No. 15-449

IN THE

Supreme Court of the United States

JOHNSON & JOHNSON AND MCNEIL-PPC, INC.,
Petitioners,

v.

LISA RECKIS AND RICHARD RECKIS,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Judicial Court of Massachusetts

REPLY BRIEF OF PETITIONERS

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REPLY BRIEF OF PETITIONERS

The importance of the question presented is underscored by the *seven* trade associations and policy groups that join Petitioners in urging this Court to grant review. Yet instead of engaging the arguments of Petitioners and *amici*, Respondents misrepresent the underlying SJC and FDA decisions in an effort to downplay the significance of the legal question here. That obfuscation provides no basis for denying review.

A. FDA Rejected The Warning That The SJC Held State Law Requires.

Respondents distort the decisions of the SJC and FDA in an attempt to conceal the conflict between state and federal law. They first deny that the SJC's decision addressed any particular warning proposed by Respondents. BIO 16-17. But the SJC could not have been clearer that its holding focused on particular warnings Respondents proposed. The SJC began its analysis by explaining that "the first step is to identify what warnings the plaintiffs claim the defendants should have provided." App. 20a. It identified two such warnings: (1) "that the Children's Motrin label should have mentioned SJS and TEN by name," and (2) "that the Children's Motrin's label should have warned of redness, rash, or blisters that might lead or be a 'pathway' to a life-threatening disease." App. 20a-21a.

The SJC then held that the "life-threatening disease" warning was not preempted and therefore state law could require it. App. 26a ("[W]e cannot glean … clear evidence that the FDA would not have approved a warning on OTC ibuprofen labels stating

that redness, rash, and blisters may lead to a life-threatening disease.").

In defense of that holding, Respondents next misrepresent FDA's Citizen Petition response to claim it somehow was consistent with the SJC's holding. BIO 17. But even the SJC conceded that the Citizen Petition proposed a warning about "life-threatening disease" and that FDA decided *not* to require the proposed language. App. 23a ("The proposed language, 'potentially life-threatening diseases,' was part of the same sentence [in which the Petition proposed reference to specific disease names, and] FDA deci[ded] not to request that manufacturers add a warning about life-threatening diseases."). Contrary to Respondents' suggestion, it is beyond dispute that the specific warning language the SJC said Massachusetts law required was proposed to FDA, rejected by FDA, and then proposed again at trial by Respondents.

The SJC nonetheless held that FDA's rejection did not preempt state law from requiring the same warning for two reasons. First, it speculated that FDA's rejection "could well have been merely a by-product of its rejection of [other] requested warnings," such that it was "anybody's guess" whether FDA would have rejected "a mention of life-threatening diseases, by itself." App. 23a. Second, the court speculated that even if FDA "would have rejected a citizen petition proposal to add only this warning," it still might have accepted the same proposal "had it been sought by the defendants themselves." App. 24a.

Yet Respondents tellingly make no effort to de-

fend these two holdings—because both are plainly inconsistent with this Court's preemption jurisprudence. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011) (holding that "conjectures" about what "the Federal Government *might* do" are insufficient "to prevent federal and state law from conflicting for Supremacy Clause purposes"). Instead, Respondents attempt to obscure the SJC's decision by claiming it did not really hold that Petitioners were obligated to propose the language in question, BIO 19, and that FDA actually sanctioned use of the term "'life-threatening' … in [an] educational tool and medication guide" for ibuprofen products. *Id*. at 17; *see also id*. at 14.

Nonsense. The SJC disregarded FDA's rejection of the proposed warnings precisely because "the defendants were not involved in the submission of the citizen petition." App. 24a. Citing cases that rejected preemption claims because the defendants had not proposed warnings themselves, the SJC fully adopted that position: "[E]ven assuming … we could predict the FDA would have rejected a citizen petition proposal to add only this warning, that would not answer whether the FDA would have rejected the warning had it been sought by the defendants themselves." *Id*.

While Respondents are correct that FDA separately approved a Medication Guide warning of "life-threatening skin reactions" and an Information for Patents section warning of "hospitalizations and even death," BIO 14; *id*. at 17, they fail to inform the Court that FDA did so *only for prescription ibuprofen products*, not OTC products like Children's Motrin®.

Pet. 16-17 (citing App. 160a, 162a). That fatally undermines both Respondents' position and the SJC's. The fact that FDA adopted the "life-threatening" language *for prescription products alone* sharply underscores that its rejection of such language for OTC products was intentional. Just as Congress "acts intentionally and purposely" when it "includes particular language in one section of a statute but omits it in another," *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993), FDA acts intentionally and purposely when it includes particular language in one label (for patients under a physician's care) but rejects its inclusion another label (for OTC consumers)—especially given that this same language was proposed for both products. Yet the SJC refused to respect FDA's decisions, instead engaging in impermissible speculation to avoid preemption.

B. The SJC's Decision Conflicts With The Seventh Circuit.

Not content only to misrepresent the SJC and FDA decisions, Respondents next misrepresent the Seventh Circuit's decision in *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010), in order to deny the conflict between these cases. While Respondents claim *Robinson* addressed only whether FDA would have permitted specific mention of SJS/TEN, the Seventh Circuit made clear that the plaintiff proposed, and the court rejected, further warnings: "[P]laintiff argues that the label on the bottle of Children's Motrin … should have mentioned SJS/TEN as one of the possible allergic reactions *and (since virtually no consumer who was not a physician would have heard of the disease) recited its*

horrific consequences." *Id.* at 869 (emphasis added). The claim in *Robinson* that Children's Motrin® should have "recited [the] horrific consequences" of SJS/TEN because the disease names are unfamiliar to consumers perfectly parallels Respondents' claim that Children's Motrin® should have warned of "life-threatening disease" because the disease names are unfamiliar. *See* App. 27a-28a.

In particular, the *Robinson* plaintiff "testified that if the Children's Motrin bottle had indicated that an extraordinarily dangerous reaction could occur, Ms. Robinson would not have had it in her house." Reply Br. of Plaintiffs-Appellants at 13, *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010) (No. 09-4011), 2010 WL 2624766, at *13. Here, Mr. Reckis likewise testified that if the Children's Motrin® bottle warned that redness and rash "could be the pathway to a life-threatening disease," he would not have administered the medication. App. 16a n.23. There is no daylight between these claims: The *Robinson* plaintiffs sought a warning about "an extraordinarily dangerous reaction" and the *Reckis* plaintiffs sought a warning about "a life-threatening disease"—for the same product, because of the same reaction, and based on the same evidence.

Yet these appellate courts reached opposite results. The Seventh Circuit held the plaintiff's proposed warning preempted because there was "'clear evidence' that the FDA would not approve it" based on the agency's Citizen Petition response. *Robinson*, 615 F.3d at 873. The SJC, by contrast, looked at the same Citizen Petition response and declared it "any-

body's guess" whether FDA would approve Respondents' proposed warning. App. 23a. It therefore upheld a massive verdict premised on a state-law duty to add that warning. Respondents' misrepresentations cannot obscure the direct conflict between these decisions over the clear-evidence standard this Court identified in *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), and discussed in *Mensing*, 131 S. Ct. at 2581 & n.8.

Even so, Respondents assert that any such conflict "is entirely fact-specific," BIO 21, and unworthy of review. Not so. The disagreement between the SJC and the Seventh Circuit concerns the legal standard to be applied rather than the mere interpretation of evidence. In applying *Wyeth*'s clear-evidence standard, the Seventh Circuit accepted FDA's rejection of "life-threatening" and related language as conclusive, while the SJC thought *Wyeth* permitted (indeed, obligated) courts to speculate about how FDA might act under different circumstances in order to accommodate a purported state-law duty. These are exactly the conflicting approaches that this Court has addressed in its preemption decisions. In *Mensing*, this Court observed that a court "can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* at 2579. But preemption cannot hinge on such speculation. This Court rejected an approach that would have required manufacturers "to start the process that might ultimately have allowed them to use a safer label" in order to demonstrate that

FDA affirmatively disallowed "compliance with state law." *Id.* at 2578-79.

Despite *Mensing*, the SJC's reasoning resuscitates that forbidden approach. By holding that "clear evidence" exists only where (1) the defendant itself proposes precise language and (2) the FDA rejects the precise language and only the precise language the defendant proposed, the SJC's approach guts *Wyeth*'s clear-evidence standard. Respondents admit as much, asserting that preemption can be found only where there is "an FDA prohibition of terminology proposed in a Citizen Petition that a court then finds should have been part of a warning label." BIO 28. There is a reason why that is "a result that a diligent search of the caselaw has not unearthed." *Id.* Any plaintiff's lawyer can come up with a few words that differ from the ones FDA actually rejected. The SJC's approach would turn the clear-evidence standard into a null set.

If *Wyeth*'s "clear evidence" standard is to have meaning, such evasions cannot be countenanced—as the Seventh Circuit recognized by accepting FDA's plain rejection of the Citizen Petition without conditioning federal preemption on word-for-word identity between the plaintiff's proposed wording and that rejected by FDA. This Court should clarify that the clear-evidence standard is not an empty promise but an essential measure to protect FDA's primary authority and expertise in this area.

C. Guidance From This Court Is Necessary.

Respondents further argue that various cases ap-

plying the clear-evidence standard were correctly decided and/or might be justifiable on other grounds. BIO 25-28. The Petition identified these cases to show that the SJC's attempts to evade preemption are not unique, fact-bound applications of the clear-evidence standard but legal rules that many courts follow in order to evade preemption.

Respondents never seriously dispute that other courts likewise speculate that FDA might not have rejected a warning (which it actually rejected) if the warning had been proposed in a slightly different context. *See, e.g.*, *Newman v. McNeil Consumer Healthcare*, No. 10-CV-01541, 2012 WL 39793, at *8 (N.D. Ill. Jan. 9, 2012) ("For there to be 'clear evidence' of rejection, it may be necessary in some instances for the FDA to parse the language in a petition's explicit requests and explain why particular requests are appropriate and others are not."). Nor do they credibly deny that other courts likewise speculate that FDA might not have rejected a warning (which it actually rejected) if the warning had been proposed by the manufacturer. *See, e.g.*, *Schedin v. Ortho-McNeil-Janssen Pharm.*, 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011) ("That the FDA did not require a label change … in the face of a Citizen's Petition, not supported by the manufacturer does not constitute clear evidence that the FDA would have rejected a label change proposed by Ortho-McNeil."), *aff'd in part, rev'd in part on other grounds*, 700 F.3d 1161 (8th Cir. 2012); *Baumgardner v. Wyeth Pharm.*, No. 06-2519, 2010 WL 3431671, at *1 (E.D. Pa. Aug. 31, 2010) ("None of this evidence proves that the FDA would have re-

jected relevant warnings had Wyeth, the manufacturer, proposed them.").

Respondents of course regard these decisions as "thoughtful applications of *Wyeth*." BIO 27. But Respondents do so precisely because they render *Wyeth*'s clear evidence proviso illusory despite clear conflicts between state duties and FDA's application of federal law.

Yet not all courts follow that approach. *See, e.g.*, *In re Incretin-Based Therapies Products Liab. Litig.*, No. 13-MD-2452, 2015 WL 6912689, at *12 (S.D. Cal. Nov. 9, 2015) ("[T]he Court rejects Plaintiffs' position that Defendants cannot establish preemption absent express rejection of a proposed labeling change."); *Rheinfrank v. Abbott Labs.*, No. 1:13-CV-144, 2015 WL 4743056, at *12 (S.D. Ohio Aug. 10, 2015) ("[A]n expert's opinion that the FDA would have reacted differently if the submissions to the FDA in 2005 and 2007 had been supported by different evidence is speculative."); *In re Fosamax (Alendronate Sodium) Products Liab. Litig.*, 951 F. Supp. 2d 695, 704 (D.N.J. 2013) ("Plaintiffs did not offer any evidence that [a warning] was rejected due to language … or that the FDA would have approved a properly worded label change.").

The landscape thus consists of conflicting decisions, with most courts frustrating this Court's jurisprudence by erecting artificial barriers to preemption. The *amicus* support here demonstrates that this genuine confusion among the lower courts imposes substantial costs.

D. This Case Implicates A Conflict Over The Federal Regulatory Process.

Respondents deny that the SJC's decision conflicts with the First Circuit's recognition in *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015), that federal law allows manufacturers to initiate labeling changes through the CBE procedure only to "reflect newly acquired information." *Id.* at 37. They are wrong.

Respondents first claim the "newly acquired information" language is inapplicable here because it was added by a 2008 amendment. BIO 30. But FDA made clear that this amendment simply "describe[d] FDA's *existing* labeling standards and policies." 73 Fed. Reg. 49603, 49604 (Aug. 22, 2008) (emphasis added); *id.* at 49608 ("[T]he rule simply affirms that a CBE supplement is appropriate … only to reflect newly acquired information."). Newly acquired information was *always* required. *See* 47 Fed. Reg. 46622, 46623 (Oct. 19, 1982) ("These supplements would describe changes placed into effect to correct concerns about newly discovered risks from the use of the drug.").

Second, Respondents insist that the SJC did not address the scope of the CBE regulation. But the SJC squarely held that a manufacturer can be held liable for failing to propose the *same* warning based on the *same* information even if FDA previously rejected it, on the theory that FDA might decide otherwise if the warning were "sought by the defendants themselves." App. 24a. It said the mechanism for manufacturers to do so is the CBE regulation. App. 20a n.28 ("[W]e consider the CBE regulation as

applicable to OTC drugs."). The SJC's decision thus squarely held that the CBE procedure allows manufacturers to make labeling changes that previously were considered and rejected by FDA even without newly acquired information.

Third, Respondents argue that Petitioners actually had "newly acquired information" that would have justified a labeling change. BIO 30-31. But the SJC did not take that view, and for good reason: If FDA's comprehensive review did not find a label change warranted *in 2005*, it is difficult to imagine what information Petitioners had *two years earlier in 2003* that would have justified the same label change. *Cf. Incretin*, 2015 WL 6912689, at *18 (holding that because a label change was rejected in 2014, "a label change would have been rejected at any earlier date, when presumably less scientific data existed, and less extensive research by the FDA had been conducted"). Nothing in the SJC's opinion or the record suggests that Petitioners had access to information that FDA did not consider when it rejected the Citizen Petition proposal in 2005.

The SJC's holding that the CBE procedure allows manufacturers to add previously rejected warnings without new risk information conflicts directly with the First Circuit's recognition that the procedure is available only for newly acquired information.

E. This Case Frustrates FDA's Regulatory Objectives.

Finally, Respondents observe that OTC drugs and prescription drugs are subject to the same preemption principles articulated in *Wyeth*. BIO 32-

33. Petitioners do not disagree; that is why this case has far-ranging implications for pharmaceutical regulation.[1] As the Petition explains, however, proper enforcement of the clear-evidence standard is particularly important for OTC products. If state law requires *prescription-drug* warnings beyond those FDA considers appropriate, then physicians may need to wade through extraneous information. They at least are equipped to do so. But *OTC labels* are intended for consumers, without the intervention of a trained intermediary. FDA has long made clear that the including extraneous warnings on OTC labels is highly problematic because such warnings can be "overwhelming" and dissuade beneficial use. 64 Fed. Reg. 13254, 13255 (Mar. 17, 1999).

Respondents miss this point. They again assert that FDA thought "the risk was worth warning about." BIO 35. But FDA pointedly did *not* decide to include the proposed "life-threatening" warning for OTC products. Rather, FDA determined that "the overall benefit versus risk profile for ibuprofen products remains very favorable" and therefore declined to adopt alarming warnings that could dissuade consumers from beneficial product use. App. 163a.

Given such considerations, it is even more important for courts to defer to "clear evidence" of FDA's labeling determinations in the OTC context because those determinations represent "a ceiling as well as a floor." *Geier v. Am. Honda Motor Co.*, 529

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[1] Like prescription drugs, Children's Motrin® is marketed under an NDA rather than under an OTC monograph. App. 156a. Respondents' discussion of monograph regulations is beside the point.

U.S. 861, 904 (2000). And flouting this Court's preemption jurisprudence undermines the federal regulatory regime because "ad-hoc reconsiderations on a State-by-State and lawsuit-by-lawsuit basis would undermine FDA's drug-safety determinations, which are made based on sound scientific judgments by an expert federal agency with appropriate access to pertinent safety data, and the assurance that FDA's approval provides for all participants in the market." Br. for the United States as Amicus Curiae at 28, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 314460, at *28.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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