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., *et al.*,
Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AND INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST

The National Association of Manufacturers and the International Association of Defense Counsel respectfully submit this brief as *amici curiae*. They are filing due solely to their interest in the important issues raised by this case.[1]

Amici have a substantial interest in ensuring that manufacturers operating in federally-regulated industries are provided with clear legal standards for when they can and cannot warn. Their members include manufacturers and counsel who regularly defend litigation resulting from alleged failures to warn, including in cases involving indications for which the Food and Drug Administration has not approved a pharmaceutical product. The decision of the Pennsylvania courts raises a question not directly addressed in this Court's prior decisions and which, if followed, could significantly undermine federal safety regulations and pose a direct conflict between such regulations and state tort law.

The **National Association of Manufacturers** (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all fifty states. Manufacturing employs more than twelve million men and women, contributes $2.3 trillion to the

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[1] *Amici* hereby affirms that no counsel for either party authored any part of this brief in whole or in part. No party, counsel for a party, or person other than *amici*, their members, or counsel made any monetary contribution intended to fund the preparation or submission of this brief. Amici notified all parties of their intent to submit this brief at least 10 days before it was due and all parties provided written consent to the filing of this brief.

U.S. economy annually, has the largest economic impact of any major sector, and accounts for nearly two-thirds of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The **International Association of Defense Counsel** (IADC) is an invitation-only, peer-reviewed membership organization of about 2,500 in-house and outside defense attorneys and insurance executives. IADC is dedicated to the just and efficient administration of civil justice and improvement of the civil justice system. IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries, responsible defendants are held liable for appropriate damages, and non-responsible defendants are exonerated without unreasonable cost.

Amici regularly appear before the Court as amicus curiae in cases involving issues of importance to their members. *See, e.g.*, *Trans Union LLC*, *v. Ramirez*, No. 20-297, 2021 WL 533217 (Feb. 8, 2021) (NAM and IADC) (brief in support of judgment reversal) (cert granted); *Nestlé USA, Inc. v. Doe I*, Nos. 19-416 & 19-453, 2019 WL 5589062 (Oct. 28, 2019) (NAM) (brief in support of certiorari petitions) (cert granted). This is just such a case. *Amici's* members depend on the predictability of applicable federal regulations for product labeling. The Pennsylvania courts' decision threatens that predictability not only for the pharmaceutical sector but for manufacturers across industries representing a significant swath of the U.S. economy.

INTRODUCTION

This case presents an issue that urgently merits review: whether federal law prohibiting a pharmaceutical manufacturer from unilaterally amending an FDA-approved product label to warn about unapproved users preempts state law claims that require the addition of such a warning. In other words, this case addresses what course of action manufacturers must take when federal label regulations require a product to be labeled for a specific audience (here, those for whom a product is approved), but state tort law requires labeling for a different one (those for whom it is not approved). The fundamental premise of the Pennsylvania court's decision is that state tort law can be used to impose labeling requirements that conflict with a federal regulatory scheme that requires the product to be labeled for different purposes to a different audience who may face very different risks. This decision has implications that reach far beyond the pharmaceutical industry. Manufacturers across federally-regulated industries are subject to carefully calibrated federal labeling regulations that provide the certainty and predictability needed to operate. The use of state tort law to undermine federal labeling requirements will, if allowed to continue, create a confusing and ultimately destructive "dual track" system where federal agencies and state tort law will conflict and ultimately undermine the federal goal of targeting labeling to a specific audience. Granting review of this case offers the Court an important opportunity to clarify the respective roles of federal regulatory authorities and state tort law in product labeling.

SUMMARY OF ARGUMENT

In allowing liability to attach based upon a manufacturer's failure to warn about an unapproved use of

a prescription medication, the Pennsylvania court ignored the fundamental fact that federal regulation of prescription drugs restricts the audience to which drugs may be labeled—to users for whom a product has been approved. In order for a drug manufacturer to provide label warnings to those wishing to use a drug for an unapproved use—"off label"—the United States Food and Drug Administration ("FDA") must approve the label change. *See* 21 C.F.R. § 201.57(e) (2003).[2] This federal regulatory scheme allows FDA to balance its regulatory goals of limiting product labeling to approved uses and directing that labeling to reflect the particular risk profile posed by approved uses against the potential need to expand such labeling if off label uses pose additional or different risks. Although a drug manufacturer is able to unilaterally change a label in certain situations when it speaks to the audience for whom a drug is approved—and in those situations, this court has held warning Court claims are not preempted, *Wyeth v. Levine*, 555 U.S. 555, 571—it cannot do so to address an audience for which a drug is not approved. The Pennsylvania decision thus elides over an issue not directly addressed by this Court's prior rulings, *viz.*, the preclusive effects of a federal regulation that bars a manufacturer from unilaterally amending a drug label for an unapproved off-label use. Providing clear guidance on this subject merits hearing this case.

The ramifications of the Pennsylvania court's decision extend well beyond the prescription drug context.

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[2] In June 2006, § 201.57 was reorganized, and subsection (e) was recodified at § 201.57(c)(6)(i), while other provisions in the section were incorporated into a new provision, § 201.80. For consistency, this brief refers to the off-label warning provision as 201.57(e) regardless of time period.

Congress has established numerous agencies that regulate product labeling and that frequently approve labels that target a specific audience. Just as the FDA's labeling targets *approved* end users of a drug, other agencies require labeling directed to a particular type of end-user or to those using a product for industrial versus residential use. Allowing state tort law to require labels that are aimed at one audience (e.g., industrial workers) to serve as the basis of an alleged inadequate warning to a different audience (e.g., consumers) would negate the very purpose of this extensive federal regulatory regime and result in "one-size-fits-all labeling" that would undermine product safety and the public health. The Pennsylvania court's decision also undercuts the predictability and consistency that federal labeling rules provide to manufacturers. Granting this petition would permit the Court to reaffirm this federal regulatory scheme and preclude the use of state tort law to impose conflicting requirements on manufacturers.

For these reasons, NAM and IADC respectfully request the Petition for Certiorari be granted.

ARGUMENT

I. THE COURT SHOULD GRANT CERTIORARI TO ADDRESS THE PRECLUSIVE EFFECT OF A FEDERAL REGULATION BARRING MANUFACTURERS FROM UNILATERALLY CHANGING A LABEL TO SPEAK TO AN AUDIENCE FOR WHICH A DRUG IS NOT APPROVED.

The Food Drug and Cosmetic Act ("FDCA") establishes a comprehensive scheme of safety and disclosure requirements as part of the approval process for prescription drugs. In approving a drug, the FDA not

only determines whether it is safe and effective but also approves the specific indications for which the drug is used. 21 U.S.C. § 355(c)(1)(A). In regulating the content of the drug's label, the FDA directs drug manufacturers to warn of potential risks posed by the approved indications. The manufacturer is, however, precluded from providing warnings directed to risks that may arise from uses for which the drug is not approved unless the FDA requires such warning:

> A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling *may be required by the Food and Drug Administration* if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard.

21 C.F.R. § 201.57(e) (2003) (emphasis added).[3]

The term "off-label" is fittingly used to describe this audience because such use of the drug is (generally) not mentioned on the label. By restricting communication about off-label use, the FDA avoids providing misleading information that might be read as suggesting FDA approval for such uses or by patient populations diagnosed with the unapproved indication. For example, if a drug is not approved for children but contains a warning for pediatric use, the label may imply an FDA determination that such use

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[3] Manufacturers can face potential criminal liability for "misbranding" a drug if the label includes information about unapproved uses. *See* 21 U.S.C. §§ 331(a), 333(a)(2), 352(a).

is appropriate. These regulations seek to prevent such an implication.

In this case, the label for Risperdal® provided warnings targeted to those for whom that medication is approved: adults. The Pennsylvania court nonetheless held Johnson & Johnson liable for not warning a different audience, children, who might be prescribed the drug for an unapproved off-label use. Despite the fact that federal law precluded Johnson & Johnson from directing any warnings to this population, the Pennsylvania court allowed liability to attach.

This case thus presents a question not directly addressed by this Court's decision in *Wyeth*. There, the Court held that because the manufacturer of a name-brand drug could in certain circumstances unilaterally change the label pursuant to the changes be effected (CBE) regulation, failure to warn claims were not preempted unless a defendant had "clear evidence" that the FDA would have rejected the proposed label change. *Wyeth*, 555 U.S. at 571–72; *see also Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1678 (2019) (discussing *Wyeth* and stating "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."). This case presents the flip side of *Wyeth*: Are failure-to-warn claims preempted when a manufacturer is barred from unilaterally amending a drug label to address an audience for whom a medication is not approved?

The decision of the Pennsylvania court establishes that once the FDA has approved labeling for the intended audience, state tort law may also require that the manufacture provide labeling directed to a

different audience, despite the regulation precluding such labeling. Congress has set up a complex regulatory scheme for pharmaceutical products that FDA implements which manufacturers rely upon. The Pennsylvania decision not only creates a new obligation but one which is in direct conflict with an obligation created by the federal regulatory agency. Drug manufacturers accordingly are faced with the choice of adhering to the federal law and providing labels determined by FDA to be appropriate for the approved patient population or violating those federal requirements to avoid liability under state law based upon warnings claimed by state tort plaintiffs to be necessary in cases of off-label use. Given the importance of the federal objectives that inform FDA drug labeling requirements with respect to unapproved drug uses and the uncertainty for manufacturers engendered by the Pennsylvania decision, it is imperative that the Court be heard on this conflict between state tort law and preemption principles left unanswered by *Wyeth*.

II. THE COURT SHOULD GRANT CERTIORARI BECAUSE OF THE IMPACT OF THE PENNSYLVANIA COURT'S RULING ON THE FEDERAL GOVERNMENT'S SCHEME FOR TARGETING PRODUCT LABELING REQUIREMENTS TO SPECIFIC POPULATIONS WITH DIFFERING RISK PROFILES.

By requiring that a drug manufacturer label its product to address potential risks to users for which a product is not approved or directed, the Pennsylvania decision creates a legal precedent that has implications well beyond the context of prescription drugs. Federal regulation of product labels is specifically

structured to address the fact that the same product often poses much different types of risk depending on how the product is to be used and the population to which the product is being directed. Requiring that products bear a one-size-fits-all label that ignores these differences, as the Pennsylvania court has done, risks undermining this broader regulatory system and leaving manufacturers to operate with great uncertainty. Not only will manufacturers have no confidence that compliance with federal law will provide protection from state tort law, but at times it may, as in this case, place them in an impossible position where they cannot comply with both federal and state law. For example, a manufacturer, as Johnson & Johnson is here, could be in compliance with federal labeling laws applicable to a certain product, yet still face a $70 million jury verdict in one case with 10,000 similar cases pending. Granting review in this case would provide the Court with the opportunity to provide guidance regarding this critical issue.

Numerous federal labeling regulations seek to ensure safety regarding the manufacture and use of products. Beyond the FDA, agencies including the Consumer Product Safety Commission (CPSC), the Federal Hazardous Substances Act (FHSA), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA) require manufacturers to provide various warnings based upon product category, product use, and applicable safety standards. In many instances, different labels are required for similar or even substantively identical products depending on who will use them, and often multiple agencies regulate a

single product, requiring different labeling aimed at different users. For example:

- The CPSC enforces several labeling laws including requiring precautionary labeling on the containers of *household* products, *see* 15 U.S.C. §§ 1261–1278 (Federal Hazards Substances Act). Congress has promulgated certain CPSC-enforced requirements that are aimed at specific audiences, *see, e.g.*, 15 U.S.C. § 1277 (Labeling of Hazardous Art Material Act), or certain types of products, *see* 15 U.S.C. §§ 1191–1204, 16 C.F.R. § 1609.1 (Flammable Fabrics Act).
- The FHSA imposes labeling requirements for substances that are intended for household use, but products "developed and marketed for use by professionals do not require the FHSA's protective measures which were designed in part to help prevent accidents involving children." *Canty v. Ever-Last Supply Co.*, 685 A.2d 1365, 1369 (N.J. Super. Ct. Law Div. 1996).
- OSHA requires that the manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) for each hazardous chemical to communicate information about hazards. *See* 29 C.F.R. 1910.1200(g). Unlike labeling required for consumer audiences, SDSs are targeted to hazards of working with the material in an occupational fashion, which can pose dramatically different exposure scenarios and risks. *See* 29 C.F.R. § 1910.1200(e)(2). Thus, federal regulations require that

> only certain audiences—distributors and employers—are provided with it. *See, e.g., Messer v. Amway Corp.*, 210 F. Supp. 2d 1217, 1230 (D. Kan. 2002) (citing 29 C.F.R. § 1910.1200(g)(6)(i)). The SDS is not designed for nor even seen by every user of the product. *See, e.g., Irrer v. Milacron, Inc.*, 484 F. Supp. 2d 677, 688–89 (E.D. Mich. 2007) ("The regulations do not require chemical manufacturers to provide the MSDS[4] to the ultimate user."). And the SDS requirement is not simply part of a federal scheme but also part of an effort to standardize labeling requirements to conform with the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals. *See* Final Rule, Hazard Communication, 77 Fed. Reg. 17,574, 17,724 (Mar. 26, 2012); *see also* 29 C.F.R. § 1910.1200(g)(2) (standardizing and requiring use of SDS).[5]

Many of these regulatory requirements vary depending on the audience. For example, the EPA's labeling requirements for outdoor, residential consumer pesticides, EPA Label Review Manual Ch. 8,

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[4] The Material Safety Data Sheet (MSDS) is a prior term used for the SDS before the adoption of the Globally Harmonized System. *See* Final Rule, Hazard Communication, 77 Fed. Reg. 17,574, 17,785 (Mar. 26, 2012) (removing the word "material" as part of OHSA's amendments to the Hazard Communication Standard to conform to the Globally Harmonized System).

[5] OSHA, *Side-by-Side Comparison of OSHA's Existing Hazard Communication Standard (HCS 1994) vs. the Revised Hazard Communication Standard (HCS 2012)* (emphasizing the "uniformity oriented approach" of the HCS amendments) (emphasis in original), https://www.osha.gov/hazcom/side-by-side.

III.C., are different than the labeling required for use by agricultural workers, *id.* at Ch. 10, VII., which is different than the distributor label requirements, *id.* at Ch. 3, II.F., *see generally* EPA Label Review Manual (consistent with the EPA regulation, 40 C.F.R. § 156).[6] And the labeling requirements approved by OSHA on a chemical used in the manufacture of that pesticide are directed to those exposed to it in an occupational setting. These labels will all invariably differ from one another as these regulatory bodies weigh the various quantities and types of exposure different individuals in different settings will have.

Allowing warnings required by EPA on an agricultural product or by OSHA for use of a chemical in the occupational setting to serve as the basis of a state law failure-to-warn claim brought by a home user would turn the regulatory system on its head. The warnings required by those working with chemicals are vastly different than the end-user of certain products that contain those materials. At times, warnings directed to a different audience would make no sense and in others would upset the careful balance that the federal regulatory system seeks to ensure given the risks of both under and over warning, *see, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000) (noting that Department of Transportation has rejected "the more … the better" approach). This type of regime would make it impossible for manufacturers to comply with the warnings required by federal and state law.

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[6] EPA, *Label Review Manual* (stating that the manual "compiles existing interpretations of statutory and regulator provisions and reiterates existing Agency policies"), https://www.epa.gov/pesticide-registration/label-review-manual.

In the context of prescription drugs, the applicable regulatory agency has decided that no warning should be directed to an unapproved audience without FDA approval. This regulatory scheme allows the FDA to require labeling that is properly targeted to approved drug indications and that provides the most accurate and relevant information for that patient population. This scheme also avoids the confusion that could arise from warnings that would be appropriate only for different (and unapproved) end-users. Allowing state tort law to undermine the federal regulatory system on labeling properly targeted for the protection of specific user populations, as the Pennsylvania court has done, provides a further reason for this Court to review that decision. Manufacturers need to know that by complying with federal law they are not risking noncompliance with state tort law.

CONCLUSION

The Court in *Wyeth* held that federal law regulating drug warning labels for an approved audience did not preempt failure-to-warn claims because drug manufacturers could in certain situations unilaterally change that label. The decision did not, however, address an instance in which a drug manufacturer is precluded from changing the label to address alleged different risks arising from unapproved uses aimed at unapproved audiences. In allowing liability to attach in this case, the Pennsylvania court not only allowed state law to directly conflict with FDA requirements but also endorsed a state tort law "one-size-fits-all" labeling requirement that would undermine a wide range of federal regulations properly crafted to protect specific user populations against specific, associated product and user risks. To ensure that the federal regulatory system operates as intended and that

manufacturers remain confident that complying with the system will not run afoul of state tort law, the Petition for Certiorari should be granted.

Respectfully submitted,

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