. 3d at 117, 120. It reasoned that FDA's regulations "prohibited [Janssen] from unilaterally updating Risperdal's label for pediatric use." *Id.* at 117. This is because the pediatric use of Risperdal was off-label and only the FDA can order a warning for off-label use. *See id.*

The issue here is identical to the issue in *Byrd*. Yet the Superior Court refused to even acknowledge the Northern District of New York's holding. Nor did the Superior Court explain why *Byrd*'s analysis was wrong.

Decisions from the federal courts of appeals and district courts do not bind the Superior Court. Rather, only the Supreme Court of Pennsylvania and this Court's decisions are binding. *Commonwealth v. Huggin*s, 68 A.3d 962, 968 (Pa. Super. 2013). Because the Supreme Court of Pennsylvania abdicated its responsibility to apply this Court's well-settled precedent, this Court should intervene.

B. Decisions Addressing Off-Label Use Of Medical Devices Also Suggest That Respondents' Claims Are Preempted By Federal Law.

Manufacturers who want to market a class III medical device must go through the premarket approval process. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). "The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading." *Id.* at 318 (citations omitted).

If this sounds familiar, it should. The premarket approval process for class III medical devices tracks the FDA's approval process for drugs like Risperdal. Here, 21 C.F.R. § 201.57 prohibits unilaterally changing the label while 21 C.F.R. § 814.80 does the same for class III medical devices.

Like prescription drugs, there is a CBE regulation for class III medical devices. *See* 21 C.F.R. § 814.39(d). But as with prescription drugs, the CBE regulation cannot be used to add a warning for off-

label uses of a class III medical device. *See id.* § 814.39(a)(1).

The courts of appeals have therefore applied *Riegel*'s preemption analysis to the off-label use of class III devices. For example, in *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760 (3d Cir. 2018), the plaintiffs sued under Pennsylvania law for off-label use of a device including class III components. The Third Circuit held that the claims were preempted by federal law. *Id.* at 773-74.

The Third Circuit's application of *Riegel* to off-label use is not unique. In *White v. Medtronic, Inc.*, 808 F. App'x 290 (6th Cir. 2020) (*per curiam*), the plaintiff sued for failure to warn of an off-label use of a class III device. The Sixth Circuit held that under *Riegel*, federal law preempted those claims. *Id.* at 294-95.

The same rationale applies here. Petitioners could not unilaterally change Risperdal's label to add a warning for off-label use. Rather, the FDA alone had the authority to order a warning about off-label use. This is the same as a class III device manufacturer's inability to add a warning to its label without FDA approval. The Court's rationale in *Riegel* therefore applies with equal force here.

III. THE CONSEQUENCE OF THE SUPERIOR COURT'S DECISION ARE DEVASTATING.

If this Court declines to hear this appeal, immense consequences will follow. One of the main reasons that pharmaceutical companies are willing to devote limited resources to developing and

distributing drugs is that they are protected from frivolous state-law claims. They understand that, under the FDCA and this Court's precedent, state-law claims for simply adhering to FDA regulations are preempted by federal law.

But if the Superior Court's decision stands, this assurance will vanish. Pharmaceutical companies will have to worry about whether they will face the impossible choice of either complying with federal law or risking hundreds of billions of dollars in state-law damages. The choice they may be forced to make is scary.

Rather than innovate and release new drugs to save lives, pharmaceutical companies may choose not to release any drug that has any side effects—even when those effects arise only in off-label uses. This result flows naturally because of how doctors prescribe drugs off-label. A pharmaceutical company cannot stop a doctor from prescribing a drug for off-label use. The company can only distribute the drug to pharmacies and advertise its on-label uses. If a doctor chooses to prescribe the drug off-label, that is between the doctor and his or her patient. The pharmaceutical company is not involved in that decision.

When faced with potential liability that dwarfs possible profits, the pharmaceutical companies may decide that the risks outweigh the rewards. This means companies will produce only drugs with few side effects—for both on-label and off-label use. That means fewer life-saving and life-improving drugs.

Although this may appear to be a one-off decision, the lynchpin to our nation's pharmaceutical industry is the predictability of federal law. If a single state court can go off the rails and cost them tens of billions of dollars, then drug companies must factor that into their cost-benefit analysis. Many may decide that intolerable risk is not worth taking.

Many pharmaceutical companies must weigh this risk more because they are subject to general jurisdiction in Pennsylvania. That is why the Philadelphia Court of Common Pleas handles so many mass tort cases. *Cf.* Max Mitchell, *Phila. Mass Tort Inventory Rises as Vena Cava Filter and Essure Programs Emerge*, The Legal Intelligencer (Sept. 20, 2019), https://bit.ly/3pPOQ0B (describing the large number of mass tort cases). Pharmaceutical companies are subject to the court's jurisdiction and it is number one on the list of judicial hellholes. *See* American Tort Reform Foundation, *2020/2021 Judicial Hellholes*, https://bit.ly/37ORptL. Plaintiffs thus flock there to file suits that would be laughed out of court in most jurisdictions.

So the legal problems with the Superior Court's decision is not the only reason to grant review here. This case has serious implications for the wider pharmaceutical industry. Blessing—through silence—the Superior Court's order will discourage pharmaceutical innovation. This Court should not take that risk. Rather, it should hear this case and reaffirm the supremacy of federal law.

CONCLUSION

This Court should grant the petition.

Respectfully submitted,

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