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

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS—continued

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

TABLE OF AUTHORITIES—continued

Page(s)

TABLE OF AUTHORITIES—continued

Page(s)

Statutes and Rules:

Other Authorities:

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit corporation with 102 corporate members representing a broad cross-section of American industry. Its corporate members include manufacturers and sellers of a variety of products, including automobiles, trucks, aircraft, electronics, cigarettes, tires, chemicals, pharmaceuticals, and medical devices. A list of PLAC's corporate members is appended to this brief.

PLAC's primary purpose is to file *amicus curiae* briefs in cases that raise issues affecting the development of product liability litigation and have potential impact on PLAC's members. This is such a case. It presents an important question that has divided the lower courts involving the scope of implied conflict preemption, and more specifically the defense of "impossibility" preemption, in the aftermath of this Court's decision in *Wyeth* v. *Levine*,

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[1] Written statements of consent from all parties to the filing of this brief have been lodged with the Clerk. Pursuant to S. Ct. Rule 37.2, PLAC states that all parties' counsel received timely notice of the intent to file this brief. Pursuant to S. Ct. Rule 37.6, *amicus* states that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

555 U.S. 555 (2009). In the decision below, the Supreme Judicial Court of Massachusetts adopted a cramped and unjustifiable reading of *Wyeth* which, if permitted to stand, will severely limit the defense of implied conflict preemption for manufacturers of pharmaceutical products. PLAC and its members have a vital interest in ensuring that courts uphold conflict preemption where, as here, a federal regulatory agency has addressed an issue as directly as the United States Food and Drug Administration (FDA) has done, and where clear evidence unambiguously establishes that a plaintiff's state-law tort claim conflicts with the agency's regulatory actions and scientific and public-health judgments.

STATEMENT

The petition for certiorari in this case raises a recurring and significant question of federal law – and the meaning of the Supremacy Clause – that is of substantial importance to the pharmaceutical industry. As the petition amply demonstrates (at 25-26, 29-32), the federal and state courts are divided over the meaning of certain language in *Wyeth* v. *Levine*, 555 U.S. 555 (2009) – specifically, this Court's statement that, while an "impossibility" preemption defense was not available on the record there, it would have been available if there had been "clear evidence" that the FDA would have rejected the warning sought by the plaintiff. *Id.* at 571. Because only this Court can clarify what it meant in *Wyeth*, further review is needed.

1. *The Supremacy Clause and the Doctrine of Conflict Preemption*. The Supremacy Clause provides: "This Constitution, and the laws of the

United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. State and local laws that conflict with federal law are preempted "by direct operation of the Supremacy Clause." *Brown* v. *Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984).

This Court's decisions interpreting the Supremacy Clause and articulating the doctrine of conflict preemption stretch back to the earliest days of the Republic. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 209-10 (1824); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819). Although this Court sometimes has separately discussed "'conflicts' that make it 'impossible' for private parties to comply with both state and federal law" (so-called "impossibility" preemption), "'conflicts' that prevent or frustrate the accomplishment of a federal objective" ("obstacle" preemption), and other types of federal-state conflicts, such "terminological" distinctions cannot obscure the fundamental principle that the Supremacy Clause reaches *all* cases where there is an *actual* or *direct* conflict between state and federal requirements. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 873-74 (2000); see also *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941) (discussing wide range of verbal formulations used in Court's many cases involving conflict preemption).

The Supremacy Clause serves a vital structural role in our Nation's government by protecting federal law and programs against encroachment and

interference by subordinate governments. It also helps to create unified and rational markets for nationally distributed goods and services by ensuring that uniform federal regulation – often the product of expert agency decision-making pursuant to authority delegated by Congress – is not undermined or subverted by state or local law, including state tort law as applied by lay juries.

2. Wyeth *v.* Levine. In *Wyeth*, this Court addressed the preemptive effect of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, associated federal regulations relating to drug labeling, and regulatory action by the FDA, on state-law failure-to-warn claims brought against manufacturers of prescription drugs. In rejecting several broad variants of arguments for conflict preemption advanced by the drug manufacturer in that case, the Court explained that federal law does not preempt such state-law claims if the FDA would have allowed the manufacturer to alter its previously approved labeling without prior FDA approval. 555 U.S. at 568, 570-71 (discussing warnings added pursuant to the "Changes Being Effected" (CBE) regulation), 21 C.F.R. § 314.70(c)).

On the other hand, *Wyeth* also made clear that such claims *would be preempted* in cases where there was "clear evidence" showing that the "FDA would *not* have approved a change to [the] label." 555 U.S. at 571 (emphasis added). The Court concluded, however, that the trial record in *Wyeth* did not include such "clear evidence," explaining that the record contained "no evidence . . . that either the FDA or the manufacturer gave more than passing attention to" the risks in question. *Id.* at 572

(internal quotation marks omitted). In reaching that conclusion, and affirming a Vermont Supreme Court decision upholding the trial court's judgment and ruling on a post-trial motion for judgment as a matter of law, this Court also relied on factual findings made by the two lower state courts establishing both that (a) certain warnings rejected by the FDA were not materially different from the warning that actually accompanied the product, and (b) the FDA did not intend to prohibit the manufacturer from strengthening the relevant warning. See *id.* at 572 & n.5. Given those factual findings and the otherwise sparse trial record, this Court had no occasion to clarify what would qualify as "clear evidence."

3. *The Decision Below*. In the decision below, the Massachusetts Supreme Judicial Court (SJC) upheld a massive jury verdict of $140 million including interest based on a failure-to-warn claim relating to Children's Motrin®, an over-the-counter (OTC) medication. In so doing, the SJC rejected the manufacturer's conflict preemption defense, which was based on the FDA's unqualified rejection of a proposed warning that included *the very same language* that plaintiffs claimed should have been provided. That evidence did not constitute "clear evidence" showing that the "FDA would not have approved a change to [the] label" (*Wyeth*, 555 U.S. at 571), the SJC reasoned, because the warning (i) had been proposed in a citizen petition, rather than by the manufacturer, and (ii) had been accompanied by another warning that the FDA had also rejected, rather than being proposed in isolation. Pet. App. 21a-26a.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents an important and recurring issue on which this Court's guidance is needed: the scope of the defense of conflict preemption available to manufacturers of prescription and OTC drugs who are sued under state tort law for failing to provide warnings that the FDA arguably would have rejected (or, as in this case, actually did reject). More specifically, the case raises the question of what this Court meant, in *Wyeth* v. *Levine*, 555 U.S. 555, 571 (2009), when it said the preemption defense would have succeeded had there been "clear evidence" that the FDA would have rejected the warning in question. That issue arises in a potentially large category of high-stakes litigation in both the state and federal courts, and it may also affect conflict preemption in other regulatory settings. See, *e.g.*, *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2577-82 (2011) (discussing "impossibility" preemption defense under *Wyeth* in distinct regulatory setting of generic drugs). Further review by this Court is warranted.

I. As the petition for certiorari persuasively demonstrates (at 3, 5, 25-26, 28-32, 34), the lower courts are confused and sharply divided over the meaning of *Wyeth*'s reference to "clear evidence." In the decision below, Massachusetts's highest court has created conflicts with decisions of the Seventh and First Circuits. Beyond that, there are numerous tertiary or subsidiary disagreements in the lower courts over precisely what this Court meant by "clear evidence." Not surprisingly, many lower courts have suggested the need for clarification from this Court.

This case presents a valuable opportunity to bring greater coherence to federal preemption law. Contrary to the apparent view taken by the court below, *Wyeth* did not invent a novel, virtually insurmountable burden of proof. Instead, this Court's reference to "clear evidence" merely reflects – and draws upon – well-settled precedent establishing that conflict preemption requires demonstration of an *actual*, rather than merely a hypothetical or potential, conflict between federal and state law. See, *e.g.*, *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 884-85 (2000) (conflict preemption "turns on the identification of [an] 'actual conflict[]'" and should not be found "too readily in the absence of *clear evidence* of a *conflict*") (emphasis added); *English* v. *General Electric Co.*, 496 U.S. 72, 90 (1990) (rejecting conflict preemption argument where conflict was "too speculative"). So much is clear from *Geier*, which *rejected* as unworkable and unwieldy an invitation to impose on defendants a "special burden" they must overcome to establish the preemption defense.

Further review would also permit this Court to clarify the nature of the inquiry courts must undertake to determine whether the FDA, under a scenario that is "counterfactual" (*i.e.*, different from what actually occurred), "would *not* have approved a change to [the] label." *Wyeth*, 555 U.S. at 571 (emphasis added). The lower courts have misunderstood how that counterfactual inquiry should be conducted, as reflected in the suggestion of various courts that preemption cannot be established unless a manufacturer *actually proposes* the missing warning, the FDA *actually rejects the manufacturer's proposal*, or both. But requiring such proof would spare from preemption those cases involving the

most scientifically unfounded warnings, which no manufacturer would ever propose (and the FDA unquestionably would reject). That cannot possibly be right, nor can it be what this Court meant in *Wyeth*. At the end of the day, review should be granted because only this Court can clarify what it meant by "clear evidence."

II. Review is also warranted to avoid the negative consequences that otherwise would flow from the lower court's skewed approach to conflict preemption. In the decision below, the SJC has adopted an extremely cramped view that, if allowed to stand, would (a) effectively nullify "impossibility" preemption in this important setting (contrary to this Court's teachings in both *PLIVA* and *Mutual Pharmaceutical Co.* v. *Bartlett*, 133 S. Ct. 2466 (2013)), (b) unfairly impose liability on manufacturers for failing to provide warnings that the FDA not only *would likely have rejected* but *in fact did reject*, and (c) create perverse incentives for manufacturers to burden the FDA with duplicative proposed labeling changes (an institutional burden factor that this Court acknowledged was important in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)). To avoid those adverse effects, the petition should be granted.

ARGUMENT

I. REVIEW IS NEEDED TO RESOLVE CONFLICTS AND CONFUSION IN THE LOWER COURTS AND TO CLARIFY *WYETH*'S REFERENCE TO "CLEAR EVIDENCE"

As the petition persuasively shows (at 3, 5, 25-26, 28-32, 34), there is rampant confusion in the lower courts over the meaning of *Wyeth*'s reference to "clear evidence." On the same record involving the same product warning, the Seventh Circuit has concluded – directly contrary to the Massachusetts court's decision below – that there was "clear evidence" that the FDA would have rejected the missing warning. *Robinson* v. *McNeil Consumer Healthcare*, 615 F.3d 861, 869-70, 873 (2010). Moreover, the decision below establishes for the Massachusetts state courts a product-liability regime in which drug manufacturers may be held liable for failing to propose a warning that the FDA has *already rejected* (when proposed in a citizen petition), even in the absence of any new information or data that might warrant reconsideration of the FDA's decision. Because that squarely conflicts with the approach taken by the *federal* courts in Massachusetts, see *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 779 F.3d 34, 37 (1st Cir. 2015), the decision below will no doubt encourage forum-shopping. See *Baldwin* v. *Alabama*, 472 U.S. 372, 374 (1985) (describing as "significant" a conflict between federal court of appeals and the highest court of a state in that circuit).

Beyond these glaring conflicts, there are multiple tertiary disagreements – and much confusion – in the lower courts over precisely what this Court meant in *Wyeth* by "clear evidence." See Pet. 28-32 (discussing confusion). Compare, *e.g.*, *Aaron* v. *Wyeth*, 2010 WL 653984, at *6 (W.D. Pa. Feb 19, 2010) (holding that manufacturer's proposal to FDA to add warning, and FDA's rejection of that proposal, was not "clear evidence" because manufacturer "did not press its position" but "acquiesced" in FDA's decision) with *Dobbs* v. *Wyeth Pharmaceuticals*, 797 F. Supp. 2d 1264, 1279 (W.D. Okla. 2011) ("This court disagrees with *Aaron*'s interpretation of the proof standard announced in [*Wyeth*]."). Some courts, for example, in upholding the preemption defense have relied on the FDA's rejection of warnings proposed in citizen petitions and other types of regulatory submissions, not in submissions by the manufacturer under the CBE regulation, whereas other courts have insisted on the latter. Compare, e.g., *Dobbs*, 797 F. Supp. at 1274 (finding "clear evidence" where FDA rejected warning proposed in citizen petition) and *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 951 F. Supp. 2d 695, 704 (D.N.J. 2013) ("since the FDA rejected" manufacturer's proposed warning in a "PAS [Prior Approval Supplement], it would not have approved a CBE seeking to add the same language") with *Baumgardner* v. *Wyeth Pharmaceuticals*, 2010 WL 3431671, at *1 (E.D. Pa. Aug. 31, 2010) (FDA's rejection of warnings proposed in citizen petition does not show that agency would have rejected same warning if *manufacturer* had proposed it).

Moreover, the lower courts have repeatedly noted the absence of (and/or the need for) further guidance from this Court concerning what qualifies as "clear evidence" in this important and recurring setting. See, *e.g.*, *Mason* v. *Smithkline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010) (because *Wyeth* "did not clarify what constitutes 'clear evidence[,]' . . . the only thing we know for sure" is that the evidence in that case "did not meet" that "standard"); *Dobbs*, 797 F. Supp. 2d at 1270 (noting that "'lower courts are left to determine what satisfies this 'clear evidence' standard'") (quoting *Schilf* v. *Eli Lilly & Co.*, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010)). Review is needed so that this Court can provide this much-needed guidance.

A. The Lower Courts Have Misunderstood *Wyeth*'s Reference To "Clear Evidence"

In the absence of clearer guidance from this Court, some lower courts – including the SJC below – have taken the view that this Court's reference to "clear evidence" creates a special, and exacting, new standard of proof that defendants must satisfy. See, *e.g.*, *Mason*, 596 F.3d at 391 (describing "clear evidence" as an "exacting standard" and a "stringent standard"); *Forst* v. *Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 953 (E.D. Wis. 2009) (under *Wyeth* "a defendant drug manufacturer faces an exacting burden"). But the lower courts have failed to examine the legal sources from which this Court drew in *Wyeth* in articulating the need for "clear evidence" in this setting. Had they undertaken such an examination, those courts would have recognized that, far from announcing a novel and "exacting" new standard of proof, *Wyeth*'s reference to "clear

evidence" merely reflects and expresses well-settled principles involving the law of conflict preemption.

Federal preemption is an affirmative defense. In civil actions, the ordinary or default burden of persuasion is proof by a preponderance of the evidence. Thus, a defendant ordinarily must prove the defense of preemption by a preponderance of the evidence.[2] In a long line of cases, this Court has made clear that ordinarily the proponent of a conflict preemption defense must demonstrate an *actual* conflict between state and federal law – potential or hypothetical conflicts are not enough. The preemptive conflict, in other words, must be "clear." See, *e.g.*, *Geier* v. *Am. Honda Motor Co.*, 529 U.S. at 861, 884 (2000) (conflict preemption "turns on the identification of 'actual conflict[]'"); *English* v. *General Electric Co.*, 496 U.S. 72, 90 (1990) (rejecting conflict preemption argument where claimed conflict was "too speculative"); *Rice* v. *Norman Williams Co.*, 458 U.S. 654, 664 (1982) (Court's decisions "enjoin seeking out conflicts between state and federal regulation where none *clearly* exists") (emphasis added; quotation marks omitted). "Clear evidence"

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[2] Although preemption is a *legal* defense, sometimes (as in this setting) the defense can hinge on case-specific regulatory facts and circumstances. In every conflict preemption case, however, a court (1) ascertains the meaning of state law; (2) determines the meaning of federal law; and (3) makes a judgment whether the former conflicts with, or serves as an obstacle to, the latter. See *Perez* v. *Campbell*, 402 U.S. 637, 644 (1971) ("Deciding whether a state statute is in conflict with a federal statute and hence invalid under the Supremacy Clause is essentially a two-step process of first ascertaining the construction of the two statutes and then determining the constitutional question whether they are in conflict.").

in this setting thus means what it always has meant: the demonstration of an *actual*, as opposed to merely a *potential*, conflict.

This reading is amply confirmed by *Geier*, which also used the "clear evidence" formulation in evaluating proof of conflict preemption. Specifically, this Court in *Geier* reasoned that conflict preemption "turns on the identification of 'actual conflict[]'" and then explained that "a court should not find pre-emption too readily in the absence of *clear evidence* of a *conflict*." 529 U.S. at 884-85 (emphasis added).

In referring to "clear evidence," the Court in *Geier* cited a portion of its previous decision in *English*. The relevant portion of *English* addressed whether administrative anti-retaliation provisions for employees in the nuclear power industry, established by Section 211 (formerly Section 210) of the Energy Reorganization Act of 1974, 42 U.S.C. § 5851(a), preempted emotional distress tort claims under state law. Rejecting the argument that Congress's inclusion of "expeditious time-frames" in the federal administrative remedy preempted state claims with longer deadlines, the Court expressed skepticism that "employees will forgo their § 210 options and rely solely on state remedies for retaliation." *English*, 496 U.S. at 89-90. "Such a prospect," the Court explained,

> is simply *too speculative* a basis on which to rest a finding of pre-emption. The Court has observed repeatedly that pre-emption is ordinarily not to be implied absent an 'actual conflict.' See, *e.g.*, *Savage* v. *Jones*, 225 U.S. 501, 533 (1912). The 'teaching of this Court's decisions . . . enjoin[s] seeking out conflicts

> between state and federal regulation where none *clearly* exists.' *Huron Portland Cement Co.* v. *Detroit*, 362 U.S. 440, 446 (1960).

Id. at 90 (emphasis added). The references to "clear evidence" in *Geier* and "clear" conflicts in *English* are thus nothing more than a restatement of the basic principle that, for the Supremacy Clause to come into play, there must be an "actual," and not merely a hypothetical, conflict between federal and state requirements.

If the Court in *Wyeth* had meant more than the "clear" evidence required in *Geier* and *English* – if it had meant to create a special new (and "exacting" or "stringent") standard of proof unique to prescription drug labeling cases – then it plainly would have said so. The Court, like Congress, "does not . . . hide elephants in mouseholes." *Whitman* v. *Am. Trucking Ass'ns., Inc.*, 531 U.S. 457, 468 (2001).

That reading of *Wyeth*, moreover, is especially implausible for at least two reasons. First, in *Geier* the Court also expressly *rejected* an argument that a defendant must shoulder a "special burden" of proof in certain subcategories of implied preemption cases. 529 U.S. at 870-74. Such a "special burden," the Court explained, "find[s]" no "basis . . . in this Court's precedents" and would "promise practical difficulty by further complicating well-established pre-emption principles that already are difficult to apply." *Id.* at 872-73. In light of that unambiguous holding, *Geier*'s reference to "clear evidence" obviously did not alter the ordinary burden of establishing a preemption defense. Nor is it plausible to conclude that the Court in *Wyeth* intended to adopt the very kind of "special burden" of proof rejected in *Geier* (without

even mentioning, much less expressly overruling, this aspect of *Geier*).

Second, the lower courts' suggestion that *Wyeth* created a new and "exacting" standard of proof also overlooks the procedural posture of that case. As noted above (at page 5, *supra*), in *Wyeth* this Court reviewed a decision of the Vermont Supreme Court affirming both a liability judgment following trial and the trial court's ruling, supported by findings of fact, on a post-judgment motion for judgment as a matter of law. In so doing, this Court was evaluating the drug manufacturer's argument in light of factual findings that had been made by two lower state courts, including that (1) certain warnings rejected by the FDA were not materially different from the allegedly defective warning that actually accompanied the product, and (2) the FDA did not intend to prohibit the manufacturer from strengthening the relevant warning. See 555 U.S. at 572 & n.5. This Court's statement that there must be "clear evidence" may well have been informed by this procedural posture and what would be necessary to overcome these factual findings of the state courts.

In sum, further review would allow this Court to clarify that *Wyeth* did not adopt a novel, especially "stringent" or "exacting" standard of proof unique to pharmaceutical cases, but rather a legal regime consistent with longstanding principles governing conflict preemption. In addition to being foreclosed by *Geier*, such a novel rule would add still more complexity and uncertainty to the already complicated law of federal preemption.

B. The Lower Courts Have Misunderstood The Nature Of The Inquiry Required By *Wyeth*

Under *Wyeth*, conflict preemption exists when there is "clear evidence" that "the FDA *would not have* approved" the change sought by a plaintiff in the drug's labeling. 555 U.S. at 571 (emphasis added). This Court specified "would not have" – not "did not." In cases where a manufacturer *actually proposed* to add the warning in question but that proposal *was rejected* by the FDA, the preemptive conflict is not just "clear," but should be indisputable. See, *e.g.*, *Robinson*, 615 F.3d at 873 (*Wyeth* standard satisfied where FDA refused to approve warning desired by plaintiff).

In the cases *Wyeth* contemplated, the relevant inquiry is by nature "counterfactual": it relies on a judicial determination of whether the FDA likely *would have* rejected the additional warning in question *if* the warning had been proposed. See *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2580 (2011) (plurality) (noting that inquiry focuses on "the counterfactual conduct of the FDA"); *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341, 354 (2001) (Stevens, J., joined by Thomas, J., concurring in the judgment) (referring to "speculation as to the FDA's behavior in a counterfactual situation").[3] Such counterfactual inquiries are commonplace in the law. See generally Robert Strassfeld, *If . . . : Counterfactuals in the Law*, 60 GEO. WASH. L. REV.

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[3] In this usage, "counterfactual" simply means a scenario that did not exist in the real world, not necessarily a scenario that is "contrary" to or contradicted by the facts.

339, 345-48 (1992). In tort law, for example, they regularly arise with respect to issues of causation (but for the defendant's conduct, would the injury have occurred?). And in failure-to-warn cases involving avoidable risks, the question whether a plaintiff would have heeded a warning not provided requires a similar counterfactual inquiry. As made clear by *Wyeth*, *PLIVA*, and *Buckman*, counterfactual issues arise with regularity even in the quite limited setting of implied preemption arguments involving regulatory decisions by the FDA (or other federal agencies).

Numerous lower courts have misunderstood the basic nature of this inquiry. The inquiry is *counterfactual* – it does not require the manufacturer to have *actually* proposed the relevant warning, much less actually added it (if only temporarily, before it was rejected by the FDA) through the CBE process. Neither does it require that the FDA have *actually* rejected the warning – although the record here clearly reflects such a rejection. On the contrary, in discussing the absence of "clear evidence," this Court in *Wyeth* noted various things missing from the record, including facts establishing that the manufacturer "supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method." 555 U.S. at 572-73. Thus, *Wyeth* itself arguably suggests that a manufacturer could establish impossibility in the absence of actually proposing a warning or having a warning rejected, such as for example by providing data demonstrating that a particular warning *lacked any scientific basis* (and thus clearly would have been rejected by the FDA had it been proposed).

Indeed, requiring proof that a manufacturer actually propose to the FDA the precise warning sought by the plaintiff (through the CBE process or otherwise) – as the SJC required here (Pet. App. 24a) – would have the perverse effect of eliminating the impossibility defense in cases involving the most scientifically unfounded risks. If a risk warning has no *scientific basis whatsoever* (or, indeed, is demonstrably false under the data), no rational manufacturer would even think to propose it. Such wild claims should be preempted. And it should be enough for a manufacturer to show through "evaluation or analysis," 555 U.S. at 572-73, including through expert testimony, that the warning was scientifically unfounded and would have been rejected by the FDA on that (or some other) ground. The lower court decisions suggesting that a CBE application (or other proposal) submitted by the manufacturer is a *necessary prerequisite* to satisfying the *Wyeth* standard, see, *e.g.*, *Schedin* v. *Ortho-McNeil-Janssen Pharmacueticals, Inc.*, 808 F. Supp. 2d 1125, 1132-33 (D. Minn. 2011), are thus contrary to common sense.

This case is an excellent vehicle for clarifying the proper inquiry under *Wyeth*. The SJC's misguided focus on the *source* of the warning proposed to the FDA (a citizen petition rather than a regulatory submission made by the manufacturer) instead of on that warning's *content* disregarded the fundamental nature of the requisite inquiry into what *the FDA would have done* (which as the petitioners show would turn on the content, not the source, of the proposed warning). Further review would permit the Court to make clear that the *Wyeth* inquiry must focus on the FDA's likely evaluation of

the specific warning in question, at the relevant time, under the governing legal standards applicable to new warnings. The proper inquiry must also take into account the FDA's *scientific standards* as well as *the public-health concerns* that animate the FDA's labeling decisions in a particular setting (such as concerns about overwarning). And, because this case involves the FDA's special concerns relating to OTC labeling, see Pet. 8, 35-38, it is an ideal vehicle for clarifying the nature of the proper inquiry required under *Wyeth*.

C. Only This Court Can Clarify What It Meant in *Wyeth*

At bottom, the conflict and confusion in the lower courts stems from this Court's unelaborated reference in *Wyeth* to "clear evidence." For that reason, further litigation of this issue in the lower courts is unlikely to lead to greater clarity. At the end of the day, only this Court can offer definitive guidance on what it meant in *Wyeth*. For that reason as well, the petition should be granted.

As this Court has recognized, the law of federal preemption is complicated and "difficult to apply." *Geier*, 529 U.S. at 873. Some of this Court's preemption decisions have featured multiple opinions that combine to form the Court's majority. See, *e.g.*, *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). When ambiguities in those decisions have led to conflicting interpretations and confusion in the lower courts, this Court has not hesitated to step in and restore uniformity to federal law. See, *e.g.*, *Freightliner* v. *Myrick*, 514 U.S. 280, 288-89 (1995)

(clarifying statement in *Cipollone* that had spawned confusion in the lower courts about the availability of implied preemption defense in cases involving express preemption clauses); *Geier*, 529 U.S. at 872-73 (discussing same). The Court should do so here too.

II. THE LOWER COURT'S APPROACH THREATENS TO UNDERMINE AND BURDEN THE FEDERAL REGULATORY SCHEME AND PERMITS LIABILITY FOR FAILURE TO PROVIDE WARNINGS THAT THE FDA HAS REJECTED

The SJC gave two reasons for concluding that the record lacked "clear evidence" that the FDA would have rejected the warning sought by the plaintiffs in this case: the missing warning, which the FDA *actually rejected*, (1) had been proposed by a third party in a citizen petition, rather than by the drug manufacturer; and (2) had been accompanied by another warning that the agency *had also rejected*, rather than being proposed in isolation. Pet. App. 21a-26a. If the manufacturer rather than a third party had proposed the identical warning, the SJC speculated, and had done so in isolation rather than together with the other rejected warning, then it was "anybody's guess" whether the FDA would have reached the same result. Pet. App. 23a-24a.

The SJC's strained effort to conjure up a speculative basis on which to deny the preemption defense ignores this Court's teachings in both *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co.* v. *Bartlett*, 133 S. Ct. 2466 (2013). In both of those cases, this Court

declined to credit speculative scenarios advanced by plaintiffs seeking to demonstrate that it was not impossible, after all, for a drug manufacturer to comply with a state-law tort duty without running afoul of federal requirements. Thus, in *PLIVA*, the Court rejected the argument that a generic drug manufacturer (which is obligated by federal law to use the same labeling as the brand-name drug) could have asked the FDA to change both its own and the brand-name label, and such a request might have resulted in FDA permission to change the generic-drug labeling. 131 S. Ct. at 2578-79. Because the manufacturer had not even *tried* to persuade the FDA to do so, the plaintiffs in *PLIVA* contended, the manufacturer could not establish conflict preemption. This Court emphatically rejected that argument, explaining that "[i]f these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes," then conflict preemption would be rendered "largely meaningless." *Ibid.* And for exactly the same reason, this Court in *Bartlett* rejected the plaintiff's contention that a drug manufacturer could avoid the direct conflict between federal and state law merely by electing to stop selling the medication altogether. See *Bartlett*, 133 S. Ct. at 2477 (explaining that accepting argument would render impossibility preemption "meaningless").

So, too, here. The SJC did not offer any basis for its speculation that the FDA might examine proposed warnings under different standards if they are proposed in a citizen petition rather than by a manufacturer. Nor did it point to any basis for its speculation that the FDA, in rejecting the warning at issue, might have made a mistake because it acted at

the same time on *another* warning that it also rejected. These reasons are so speculative that they are indistinguishable from the arguments rejected in both *PLIVA* and *Bartlett*.

Even apart from its inconsistency with this Court's decisions, the lower court's approach warrants review because, if left uncorrected, it could lead to disruption of the federal regulatory process governing drug labeling as well as produce manifestly unfair results. The decision below creates incentives for drug manufacturers to propose duplicative labeling changes to the FDA even though the same changes *have already been rejected* by the agency (when proposed in a citizen petition). It also creates incentives for manufacturers to propose warning changes individually and *seriatim* rather than together as a group, so as to ensure that the rejection of multiple warnings by the FDA will not (as the SJC ruled) open up the argument that the agency might not have rejected one or more of the warnings if they had been proposed individually. The foreseeable consequence of the SJC's flawed reasoning, in other words, is greater duplication and inefficiency in submissions to the FDA and therefore greater burdens on the agency.

In *Buckman*, this Court emphasized the need to avoid such unwarranted burdens on, and interference with, the FDA's regulatory processes in holding that fraud-on-the-FDA claims are impliedly preempted. Specifically, the Court explained the negative impact such claims would have on the agency's approval of "substantially similar" medical devices under the so-called "510(k) process" (named

after a provision of the Medical Device Amendments):

> [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application. As a result, the comparatively speedy § 510(k) process could encounter delays . . . .

531 U.S. at 351. In much the same way, the SJC's flawed approach to conflict preemption will multiply the burdens on and clog up the FDA's review process with respect to drug labeling. And the avoidance of such burdens on the FDA likely was one reason this Court granted the petition in *Buckman*. See No. 98-1768 Pet. 18, *Buckman* v. *Plaintiffs' Legal Committee* (filed May 1999) (noting that, if allowed to proceed, fraud-on-the-agency claims would spur manufacturers to "inundate the agency with unnecessary data and speculative impressions in order to foreclose future state law claims that they procured the FDA's clearance through fraudulent concealment").

Finally, it is worth adding that the lower court's approach creates outcomes that are unfair to drug manufacturers. In this case, the Massachusetts courts have imposed a massive jury verdict of $140 million including interest based on the manufacturer's failure to give a particular warning that the FDA, the expert agency charged by

Congress with regulating drug labeling, *had already rejected*. A clearer collision between the requirements of state tort law and the mandates of federal regulation is difficult to imagine.

CONCLUSION

For the foregoing reasons, and those set forth in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

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APPENDIX

PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
LIST OF CORPORATE MEMBERS

3M
Altec, Inc.
Altria Client Services Inc.
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
The Boeing Company
Bombadier Recreational Products, Inc.
Boston Scientific Corporation
Bridgestone Americas, Inc.
Bristol-Myers Squibb Corporation
C.R. Bard, Inc.
Caterpillar Inc.
CC Industries, Inc.
Celgene Corporation
Chevron Corporation
Cirrus Design Corporation
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Crane Co.
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
Delphi Automotive Systems
Discount Tire
The Dow Chemical Company

E.I. duPont de Nemours and Company
Eisai Inc.
Emerson Electric Co.
Endo Pharmaceuticals, Inc.
Exxon Mobil Corporation
FCA US LLC
Ford Motor Company
Fresenius Kabi USA, LLC
General Electric Company
General Motors LLC
Georgia-Pacific LLC
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
The Home Depot
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works Inc.
Isuzu North America Corporation
Jaguar Land Rover North America, LLC
Jarden Corporation
Johnson & Johnson
Kawasaki Motors Corp., U.S.A.
KBR, Inc.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Lincoln Electric Company
Magna International Inc.
Mazak Corporation
Mazda Motor of America, Inc.
Medtronic, Inc.
Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.

Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Mueller Water Products
Novartis Pharmaceuticals Corporation
Novo Nordisk, Inc.
NuVasive, Inc.
Pella Corporation
Pfizer Inc.
Pirelli Tire, LLC
Polaris Industries, Inc.
Porsche Cars North America, Inc.
RJ Reynolds Tobacco Company
Robert Bosch LLC
SABMiller Plc
The Sherwin-Williams Company
St. Jude Medical, Inc.
Stanley Black & Decker, Inc.
Subaru of America, Inc.
Takeda Pharmaceuticals U.S.A., Inc.
TAMCO Building Products, Inc.
TASER International, Inc.
Techtronic Industries North America, Inc.
Teleflex Incorporated
TK Holdings Inc.
Toyota Motor Sales, USA, Inc.
TRW Automotive
U-Haul International
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Western Digital Corporation
Whirlpool Corporation

Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.