No. 21-348

In the Supreme Court of the United States

JOHNSON & JOHNSON, et al.,
Petitioners,

v.

MISSISSIPPI, ex. rel. LYNN FITCH,
ATTORNEY GENERAL OF MISSISSIPPI,
Respondent.

On Petition for a Writ of Certiorari to the
Mississippi Supreme Court

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 nation's leading research-based pharmaceutical and biotechnology companies. 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 nearly $1 trillion into discovering and developing new medicines, including an estimated $83 billion in 2019 alone. *See* PhRMA, *Research and Development*, https://www.phrma.org/policy-issues/research-development (last visited Oct. 1, 2021). PhRMA's members are specifically leading the way in developing new vaccines and treatments for COVID-19, with nearly half of all such clinical trials using products invented by PhRMA's members. *See* PhRMA, *PhRMA COVID-19 Treatment Progress*, https://phrma.org/Coronavirus/Activity-Tracker (last updated Sept. 27, 2021).

This case presents a question of critical importance to PhRMA's members: whether, after the Food and Drug Administration ("FDA") considers a potential safety issue and decides that the available

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[1] In accordance with Rule 37.2(a), all counsel of record received timely notification of *amicus curiae*'s intent to file this brief and have filed blanket consents to the filing of all timely amicus briefs. 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.

science is inadequate to justify a warning, a company can nonetheless be held liable under state law for failing to provide that same warning, simply because the FDA communicated its scientific decision through final agency action denying a citizen petition rather than through notice-and-comment rulemaking. 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 omitting warnings deemed unwarranted by the FDA under the existing science would unfairly compound that liability in a manner that could deter development of new medicines and impede post-approval safety research. The Court should grant certiorari and reverse the Mississippi Supreme Court's judgment.

INTRODUCTION AND SUMMARY OF ARGUMENT

The state court's decision in this case presents a square challenge to the federal Food and Drug Administration's exercise of its regulatory authority. The court permitted the State of Mississippi to proceed to trial to recover up to $10,000 in penalties for every bottle of baby powder sold in the State over nearly five decades on a theory that J&J was required by state law to add a warning that the FDA specifically considered and rejected—"[a]fter careful review and consideration of the information submitted" and "an expanded literature search"—due to lack of sufficient "evidence to support causality."[2] The decision below thus second-guesses a scientific judgment that the FDA made in the exercise of its congressionally-delegated authority.

Federal law vests the FDA with ultimate responsibility for determining the nationwide warnings that must accompany medicines, cosmetics, and other products that the agency regulates. Exercising this responsibility requires the FDA to bring its unique expertise and judgment to these complex scientific questions. The FDA's authority and expertise to address warnings will be undercut if state-law litigation can effectively second-guess the FDA's judgment. Furthermore, allowing liability in this situation could

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[2] Letter from Steven M. Musser, Deputy Dir. for Sci. Operations, Ctr. for Food Safety and Applied Nutrition, FDA, to Samuel S. Epstein 1, 5, 6 (Apr. 1, 2014), *available at* https://www.regulations.gov/document/FDA-1994-P-0067-0007.

impair investment in the development of new innovations by subjecting manufacturers to potentially massive liability for not unilaterally adding warnings that the FDA has determined lack a reliable scientific footing. This unfair and irrational basis for liability would ultimately harm the very individuals that such expansive liability theories profess to benefit.

The state court's rationale for not finding evidence sufficient to support preemption—that the FDA did not memorialize its rejection in a notice-and-comment rule—cannot withstand scrutiny. There is no dispute that in response to multiple citizen petitions to add precisely the warning pressed by the State of Mississippi below, the FDA independently exercised its authority to review the science surrounding the purported link between talcum powder and ovarian cancer to ensure that the product's warnings were appropriate in light of current scientific data. Nor is there any dispute that after its extensive, careful, detailed review, the FDA rejected the warning the State seeks. That rejection embodies the FDA's regulatory judgment about whether the risk of ovarian cancer is sufficiently established to warrant a warning and is entitled to deference.

Indeed, in the context of FDA-approved medicines, this Court has held that *any* "agency action carrying the force of law" can preempt state-law tort claims. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). Courts are therefore required to give effect to the FDA's expert authority to determine how best to communicate safety information pertaining to the products it regulates, regardless of whether the FDA takes action carrying the force of law through

notice-and-comment rulemaking, rejecting a manufacturer-proposed warning, denying a citizen petition, or otherwise, such as by carrying out its statutory duties to consider whether a labeling change is merited when presented with new safety information.

The rigorous citizen petition process that the FDA utilized here ensures careful scrutiny of the scientific record and produces final, judicially-reviewable agency action that fits squarely within *Albrecht*'s preemption rubric. If left to stand, the ruling below will require the FDA to jettison the various means by which it ordinarily expresses its scientific judgments in favor of the notice-and-comment rulemaking process that it rarely utilizes for the vast majority of products it regulates. The typically multi-year notice-and-comment rulemaking process would overburden the FDA, subject regulated parties to uncertainty in the interim, and deprive the FDA and manufacturers of needed flexibility to quickly change course to address ever-evolving science, without any countervailing benefit to public safety.

ARGUMENT

I. PROPER APPLICATION OF SETTLED PREEMPTION PRINCIPLES IS NECESSARY TO EFFECTUATE THE FDA'S EXPERT SCIENTIFIC JUDGMENTS.

This case presents a core question that manufacturers of prescription medicines frequently confront in lawsuits: when the FDA duly considers a safety issue and finds no substantiating scientific support for a

warning, can the manufacturer still be held liable under state tort law for not adopting that warning? This Court's preemption jurisprudence involving prescription medicines has answered that question largely in the negative. PhRMA sets forth that framework below, because the state court's decision in this case cannot be reconciled with this Court's approach in cases concerning prescription medicines.

The Supremacy Clause bars a state-law claim where it is "impossible for a private party to comply with both state and federal requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). As the Court has held in addressing claims against manufacturers of FDA-regulated medications, "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law [allegedly] requires." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). In other words, the manufacturer must have had the right under federal law to make the change at issue "unilaterally," without prior FDA approval. *Id.*; *see also Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 490 (2013); *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Even when a manufacturer can unilaterally amend a medicine's labeling—as it

can when the "changes being effected" ("CBE") regulation applies[3]—state law is still preempted if there is "clear evidence" that the FDA would have rejected the unilateral labeling change. *Levine*, 555 U.S. at 571.

The Court's preemption trilogy of *Levine, Mensing,* and *Bartlett* properly recognizes the critical responsibilities of the FDA and sensibly holds that manufacturers cannot be held liable under state law for failing to take actions prohibited by federal law. Permitting liability for not unilaterally implementing warnings expressly rejected by the FDA would disrupt FDA regulation and impair manufacturer innovation and public health.

In regulating prescription medicine and other labeling, the FDA must strike a delicate balance. Labeling conveys a wealth of information necessary for the safe and effective use of a product. But this information must be communicated in a manner that is useful to healthcare professionals (in the case of medicines or medical devices) and consumers (in the case of other regulated products).

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[3] Before a pharmaceutical manufacturer can amend its labeling, it generally must obtain the FDA's approval through the submission of a "prior approval supplement" to its New Drug Application. *See* 21 C.F.R. § 314.70(b)(2)(v). Manufacturers can, in some circumstances, add or strengthen a warning to reflect "newly acquired information." *See id.* § 314.70(c)(6)(iii). Even then, however, a manufacturer cannot distribute the new labeling until it submits a "changes being effected" supplement to the FDA. *See id.*

Striking this proper balance is critically important. End-users may be harmed when labeling communicates safety information in a manner that leads risks to be downplayed or disregarded. Physicians and consumers may disregard lengthy labeling that is replete with speculative or less relevant warnings, and thus overlook more germane and scientifically sound safety information.[4] Moreover, unfounded or inapplicable warnings can discourage the beneficial use of medicines and other products.[5] Through its regulatory oversight, the FDA brings to bear its expert judgment about whether a risk should appear in a product's labeling and, if so, how best to convey that information without diluting the labeling by including speculative or scientifically-unfounded warnings.

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[4] *See, e.g.*, *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) ("The resulting information overload [from describing every remote risk] would make label warnings worthless to consumers."); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 816 n.40 (5th Cir. 1992) (noting that if manufacturers were required to clutter their warnings with "every possible risk," then "physicians [would] begin to ignore or discount the warnings provided"); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605–06 (Aug. 19, 2008) (unjustified statements in FDA labeling may cause "more important warnings" to be "overshadow[ed]").

[5] *See, e.g.*, *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) ("[O]verwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted . . . ."); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 14 (Cal. 2004) ("[A] truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product . . . .").

Preemption prevents interested advocates and lay factfinders from second-guessing the FDA's expert judgment. Indeed, it has never been more important to foster respect for the careful application of scientific principles to make evidence-based decisions, making the need to adhere to the FDA's impartial conclusions paramount. Because state tort lawsuits center on allegations that a warning was deficient, and do so in the context of an injured individual plaintiff, they can encourage the harmful overwarning that the FDA's extensive oversight is meant to prevent. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("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."); *Cotton v. Buckeye Gas Prods. Co.*, 840 F.2d 935, 937–38 (D.C. Cir. 1988) ("Failure-to-warn cases have the curious property that, when the episode is examined in hindsight, it appears as though addition of warnings keyed to a particular accident would be virtually cost free.").

Laypersons, who are generally not well-versed in the complex duties and responsibilities of the FDA, cannot provide the same assurances for patient safety as the agency to which Congress assigned that task. Having many lay factfinders reach their own disparate views on how a company should warn about risks threatens to seriously disrupt the FDA's efforts to regulate how and when risk information is conveyed by manufacturers. Decisions that contravene the FDA's expert judgments come at the expense of the broader population's health and safety. *See* 153 Cong. Rec. S11831–01 (daily ed. Sept. 20, 2007) (statement of

Sen. Coburn) ("[T]here is an overriding Federal interest in ensuring that the FDA, as the public health body charged with making these complex and difficult scientific judgments, be the ultimate arbiter of how safety information is conveyed.").

At the same time, allowing liability because a company does not take unilateral action that the FDA deems scientifically unsupported may harm innovation and thus harm public health. As the Tenth Circuit observed in the context of medical devices, "[r]equiring manufacturers to comply with fifty states' warning requirements . . . on top of existing federal . . . warning requirements, might introduce sufficient uncertainty and cost that manufacturers would delay or abandon at least some number of life-saving innovations." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) (Gorsuch, J.).[6]

[6] More broadly, allowing 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 initiatives," among other effects. Perryman Group, 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.

II. THE FDA EXPRESSES ITS SCIENTIFIC EXPERTISE THROUGH NUMEROUS ACTIONS CARRYING THE FORCE OF LAW OTHER THAN NOTICE-AND-COMMENT RULEMAKING.

The Mississippi Supreme Court's holding that preemption attaches only when the FDA "follow[s] the notice and comment rule making process," Pet. App. 15a, conflicts with numerous lower court decisions and fails to account for the many ways in which the FDA articulates its scientific judgment. Indeed, in the pharmaceutical context, this Court has recognized that preemption can attach to any "agency action carrying the force of law." *Albrecht*, 139 S. Ct. at 1679. *Albrecht* makes clear that notice-and-comment rulemaking is not the only way the FDA acts with the force of law. *Id.* (holding that preemption exists whenever the FDA "communicate[s] its disapproval of a warning" (1) "by means of notice-and-comment rulemaking setting forth labeling standards," (2) "by formally rejecting a warning label that would have been adequate under state law," *or* (3) "with other agency action carrying the force of law"); *see also United States v. Mead Corp.*, 533 U.S. 218 (2001). Following *Albrecht*, lower courts have correctly recognized that at least four different types of agency action other than notice and comment rulemaking can trigger preemption:

1. Rejection of a Manufacturer's Proposed Warning: *Albrecht* itself makes plain that preemption can be triggered by the FDA "formally rejecting a warning label that would have been adequate under state law." 139 S. Ct. at 1679 (citing 21 C.F.R. §§ 314.110(a),

314.125(b)(6)); *see also Dolin v. GlaxoSmithKline LLC*, 951 F.3d 882, 886, 891 (7th Cir. 2020) (clear evidence established by FDA's "unambiguous[] reject[ion]" of manufacturer's proposed warning); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 1:15-MD-2657, 2021 WL 2209871, at *31 (D. Mass. June 1, 2021) (clear evidence established when FDA "rejected language proposed by [sponsor]"); *Lyons v. Boehringer Ingelheim Pharms., Inc.*, 491 F. Supp. 3d 1350, 1367 (N.D. Ga. 2020) ("The FDA's repeated refusal to allow Defendant to warn . . . constitutes clear evidence that the FDA would have rejected the warning the Plaintiff seeks."). Such rejections are communicated to the sponsor via "complete response letters" issued under the FDA's regulatory framework. 21 C.F.R. § 314.110(a).

2. Approval of an Inverse Warning: Lower courts recognize that the FDA's approval of warnings that are opposite the warnings that state law allegedly requires supports preemption. *See Drescher v. Bracco Diagnostics Inc.*, No. 19-CV-00096, 2020 WL 699878, at *5 (D. Ariz. Jan. 31, 2020) (approval of warning that "explicitly refutes a causal association" confirms that FDA would have disallowed plaintiff's proposed warning of causality), *report and recommendation adopted*, 2020 WL 1466296 (D. Ariz. Mar. 26, 2020); *Thomas v. Bracco Diagnostics Inc.*, No. 3:19-CV-00493, 2020 WL 1016273, at *10 (W.D. La. Feb. 27, 2020) (FDA's approval of warning that "specifically stat[ed] facts contrary to the warning sought by the Plaintiff[] is clear evidence that the FDA would not have approved a label change which warned of such adverse effects"), *report and recommendation adopted*, 2020 WL 1243389 (W.D. La. Mar. 13, 2020); *In re Risperdal &*

Invega Prod. Liab. Cases, 263 Cal. Rptr. 3d 412, 425 (Ct. App. 2020) (FDA would clearly have rejected warning disclosing the results of two studies, where FDA "expressly asked for the rate of [condition] to be calculated using pooled results from all studies (not just the select few identified by plaintiffs)"). Warning approvals are communicated via approval letters. 21 C.F.R. § 314.105(a).

3. Denial of a Citizen Petition: Because the FDA applies the same labeling standard to citizen petitions as it does to labeling changes sought by manufacturer supplements, the FDA's denial of a citizen petition—a "final agency action" made publicly after opportunity for comment and subject to judicial review, 21 C.F.R. §§ 10.30(d), 10.45(d)—provides clear evidence that the FDA would have rejected a CBE supplement on the same subject. *See Cerveny v. Aventis, Inc.*, 783 F. App'x 804, 808 n.9 (10th Cir. 2019) (preemption applies by virtue of "FDA's unequivocally having rejected [a] citizen petition advocating for the warning that [plaintiffs] now assert"); *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 508 F. Supp. 3d 71, 86 (E.D. La. 2020) (FDA rejection of citizen's request to add a black box warning triggered preemption); *In re Incretin-Based Therapies Prods. Liab. Litig.*, No. 13-MD-2452, 2021 WL 880316, at *17 (S.D. Cal. Mar. 9, 2021) (by rejecting citizen petition, "FDA effectively informed [manufacturer] that it would not approve the label change"); *Zofran*, 2021 WL 2209871, at *31 (preemption based in part on rejection of citizen petition); *State v. Purdue Pharma L.P.*, No. 08-2018-CV-01300, 2019 WL 3776653, at *3 (N.D. Dist. July 22, 2019) (same). A citizen petition denial is communicated via a letter to the petitioner published on

Regulations.gov after an opportunity for public comment on the petition. *See, e.g.*, Letter from Steven M. Musser, Deputy Dir. for Sci. Operations, Ctr. for Food Safety and Applied Nutrition, FDA, to Samuel S. Epstein 1, 5, 6 (Apr. 1, 2014), *available at* https://www.regulations.gov/document/FDA-1994-P-0067-0007.

4. FDA's Decision Not to Require a Labeling Change Upon Receipt of New Safety Information: The Food and Drug Administration Amendments Act of 2007 (FDAAA), 21 U.S.C. § 355(o)(4), *requires* the FDA to include updated safety information in a medicine's labeling when the agency becomes aware of new information about a safety risk, and grants the FDA express authority to require such labeling changes. Under section 355(o)(4), when the FDA becomes aware of a new safety issue that it determines should be reflected in labeling, the FDA *must* engage with a medicine's sponsor to add appropriate labeling. In light of that affirmative statutory obligation, where the FDA receives new information but ultimately concludes that it does not warrant new labeling, that regulatory decision necessarily provides the requisite clear evidence that the FDA would have rejected a labeling proposal containing such information. *See Albrecht*, 139 S. Ct. at 1679 ("Federal law permits the FDA to communicate its disapproval of a warning . . . with other agency action carrying the force of law, *cf., e.g.*, 21 U.S.C. § 355(o)(4)(A)."); *id.* at 1684–85 (Alito, J., concurring in the judgment) (section 355(o)(4)(A) is "highly relevant to the pre-emption analysis," because "if the FDA declines to require a label change despite having received and considered

information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified"); *see also Incretin*, 2021 WL 880316, at *16–17 (preemption applicable in part through FDA's "inaction with respect to requiring a . . . warning despite its extensive and ongoing evaluation of the issue" (citing § 355(o)(4)(A))); *Ridings v. Maurice*, 444 F. Supp. 3d 973, 998 (W.D. Mo. 2020) (preemption warranted "in light of the known issues and the ongoing give-and-take between [the manufacturer] and the FDA," with no warning being mandated by FDA); *Purdue Pharma*, 2019 WL 3776653, at *3 (FDA's "continuing decision not to change [medicine's] labeling . . . in the face of the State's evidence and the FDA's duty to change the labeling and warnings if appropriate" required preemption).

Notwithstanding the many actions that the FDA can take to ensure labeling is scientifically grounded, the Mississippi Supreme Court adopted an unduly narrow test for preemption, requiring the FDA to act through a process that it rarely utilizes for the vast majority of products (including prescription medications) it regulates: notice-and-comment rulemaking. There is no sound basis to disregard the means through which the FDA actually renders its scientific decisions in favor of an alternate procedure.

Citizen petitions like the one at issue here are a case in point. Such petitions, which are publicly docketed, must contain a "full statement . . . of the factual and legal grounds on which the petitioner relies." 21 C.F.R. § 10.30(b)(3). Once filed, any interested person may submit comments supporting or opposing the petition. *Id.* § 10.30(d). In reviewing the petition, the

FDA may, among other things, conduct hearings, convene advisory committees, and solicit information and views from the public. *Id.* §§ 10.30(h), 10.65(h). Once the FDA rules on the petition, any interested person may seek reconsideration or judicial review. *Id.* §§ 10.30(j), 10.45(d). As a senior FDA official explained to Congress in 2006, the FDA performs a "detailed analysis" of all citizen petitions, "often involving multiple disciplines." *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. 14 (2006) (statement of Gary Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, FDA). After performing that "detailed analysis," the FDA can, and frequently does, mandate labeling changes. In fact, citizen petitions have prompted at least a dozen labeling revisions since 2004.[7]

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[7] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Rsch., FDA, to James Flory et al. (Apr. 8, 2016), *available at* https://www.regulations.gov/document/FDA-2013-P-0298-0004 (labeling change for diabetes medicine); Letter from Janet Woodcock to Gary Colby et al. (Mar. 22, 2016), *available at* https://www.regulations.gov/document/FDA-2005-P-0055-0005 (labeling change for tramadol analgesics); Letter from Janet Woodcock to Andrew Kolodny (Sept. 10, 2013), *available at* https://www.regulations.gov/document/FDA-2012-P-0818-0793 (labeling change for all extended-release/long-acting opioid analgesics); Letter from Janet Woodcock to Rita F. Redberg (Apr. 10, 2013), *available at* https://www.regulations.gov/document/FDA-2005-P-0221-0009 (labeling change for two blood thinners); Letter from Janet Woodcock to Dennis J. Cotter (June 24, 2011), *available at* https://www.regulations.gov/document/FDA-2009-P-0426-0010 (labeling change for two medicines used to treat

Even where the FDA denies a citizen petition, it does not do so casually. A recent study of all citizen petitions filed by individuals and non-profit organizations between 2001 and 2013 found that denials were most commonly due to the FDA's disagreement with the "petitioner's conclusion and/or need for the requested action." Brian K. Chen et al., *Petitioning the FDA to Improve Pharmaceutical, Device, and Public Health Safety by Ordinary Citizens: A Descriptive Analysis*, PLOS ONE, May 2016, at 1, 9, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4865109/pdf/pone.0155259.pdf. The authors found that the FDA consistently "provided

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anemia); Letter from Janet Woodcock to Debra S. Dunne et al. (Dec. 20, 2010), *available at* https://www.regulations.gov/document/FDA-2010-P-0179-0007 (labeling change for three radiographic contrast agents); Letter from Janet Woodcock to Elizabeth Barbehenn et al. (Apr. 30, 2009), *available at* https://www.regulations.gov/document/FDA-2008-P-0061-0010 (labeling change for botulinum toxin); Letter from Janet Woodcock to Natasha Leskovsek (Dec. 11, 2008), *available at* https://www.regulations.gov/document/FDA-2007-P-0345-0005 (labeling change for certain over-the-counter and prescription laxatives); Letter from Janet Woodcock to Arnold L. Widen et al. (July 24, 2008), *available at* https://www.regulations.gov/document/FDA-2006-P-0390-0005 (labeling change for flouroquinolone antibiotics); Letter from Steven K. Galson, Dir., Ctr. for Drug Evaluation and Rsch., FDA, to Roger E. Salisbury (June 22, 2006), *available at* https://www.regulations.gov/document/FDA-2005-P-0130-0010 (labeling change for all non-steroidal anti-inflammatory drugs); Letter from Steven K. Galson to Richard Blumenthal (May 25, 2006), *available at* https://www.regulations.gov/document/FDA-2005-P-0004-0047 (labeling change for thalidomide); Letter from Steven K. Galson to Beth Rosenshein (Sept. 21, 2004), *available at* https://www.regulations.gov/document/FDA-2003-P-0069-0003 (labeling change for estrogen medication).

detailed, point-by-point rebuttals to the petitioner's scientific basis for the requested actions." *Id.* at 6 (emphasis added). Lawsuits like this one thus present a direct attack on the FDA's expert judgment and on its exercise of its congressionally-delegated authority to approve the labeling for the products it regulates.

III. THE DECISION BELOW WILL OVERWHELM THE FDA'S CAPABILITIES WITH UNNECESSARY REGULATORY RED TAPE.

The Mississippi Supreme Court's preemption rule creates bad policy. Mindful of not creating "additional burdens" on the FDA, this Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 (2001), that state law "fraud-on-the-FDA claims" are preempted because such claims incentivize manufacturers "to submit a deluge of information that the Agency neither wants nor needs" out of "fear that their disclosures . . . will later be judged insufficient in state court."

Hinging preemption on the FDA's completion of notice-and-comment rulemaking every time it rejects a proposed warning would create the same burdens that *Buckman* sought to avoid. One recent empirical study found that on average, it takes the FDA forty-two months to promulgate a final rule, without even accounting for the time spent prior to publishing notice of the proposed rule. Jason Webb Yackee & Susan Webb Yackee, *Delay in Notice and Comment Rulemaking: Evidence of Systemic Regulatory Breakdown*, *in* Regulatory Breakdown: The Crisis of Confidence in U.S. Regulation 163, 171 (Cary Coglianese ed., 2012). The FDA's limited time and resources should not be

expended on notice-and-comment procedures simply to ensure that the agency's scientific judgments are enforced in the courts. *See Levine*, 555 U.S. at 578 ("FDA has limited resources to monitor the 11,000 drugs on the market . . . ."). Nor should manufacturers be subjected to years of uncertainty regarding the FDA's position on proposed labeling while the agency finalizes a notice-and-comment rule.

Moreover, once the FDA promulgates a final rule, the notice-and-comment process makes it unduly difficult to change the rule in the event that evolving science shows a new or different risk. The hallmark of the FDA's safety regulation is constant surveillance and prompt response to evolving safety issues. Indeed, the FDAAA mandates rapid evaluation of new safety information and immediate labeling adjustments. The unavoidably cumbersome notice-and-comment process envisioned by the Mississippi Supreme Court would substantially undermine the FDA's ability to ensure that labeling at all times summarizes a product's known risks, and it would prevent manufacturers from communicating up-to-date information regarding a product's risks and benefits.

The Court should agree to hear this important case to ensure that the FDA's expertise to adjudicate complicated scientific and policy questions is not improperly eroded.

CONCLUSION

The petition for a writ of certiorari should be granted.

Date: October 1, 2021 Respectfully submitted,

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