No. 22-1180

In the Supreme Court of the United States

SHIRE US INC.; SHIRE LLC,

Petitioners,

v.

MARK BLACKBURN,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. PhRMA's members produce innovative medicines, treatments, and vaccines that save and improve the lives of countless individuals every day. Since 2000, PhRMA's members have invested more than $1 trillion into discovering and developing new medicines, including an estimated $102 billion in 2021 alone. *See* PhRMA, *2022 Profile: Biopharmaceutical Research Industry* 2 (2022), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Industry-Profile-2022/2022-Profile-3.pdf; PhRMA, *About PhRMA*, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/P-R/PhRMA-Profile.pdf (last visited July 6, 2023).

This case presents a question of substantial importance for PhRMA's members: whether they can face state tort-law liability for failing to unilaterally change language contained in the "Highlights" section of prescription medicine labeling—where the Food

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[1] In accordance with Rule 37.2, all counsel of record received timely notification of *amicus curiae*'s intent to file this brief. No party's counsel authored this brief in whole or in part. No party, counsel for a party, or person other than *amicus curiae,* its members, and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

and Drug Administration ("FDA") directs that the most important risk information be placed—when the FDA itself, through duly enacted notice and comment regulations, prevents companies from making such a change. The burdens of product liability litigation are already substantial for life sciences companies, and a regime that permits these companies to be held liable for failing to do what the FDA forbids them from doing would disrupt regulation, hamper innovation, and harm patient health. The Court should grant certiorari and reverse the Eleventh Circuit's judgment.

INTRODUCTION AND SUMMARY OF ARGUMENT

The FDA brings extensive scientific expertise to bear in approving medically-appropriate labeling for prescription medicines, both before and after they come to market. Congress granted the FDA this authority in recognition of its unique institutional ability to evaluate the scientific basis for proposed labeling and assess how best to communicate complex risk and benefit information about medicines.

In recognition of that authority, this Court held in *PLIVA, Inc. v. Mensing* that a state-law claim is preempted if it would require the manufacturer to take action with respect to the drug's labeling that requires "the Federal Government's special permission and assistance." 564 U.S. 604, 623–24 (2011). This Court's precedents dictate that federal regulations preempt lawsuits like this one, where the FDA forbids companies from taking the unilateral action that state tort law purports to demand.

The Eleventh Circuit erred in allowing this case to proceed in the face of federal law to the contrary. The impact of that error is grave, and it extends well beyond this litigation. The Eleventh Circuit's decision undermines the FDA's authority to control the content of medicine labeling and at the same time places manufacturers in the impossible position of facing civil liability for failing to unilaterally revise the Highlights section—an action that the FDA, through notice and comment rulemaking, has explicitly forbidden manufacturers from taking.

Despite clear precedent, unambiguous regulatory text, and a consensus among other courts that changes to the Highlights section of drug labeling require prior approval from the FDA, the Eleventh Circuit held that Shire could have unilaterally changed the Highlights section without FDA prior approval. *See Blackburn v. Shire U.S., Inc.*, 2022 WL 16729466 (11th Cir. Nov. 7, 2022). The Eleventh Circuit's ruling has the effect of creating a patchwork system of liability that will ultimately hamper manufacturer innovation and harm patient health. The decision of the Eleventh Circuit should be reversed.

ARGUMENT

I. THE ELEVENTH CIRCUIT'S DECISION UNDERMINES THE FDA'S REGULATORY FRAMEWORK AND PLACES MANUFACTURERS IN AN UNTENABLE POSITION.

A. The FDA Exercises Exclusive Control Over the Contents of the Highlights Section.

The FDA is vested with ultimate responsibility for "protecting the public health by ensuring the safety" of medicines." FDA, *What We Do*, https:///www.fda.gov/about-fda/what-we-do (last updated Mar. 28, 2018). One of the ways the FDA carries out this responsibility is through carefully scrutinizing and approving product labeling—which the FDA must do before a manufacturer may legally market a medicine in interstate commerce. *See* 21 U.S.C. § 355(a); *see*

also Wyeth v. Levine, 555 U.S. 555, 568 (2009). Product labeling, which "is written for the healthcare professional," contains a summary of the "essential scientific information needed for the safe and effective use of the human prescription drug." FDA, *Prescribing Information Resources*, https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources (follow "What is the Prescribing Information" hyperlink) (last updated May 22, 2023). After initial approval of a medicine, the FDA continuously monitors scientific information to ensure the product's labeling remains adequate; the FDA also has the power to direct changes to the labeling if it determines such changes are appropriate. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,604 (Aug. 22, 2008); 21 U.S.C. § 355(o)(4); *Merck Sharpe & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1684 (2019) (Alito, J., concurring).

Effective pharmaceutical labeling strikes a delicate balance. A drug's labeling is "often lengthy" and includes an assortment of "detailed information about the drug's medical uses and health risks." *Albrecht*, 139 S. Ct. at 1672–73. Simultaneously, it must communicate this information in a manner that is useful to healthcare professionals. Seeking to strike that balance, in 2006, and following a years-long notice and comment rulemaking procedure, the FDA fundamentally revised its regulations for the content and format of prescription medicine labeling—dictating categories required in medication labeling, precise information each category should include, and, in many cases, exact formatting standards. *See* 21

C.F.R. §§ 201.56–57, 201.66, 201.80; *see also* FDA, *Guidance for Industry: Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements* 2 (Feb. 2013), https://www.fda.gov/media/71836/download ("The rule was designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use to facilitate practitioners' use of labeling to make prescribing decisions.").

One of the critical components of the 2006 "Physician Labeling Rule" was the addition of a "Highlights" section to be placed at the beginning of the labeling for each prescription medicine. The Highlights section is designed to provide medical professionals with "a summary of the most important information for prescribing the drug safely and effectively." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3,922, 3,930–32 (Jan. 24, 2006); *see also* FDA, *Guidance for Industry* at 6 ("The purpose of Highlights is to provide immediate access to the information to which practitioners most commonly refer and regard as most important."). It must concisely summarize the key provisions of the full labeling, including the "most clinically significant information" found in the "Warnings and precautions" section. 21 C.F.R. § 201.57(a)(10). The FDA has described "developing Highlights" as one of the "most challenging aspects" of prescription medicine labeling. FDA, *Guidance for Industry* at 2.

Given that the Highlights section is an "essential element" of product labeling and important to the FDA's broader public health role, the FDA chose to

maintain strict and exclusive control over the language of that section of labeling. 71 Fed. Reg. at 3,930–31. The FDA does this for obvious reasons—if manufacturers could unilaterally update the Highlights section, that section could fail to achieve its goal of highlighting the information the FDA deems most essential. As the agency stated in promulgating the final Physician Labeling Rule:

> [B]ecause Highlights is a summary of the most important information for prescribing decisions and some comments expressed concerns about the difficulty involved in summarizing the complex and often lengthy information in the FPI (see e.g., comments 16, 23 and 27), the agency believes that it is ***essential*** for FDA to review and approve most proposed changes to the information in Highlights. . . . Under §§ 314.70(b)(2)(v)(C) and (c)(6)(iii), and 601.12(f)(1) and (f)(2)(i), applicants are ***required*** to obtain prior approval of any labeling changes to Highlights, except for editorial or similar minor changes, including removal of a listed section(s) from "Recent Major Changes" or a change to the most recent revision date of the labeling.

71 Fed. Reg. at 3,932 (emphases added).

This approach was incorporated into the final, promulgated regulations. "[M]ajor changes" to the labeling "requir[e] supplement submission ***and***

approval [from the FDA] ***prior to*** distribution of the product made using the change." 21 C.F.R. § 314.70(b) (emphases added); *see also Ignacuinos v. Boehringer Ingelheim Pharm., Inc.*, 8 F.4th 98, 102 (2d Cir. 2021). And the FDA regulations clearly identify changes to the Highlights section as a "major change" that requires that "approval prior to distribution." 21 C.F.R. § 314.70(b)(2)(v)(C) (including in definition of "major change" "Any change to the information required by § 201.57(a) of this chapter," with some inapplicable exceptions); *id.* § 201.57(a) (Highlights regulation).

By contrast, this Court has found that through the "Changes Being Effected" (CBE) provisions, the FDA "permits a manufacturer to make certain changes to its label before receiving the agency's approval." *Wyeth*, 555 U.S. at 568; *see PLIVA*, 564 U.S. at 614–15. In such limited circumstances, a manufacturer may unilaterally revise labeling where such a revision implements "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii)(A). The FDA defines "[n]ewly acquired information" to be "data, analyses, or other information not previously submitted to the Agency" that "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3.

Further reinforcing FDA's exclusive control over the Highlights, however, the CBE regulation reiterates that manufacturers are not allowed to use the CBE process to change any language in the Highlights section. *See id.* § 314.70(c)(6)(iii)(C) ("changes to the information required in § 201.57(a) of this chapter,"

the Highlights section, "must be made under paragraph (b)(2)(v)(C) of this section," which deems any change to the Highlights section to be a "major change" requiring a Prior Approval Supplement). Finally, the FDA has reinforced this point through guidance: the FDA's guidance states that "changes to Highlights ***require a prior approval***." FDA, *Guidance for Industry*, at 23 (emphasis added). In short, the FDA's regulations are crystal clear: the FDA's prior approval is *required* before a manufacturer may make changes that implicate the Highlights section. *See id.* §§ 201.57(a), 314.70(b)(2)(v)(C).

The Eleventh Circuit's decision badly misreads this structure. The court focused on 21 C.F.R. § 314.70(b)(2)(v)(A), which states that "[c]hanges in labeling, except those described in paragraphs (c)(6)(iii), (d)(2)(ix), or (d)(2)(x) of this section," are major changes requiring the FDA's prior approval. Because "paragraph[] (c)(6)(iii)" is the CBE regulation, the court concluded that the implementation of newly acquired information in the Highlights section was a change that could be made by CBE and thus was excluded from paragraph (b)(2)(v)(A). *Blackburn*, 2022 WL 16729466, at *3. But that interpretation leaves no purpose for paragraph (b)(2)(v)(C), which in separately identifying changes to the Highlights section as requiring prior approval distinguishes it from other portions of labeling subject to the CBE regulation. Nor does the decision below even acknowledge the language within the CBE regulation itself repeating that changes to the Highlights section must be made via prior approval. *See id.* at *3.

B. The Eleventh Circuit's Disregard of the Regulatory Framework Creates Improper Liability.

This Court has drawn a crucial distinction between labeling changes that can be made unilaterally pursuant to the CBE process and those that require prior approval of the FDA. When a manufacturer could have made a labeling change required by state law pursuant to the CBE process, state-law failure to warn claims are not preempted. *See Wyeth*, 555 U.S. at 573. But where a manufacturer lacks the right under federal law to unilaterally change its labeling in the first instance—for example, because the type of labeling change is not allowed by the CBE regulation—then the claim is preempted. *See PLIVA*, 564 U.S. at 624; *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 486–87 (2013). Changes to the Highlights section are preempted under this Court's precedent because they fit squarely into the category of labeling changes that a manufacturer cannot unilaterally implement.

Not surprisingly given the clarity of this Court's decisions, lower courts uniformly have explained that major changes to a medicine's labeling (including, specifically, changes to the Highlights section) require prior approval from the FDA and thus are not subject to change through the CBE process. *See, e.g.*, *Brashear v. Pacira Pharms., Inc.*, 2023 WL 3075403, at *4 (S.D. Ohio Apr. 25, 2023) ("[A]ny change to the Highlights section requires prior FDA approval of a supplement to the drug's labeling before distribution can occur."); *see also Patton v. Forest Lab'ys, Inc.*, 2018 WL 5269239, at *3 (C.D. Cal. Sept. 19, 2018) ("NDA holders may not make any changes to the Highlights

section of a drug's labeling without prior FDA approval."). Lower courts have likewise found that state tort law claims requiring major changes to a medication of any type, and therefore requiring FDA prior approval, are preempted. *See Gustavsen v. Alcon Lab'ys, Inc.*, 903 F.3d 1, 11 (1st Cir. 2018) (changes to a drug product container closure system); *Ignacuinos*, 8 F.4th at 102 (changes to a drug product container closure system); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (changes to the dosage level of the active ingredient). The Eleventh Circuit's decision below stands in sharp contrast.

Respondent Blackburn's contention regarding the particular warning in this suit demonstrates the error of the ruling below. The Highlights section of the labeling for Petitioner Shire's medication Lialda instructs doctors to monitor patients' kidney function "periodically." *Blackburn v. Shire US, Inc.*, 2017 WL 1833524, at *1, *6 (N.D. Ala. May 8, 2017). Mr. Blackburn asserts that Shire should have instead specified that the monitoring be performed at monthly and then quarterly intervals. *See id.* As evident from the face of the claim, Mr. Blackburn's proposed warning is nearly identical in substance to that approved by the FDA and which the FDA deemed in the Highlights section best conveyed the essential risk information succinctly and accurately. The Eleventh Circuit's ruling would, therefore, require Shire to face state tort liability for not altering that language in a way that Mr. Blackburn's lawyers, years later, now argue would have resulted in a marginal improvement in patient care. (Mr. Blackburn's physician never read the Lialda labeling, *see id.* at *8, rendering the argument

functionally irrelevant with respect to *his* care.) The FDA guards the language of the Highlights section in part for this reason: creative lawyers can always come up with different ways to criticize words in labeling. *See, e.g.*, Br. for the United States as *Amicus Curiae* Supporting Petitioner, *Wyeth v. Levine*, 2008 WL 2308908, at *25 (U.S. June 2, 2008) ("[I]t would underestimate the post hoc imagination of lawyers to think such an exhaustion of potential variants by the manufacturer or the agency is even possible."); *see also* 71 Fed. Reg. at 3,935 ("Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional [state law] requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use."). Through its adoption of the Physician Labeling Rule, the FDA flatly barred this kind of quibbling over language in the Highlights section.

If allowed to stand, the Eleventh Circuit's ruling would result in a patchwork system wherein manufacturers would have a purported legal duty to unilaterally (and impermissibly) change the Highlights section of medication labeling *without* the FDA's approval in the Eleventh Circuit, but must await the FDA's approval before amending the Highlights section in the rest of the United States. This is obviously untenable in a nationwide, highly-regulated industry. Manufacturers do not—and cannot—make medications for use only within the Eleventh Circuit. As a result, manufacturers would be subject to liability within the Eleventh Circuit for not taking

unilateral steps that federal law forbids and that other courts around the country recognize cannot be required through private lawsuits.

II. THE DECISION BELOW UNDERMINES THE FDA'S REGULATORY AUTHORITY AND HAMPERS INNOVATION AND PATIENT HEALTH.

This Court's preemption cases properly recognize the critical responsibilities of the FDA and hold that manufacturers cannot be held liable for failing to take actions prohibited by federal law. Permitting liability for failing to unilaterally amend the Highlights section would undercut the FDA's authority to promulgate binding rules on prescription medicine labeling in a manner that would both hamper manufacturer innovation and ultimately harm patient health.

A. The Eleventh Circuit's Ruling Fails To Accord Appropriate Respect to the FDA's Central Role in Medicine Labeling Decisions.

This Court has recognized that the process of ensuring a medicine's "proposed label is accurate and adequate . . . [is] costly." *PLIVA,* 564 U.S. at 612 (citations omitted). Developing the proper language for the key risk information for a medicine is a lengthy and iterative process, but that process is critical to the ultimate safe and effective use of a medicine. Through notice and comment rulemaking, the FDA has developed a comprehensive regulatory regime designed to

ensure that the FDA and manufacturers work together to reach the best, scientifically-based way to accurately describe a medicine's risks and benefits. In that process, the FDA brings to bear its substantial expertise, which in turn benefits manufacturers and ultimately the public in deriving clear, accurate, and science-based labeling for prescription medicines.

Labeling discussions begin long before the FDA approves a medicine. Prior to submitting draft Prescribing Information to the FDA in a New Drug Application, manufacturers are encouraged to ask the FDA specific questions about their proposed Prescribing Information based on the studies they conducted or plan to conduct. *See* FDA, *Frequently Asked Questions about Labeling for Prescription Medicines* (last updated Jan. 19, 2023), https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines.

After communicating with the FDA about specific labeling questions, a manufacturer submits draft prescribing information with its marketing application to the FDA. The FDA's Prescribing Information Review Team then conducts an active and ongoing review of the Prescribing Information. This review begins when a marketing application is received, but it continues throughout the review cycle. *See id.*

The FDA's Review Team is responsible for identifying and addressing labeling issues that require resolution before approving the marketing application. To account for the complexity of labeling review, the Review Team often contains "FDA reviewers with

specific subject matter expertise . . . based on the medicine's proposed uses." *Id.* (follow "How Is Prescribing Information Approved?" hyperlink). The Review Team also includes "doctors with a specialty in the disease/condition being treated . . . clinical pharmacology staff, labeling specialists, pharmacology/toxicology staff, product quality reviewers, promotional content specialists, regulatory project managers, safety experts . . . statisticians, a cross-discipline team leader, and division and office management." *Id.*

The Review Team and the manufacturer then engage in extensive discussions about the draft prescribing information. The FDA itself has noted that "Final Prescribing Information development is an iterative process, typically involving several rounds of editing and discussions between FDA and the drug company to arrive at a final agreed-upon Prescribing Information." *Id.*; *see also* Off. of the Inspector Gen., *FDA's Review Process for New Drug Applications: A Management Review* iv (2003) ("[L]engthy discussions . . . occur between FDA and the sponsor regarding the information to include on the label."). The dynamics of the FDA-manufacturer relationship thus involve frequent communications throughout a tightly-regulated process. And this process continues after approval: the FDA monitors the adequacy of the labeling, and, if it becomes aware of information that it believes should be included in the labeling, it engages with the manufacturer to make appropriate amendments. *See* 21 U.S.C. § 355(o)(4). Ultimately, though, the FDA has the power to *require* the inclusion of new information, even over the manufacturer's objections. *Id.*

In this resource-intensive process, manufacturers benefit from the FDA's subject matter expertise. The FDA's labeling prowess is so singular, in fact, that the agency has determined through notice and comment rulemaking that it, and it alone, may make changes to the Highlights section of a drug's labeling. *See* 71 Fed. Reg. at 3,922; *see also Albrecht,* 139 S. Ct. at 1679 (endorsing the preemptive power of "notice-and-comment rulemaking setting forth labeling standards"). That decision is justified. Among other reasons, the Highlights section serves a key patient safety function by "improv[ing] the accessibility, readability, and usefulness of information in prescription drug labeling and reduc[ing] the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information." 71 Fed. Reg. at 3,930–31.

The Eleventh Circuit's decision in this case runs roughshod over the FDA's expertise—and the notice and comment rulemaking process more broadly—by punishing a company for not unilaterally making a labeling change that the FDA has determined lies in such an important area that it has reserved changes in that area for itself. Not only does the FDA reserve to itself the responsibility for approving changes to the Highlights section, but it possesses the full range of tools necessary to effectively exercise that responsibility. In this sense, there is no credible suggestion that state tort law is a necessary complement to the federal regulation of Highlights section revisions.

B. The Eleventh Circuit's Ruling Hampers Manufacturer Innovation and Harms Patient Health

Bringing a new medicine to market is a lengthy and expensive process. *See Bartlett*, 570 U.S. at 476 ("The process of submitting an NDA is both onerous and lengthy."); *PLIVA,* 564 U.S. at 612 ("[A] manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. . . . Meeting those requirements involves costly and lengthy clinical testing." (citations omitted)).

On average, developing a new medicine and obtaining the FDA's approval to market that medicine takes ten to fifteen years and costs $2.6 billion. PhRMA, *Biopharmaceuticals in Perspective* 27 (2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf. These efforts also involve astounding risk, as most compounds invented never attain the FDA's approval. Less than 12% of the candidate medicines that enter Phase I clinical trials are ultimately approved by the FDA. *See id.* at 27.

Given the enormous cost and risk associated with bringing a medicine to market, the prospect of litigation bears heavily on a company's decision to invest in innovation. *See* W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1419 (1994) ("T]he net effect of the surge in liability costs ha[s] been to

discourage innovation in the pharmaceutical industry."). Permitting an "overly aggressive tort environment" can lead to "increased costs and risks of doing business in an area," "disincentives for innovations which promote consumer welfare," and "deterrence of economic development and job creation incentives. The Perryman Grp., *Economic Benefits of Tort Reform* 4 (Nov. 2019), https://www.perrymangroup.com/media/uploads/report/perryman-economic-benefits-of-tort-reform-in-louisiana-11-04-19.pdf.

The current scope of litigation against life sciences companies is immense and rapidly expanding. In 2022, 16,287 product liability lawsuits were filed against pharmaceutical companies in federal courts alone. *See* Admin. Off. of the U.S. Courts, Table C-2A: *U.S. District Courts—Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2018 Through 2022*, https://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2022.pdf (last visited July 6, 2023). This number reflects a nearly three-fold increase from the 6,791 product liability lawsuits filed against pharmaceutical companies in federal courts a decade ago. *See* Admin. Off. of the U.S. Courts, Table C-2A: *U.S. District Courts—Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2012 Through 2016,* https://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf (last visited July 6, 2023).

Today, out of sixty-three pending product liability multidistrict litigation proceedings, sixteen involve pharmaceuticals. *See* U.S. Jud. Panel on Multidist.

Litig., *MDL Statistics Report—Docket Type Summary* (June 15, 2023), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Docket_Type-June-15-2023.pdf. By comparison, between 1960 and 1999, there were only five MDL product liability actions involving FDA-approved medicines. *See* Deborah R. Hensler, *Has the Fat Lady Sung? The Future of Mass Toxic Torts*, 26 Rev. Litig. 883, 897-902 tbl. 1 (2007). This alarming growth of litigation does not imply that medicines are becoming less safe or that the FDA has shirked its regulatory duties. To the contrary, more than four out of every five federal product liability cases resolved on the merits from 2015 to 2019 were resolved in the defendant's favor. *See* Ronald C. Porter, *Product Liability Litigation Report* 21, Lex Machina (2020), https://images.law.com/contrib/content/uploads/documents/292/68165/LexMachina_2020_Product_Liability_Litigation_Report.pdf.

Holding manufacturers liable for failing to do what FDA regulations prohibit—such as unilaterally amending the Highlights section—would shift resources away from innovation and toward litigation defense. Commentators have also raised the concern that it would result in the adoption of "defensive labeling to the detriment of optimal patient care." Steven Garber, RAND Inst. for Civ. Just., *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals* 51 (2013), https://www.rand.org/pubs/monographs/MG1259.html; *see also In re Zofran (Ondansetron) Prod. Liab. Litig.*, 541 F. Supp.3d 164, 168 (D. Mass. 2021) ("[T]he FDA's approach to warning labels is very different from the manner in which

state-law tort principles drive the labeling of consumer products as a general matter. The FDA is concerned not only with avoiding insufficient warnings (that is, failing to warn against risks), but also avoiding over-warning (that is, warning against risks that are unduly speculative, hypothetical, or not adequately supported by science)."). When a medicine's labeling does not reflect a fair assessment of the available scientific evidence, patients who might otherwise benefit from the medicine might be dissuaded from its use, resulting in overall lower patient well-being.

When it comes to clearly and concisely conveying the most critical risk information in the Highlights section of labeling for a prescription medicine, the FDA has determined that it alone should be the final arbiter. Under the Eleventh Circuit's ruling, juries—rather than the FDA—would be tasked with whether the language in the Highlights section is appropriate. But as this Court has recognized, lay jurors are uniquely ill-suited to make the sort of nuanced, complex risk-benefit calculations that animate the FDA's views on appropriate labeling language. *See Riegel v. Medtronic, Inc.,* 552 U.S. 312, 325 (2008) (whereas "the experts at the FDA" apply a "cost-benefit analysis," a jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."); *see also* 150 Cong. Rec. S8657 (daily ed. July 22, 2004) (statement of former FDA Chief Counsels) ("If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, . . . FDA's ability to advance the public health by allocating scarce space in product labeling to the

most important information would be seriously eroded.").

CONCLUSION

The petition for a writ of certiorari should be granted.

Date: July 7, 2023

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