No. 17-290

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

DORIS ALBRECHT, ET AL.,
Respondents.

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

BRIEF IN OPPOSITION FOR RESPONDENTS

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QUESTION PRESENTED

The label for petitioner's drug Fosamax has included a warning about atypical femoral fractures since 2011, reflecting petitioner's and the Food and Drug Administration's acknowledgment that reasonable evidence exists that Fosamax causes those fractures. Respondents are more than 500 patients who took Fosamax and suffered atypical femoral fractures before the 2011 label change. Respondents assert, among other things, that petitioner should have updated the Fosamax label to add warnings about atypical femoral fractures earlier than it did.

Petitioner concedes that respondents' failure-to-warn claims are not preempted, because it could have added an earlier warning to the Adverse Reactions section of the Fosamax label. Petitioner seeks only to narrow the failure-to-warn claims to exclude consideration of the Warnings and Precautions section. Petitioner contends that the FDA's rejection of a proposed warning about "stress fractures" (which are widely understood to be minor, incomplete fractures, in contrast to the severe atypical femoral fractures suffered by respondents) is clear evidence that the FDA also would have rejected a warning about atypical femoral fractures. The Third Circuit held that factual disputes existed regarding how the FDA would have reacted to a properly worded warning about atypical femoral fractures, and reversed summary judgment on petitioner's preemption defense.

The question presented is:

Whether the Third Circuit accurately assessed the record evidence in determining that petitioner had failed to show that the FDA would have rejected a properly worded warning about atypical femoral fractures.

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Petitioner concedes that respondents' failure-to-warn claims are not preempted insofar as those claims are based on petitioner's failure to update the Adverse Reactions section of the Fosamax label to include atypical femoral fractures. Pet. 13 n.1. Petitioner also does not challenge the Third Circuit's ruling that none of respondents' non-failure-to-warn claims (such as design defect, breach of warranty, and negligence) are preempted. App. 74a. Thus, even if petitioner prevails, it will not win dismissal of any claim of any respondent. This case therefore does not present a broad question regarding the scope of conflict preemption. It presents only the narrow question whether, upon remand to the district court, respondents will be permitted to argue that petitioner should have warned of atypical femoral fractures on one section of the Fosamax label (Adverse Reactions) or two (Adverse Reactions, and Warnings and Precautions).

Even for the Warnings and Precautions section, this is not the typical preemption case where a defendant argues that the scientific evidence that the drug causes the side effect is insufficient to support a warning. Here, petitioner and the Food and Drug Administration ("FDA") have determined that reasonable evidence exists that Fosamax causes atypical femoral fractures, and petitioner has properly included a warning about those fractures on the Fosamax label for more than six years. The only question is whether, as petitioner contends, the FDA would have prevented petitioner from adding a proper warning of atypical femoral fractures at any earlier date than when the FDA mandated that warning.

That question is hypothetical, because petitioner never proposed such a warning. Instead, petitioner proposed a warning only about a different risk —

minor stress fractures. Because petitioner never proposed a warning about "the risk at issue" (Pet. i), and the FDA never rejected such a warning, the question as to which petitioner seeks review is not in fact presented in this case.

The FDA's response to petitioner's proposed stress-fracture warning confirms that conclusion. In the FDA's "Complete Response" letter, in which it was required by regulation to list *all* deficiencies with petitioner's proposal, *see* 21 C.F.R. § 314.110(a)(1), the FDA identified only the inaccurate description of the risk as "stress fractures." C.A.App. 1500-01. Petitioner hypothesizes that the FDA violated its own regulations by submitting a false Complete Response, listing as its only justification what petitioner calls (at 24) a mere "language quibble." According to petitioner, the decision was actually motivated by a concern — contained nowhere in the Complete Response — that the scientific evidence was insufficient to justify *any* warning. When pressed by the Third Circuit for evidence to support this theory, petitioner's counsel pointed to a piece of double hearsay: a memorandum written by petitioner's employee of a telephone conversation that she purportedly had with an FDA official. App. 49a n.125; C.A.App. 1970.

Faced with what can be described most charitably to petitioner as conflicting evidence, the Third Circuit held that factual disputes remained regarding petitioner's preemption defense. In so ruling, the Third Circuit faithfully applied this Court's holding in *Wyeth v. Levine*, 555 U.S. 555 (2009), that failure-to-warn claims against brand-name drug manufacturers are not preempted "absent clear evidence that the FDA would not have approved" a label change. *Id.* at 571. That conclusion followed from

this Court's recognition that the "central premise of federal drug regulation" is "that the manufacturer bears responsibility for the content of its label at all times," *id.* at 570-71, and that the "Changes Being Effected" ("CBE") regulation "provides a mechanism for adding safety information to the label prior to FDA approval," *id.* at 571. Petitioner acknowledges that the Third Circuit applied the "clear evidence" standard, and it identifies no conflict among the lower courts regarding the legal standard for preemption in this context. There is accordingly no need for this Court to review the Third Circuit's decision, which correctly applied this Court's precedent and did not create any circuit conflict.

Moreover, this case would present a poor vehicle for considering the scope of conflict preemption in any event. Petitioner seeks review of just one aspect of the Third Circuit's decision reversing summary judgment. Even if this Court were to grant review in this interlocutory posture and adopt petitioner's position, all of respondents' claims, including claims for failure to warn in the Adverse Reactions section, would remain to be litigated in the district court. In addition, the record on preemption is underdeveloped in these cases because the district court followed the extraordinary procedural path of granting all of the more than 500 respondents just 45 days to show cause why their claims were not preempted. The Third Circuit did not need to consider respondents' objections to this procedure because it held that petitioner had failed to prove preemption, but, if this Court were to grant certiorari, respondents would raise their procedural arguments as an independent basis for affirmance, which may prevent this Court from reaching the question presented. The Court should deny the petition.

STATEMENT

A. Statutory And Regulatory Background

It is and always has been a "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). An application for FDA approval to market a drug must include proposed labeling that is neither false nor misleading. *See* 21 U.S.C. § 355(b)(1)(F), (d)(7). FDA approval of a drug encompasses approval of the label. *See* 21 C.F.R. § 314.105(b). After approval, a manufacturer may unilaterally, without prior FDA approval, "add or strengthen a contraindication, warning, precaution, or adverse reaction" on the drug label "to reflect newly acquired information," by submitting a supplement under the CBE regulation. *Id.* § 314.70(c)(6)(iii)(A). A manufacturer can also apply for FDA approval to add a warning through a "Prior Approval Supplement" ("PAS"). *Id.* § 314.70(b)(3). Label changes under a CBE supplement are exempted from the PAS prior approval requirement. *Id.* § 314.70(b)(2)(v)(A).

Two sections of the drug label are relevant here: Adverse Reactions, and Warnings and Precautions. The Adverse Reactions section includes a listing of all "undesirable effect[s], reasonably associated with use of a drug." *Id.* § 201.57(c)(7). A manufacturer must include an adverse reaction if "there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." *Id.* The Warnings and Precautions section contains descriptions of "clinically significant adverse reactions," which must be included "as soon as there

is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." *Id.* § 201.57(c)(6)(i). Those standards also apply to warnings added through a CBE supplement. *Id.* § 314.70(c)(6)(iii)(A).

In 2007, Congress enacted a provision allowing the FDA to require label changes. 21 U.S.C. § 355(*o*)(4). Congress contemporaneously adopted a "[r]ule of construction" that the new provision "shall not be construed to affect the responsibility of the [drug manufacturer] . . . to maintain its label in accordance with existing requirements, including [the CBE regulation]." *Id.* § 355(*o*)(4)(I).

B. Factual History

1. Atypical femoral fractures are severe injuries in which the thigh bone, or femur, breaks in two, despite the absence of any trauma. C.A.App. 1226 (x-rays). In October 2010, the FDA ordered petitioner and all manufacturers of similar drugs (called bisphosphonates) to inform the public in the Warnings and Precautions section of their drug labels of "the risk of atypical fractures of the thigh." C.A.App. 1118. That decision required the FDA to determine that "reasonable evidence of a causal association" existed. 21 C.F.R. § 201.57(c)(6)(i). Petitioner did not challenge this determination and, in January 2011, voluntarily added a warning that "[a]typical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients." C.A.App. 1070. That warning still appears on the Fosamax label today. The preemption question in this case is whether the FDA would have blocked petitioner from adding such a warning at an earlier date.

2. The FDA approved Fosamax in the 1990s to treat and prevent osteoporosis, and the drug is used

most commonly by post-menopausal women. App. 5a. Human bones constantly undergo a remodeling process in which bone breaks down (resorption) and is rebuilt (formation); in post-menopausal women, the rate of resorption often exceeds that of formation, leading to bone loss. *Id.* Fosamax slows resorption in order to reduce bone loss, but it also inhibits bone formation. App. 6a; C.A.App. 865, 1099. Bones frequently develop tiny fractures called "microcracks" that heal naturally through formation, but Fosamax prevents this healing, causing microcracks to accumulate. App. 6a; C.A.App. 865-66. For many patients, years of Fosamax usage can cause such a large accumulation of microcracks that the femur breaks completely, even without trauma, in an atypical femoral fracture. App. 6a; C.A.App. 884.

Petitioner has known since at least 1992 that Fosamax could weaken bone by inhibiting bone remodeling. App. 12a. As early as 1999, petitioner received adverse event reports indicating that long-term Fosamax users were suffering atypical femoral fractures. C.A.App. 874-75. "Between 1995 and 2010, scores of case studies, reports, and articles were published documenting possible connections between long-term bisphosphonate use and atypical femoral fractures." App. 13a. Because of the surge in these previously rare fractures among Fosamax patients, orthopedic surgeons began referring to them colloquially as "Fosamax Fracture[s]." C.A.App. 875-76, 1261.

3. Fosamax's label contained no mention of femur fractures from its approval in 1995 through 2008. App. 12a-14a. In June 2008, the FDA informed petitioner that it was "aware of reports" of bisphosphonate users suffering atypical femoral fractures and was "concerned about this developing safety signal."

App. 14a. In September 2008, petitioner submitted a PAS to the FDA to add mentions of fractures to the Adverse Reactions and Warnings and Precautions sections of the Fosamax label. The proposed Warnings and Precautions language six times referred to the fractures at issue as "stress fractures" and stated that "risk factors" for such stress fractures included "extreme or increased exercise." *See* Pet. 8. As the FDA later explained, characterizing the risk as "stress fractures" would "contradict the seriousness of the atypical femoral fractures associated with bisphosphonate use" because, "for most practitioners, the term 'stress fracture' represents a minor fracture." App. 22a-23a (quoting C.A.App. 1540). Petitioner has acknowledged that, for most physicians, stress fractures "are associated with repetitive stress injury related to exercise (e.g., running) in younger adults, and that this type of stress fracture generally heals well with rest." C.A.App. 1573.

On May 22, 2009, the FDA submitted a "Complete Response" by Dr. Scott Monroe, granting in part and denying in part petitioner's application. App. 18a; C.A.App. 1500-01. The FDA approved the addition of "low energy femoral shaft and subtrochanteric fractures" to the Adverse Reactions section, C.A.App. 1501, reflecting the conclusion that "there is some basis to believe" that Fosamax causes these fractures, 21 C.F.R. § 201.57(c)(7), but the FDA did not approve the proposed Warnings and Precautions language. By regulation, a complete response letter must "describe all of the specific deficiencies that the agency has identified in an application." *Id.* § 314.110(a)(1). The *only* deficiency described by the FDA was that "'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been

reported in the literature" and the "risk factors for stress fractures" were unsupported. App. 18a-19a. Contrary to petitioner's repeated assertions (at 1, 3, 13), the FDA's Complete Response did not mention any doubt about the scientific evidence that Fosamax causes atypical femoral fractures. *See* C.A.App. 1500-01.

The FDA invited petitioner to "resubmit" its application, C.A.App. 1501, and around the same time informed petitioner it would like to "work with" petitioner "on language for a [Warnings and Precautions] atypical fracture language, if it is warranted," C.A.App. 1498. Petitioner rebuffed the FDA's repeated entreaties for further engagement, and "fail[ed] to re-submit a revised CBE or PAS." App. 67a. Thus, the record contradicts petitioner's assertion that the FDA did not "initiate discussions to reach agreement" on alternate warning language and was unwilling to "work with Merck on a warning that would properly warn the public of the risk." Pet. 13, 24.

Petitioner argued below that the FDA denied the PAS on the basis of a concern not expressed in the Complete Response: "that there was no reasonable evidence of a causal link." App. 60a-61a. Petitioner theorized that the only deficiency actually identified in the Complete Response — the misleading characterization of the risk as "stress fractures" — was a mere "language quibble" that had nothing to do with the FDA's decision. App. 61a. Pressed at oral argument for evidence to support this theory, petitioner "stated that the single best piece of evidence" was a piece of double hearsay: "a set of notes, prepared by [petitioner's] employee, recounting a telephone conversation with Dr. Monroe of the FDA — the same official who wrote the [Complete Response]." App. 49a n.125. In that memorandum, the employee,

Charlotte Merritt, wrote that "[t]he conflicting nature of the literature does not provide a clear path forward, and more time will be need [sic] for FDA to formulate a formal opinion on the issue of a precaution around these data." C.A.App. 1971.

4. In March 2010, the FDA stated that it was "working closely with outside experts . . . to gather additional information" about the relationship between bisphosphonates and atypical femoral fractures. C.A.App. 1508. In October 2010, the FDA announced that it would require all bisphosphonate manufacturers to warn of atypical femoral fractures in the Warnings and Precautions section, because "these atypical fractures may be related to long-term . . . bisphosphonate use." App. 20a (alteration in original). The FDA specifically ordered petitioner to add a warning. App. 21a-22a. Petitioner did not dispute the FDA's conclusion that the scientific evidence justified an atypical femoral fracture warning, but petitioner proposed language describing the fractures five times as "stress fractures." App. 22a. The FDA circulated a redline striking out every instance of "stress fractures," explaining that, "for most practitioners, the term 'stress fracture' represents a minor fracture and this would contradict the seriousness of the atypical femoral fractures associated with bisphosphonate use." App. 22a-23a; C.A.App. 1540, 1556-57.[1] Since January 2011, the Warnings and Precautions section of the Fosamax label has included an atypical femoral fracture warning. App. 23a; C.A.App. 1070 (Jan. 2011 label).

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[1] Petitioner omits the fact that it proposed "stress fracture" language a second time, and the FDA rejected its proposed language as misleading. Pet. 11.

C. Procedural History

Respondents are more than 500 individuals who allegedly suffered an atypical femoral fracture caused by Fosamax usage. App. 4a. Respondents filed separate complaints, which were consolidated for pretrial administration in a multi-district litigation ("MDL"). *Id.* Although each complaint is different, respondents assert failure-to-warn claims, as well as several non-warning claims, including design defect, negligence, and breach of warranty. App. 55a-56a. Apart from a small set of designated "Early Discovery Cases," discovery in individual cases has not yet begun. C.A.App. 734.

In 2013, the district court held the first bellwether trial in the *Glynn* case. App. 24a. The jury found that Ms. Glynn failed to prove that she suffered an atypical femoral fracture. App. 25a. Even though the jury had already rejected Ms. Glynn's claims on the merits, the district court issued a post-trial opinion that her claims were preempted. *Id.* Shortly after that opinion, in August 2013, the court issued an order requiring all respondents to show cause why their claims were not preempted. App. 26a. The court gave respondents 45 days to obtain evidence and submit briefs opposing preemption. C.A.App. 769.

The district court granted judgment to petitioner on all of respondents' claims "because Plaintiffs have failed to show cause why their claims are not preempted under this Court's ruling in *Glynn*." App. 152a. The court held that claims that petitioner should have added a warning to the Warnings and Precautions section were preempted because the court had "already considered and rejected" respondents' arguments in *Glynn*. App. 150a. Respondents also argued that petitioner should have warned of

atypical femoral fractures in the Adverse Reactions section before June 2009. The court did not find that theory preempted but dismissed it as "illogical." App. 146a-147a. The court also concluded, without citing any of the complaints, that the theory was not pleaded in any of the more than 500 complaints. App. 147a. As to the non-failure-to-warn claims, the court concluded on the basis of a single allegation in a single complaint that all respondents' non-failure-to-warn claims were "merely disguised failure to warn causes of action" and were therefore preempted. App. 142a.

The Third Circuit vacated and remanded. The Third Circuit began by noting that this Court's *Levine* decision provided the governing framework. Under that decision, failure-to-warn claims are preempted only "when there is 'clear evidence' that the FDA would not have approved the warning that a plaintiff claims was necessary." App. 30a-31a. Citing cases from this Court using "clear evidence" interchangeably with "clear and convincing evidence," the Third Circuit concluded that *Levine* set forth a standard of proof for the facts underlying the preemption analysis. Under that standard, the inquiry is whether "it is highly probable that the FDA would not have approved a change to the drug's label." App. 37a.

Closely scrutinizing the factual record, the Third Circuit concluded that factual disputes existed regarding whether the FDA would have rejected a properly worded atypical femoral fracture warning in the Warnings and Precautions section. App. 67a-68a. The Third Circuit posited that, while the FDA's rejection of proposed warning language could support the inference that the FDA would have rejected any warning, the FDA's repeated objections to proposed

"stress fracture" language supported the opposite inference that the FDA would have approved a properly worded warning about atypical femoral fractures. App. 5a, 59a-68a. The Third Circuit noted that petitioner's reliance on Ms. Merritt's memorandum as its best piece of evidence raised numerous factual disputes regarding the credibility of Ms. Merritt and the intentions of Dr. Monroe. App. 49a n.125. Citing this Court's decision in *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988), which held that "whether the facts establish the conditions for [a preemption] defense is a question for the jury," *id.* at 514, the Third Circuit held that resolution of these factual disputes could not be resolved on summary judgment. App. 42a-55a.

The Third Circuit further held that other district court rulings were also erroneous. It ruled that the district court erred in holding that respondents could not pursue failure-to-warn claims based on the theory that petitioner should have added atypical femoral fractures to the Adverse Reactions section before June 2009. The court of appeals explained that this theory was not preempted because petitioner had presented no evidence it could not have added the warning earlier and that the district court erred in summarily dismissing the theory on the merits. App. 70a-73a. The Third Circuit also held that the district court had erroneously dismissed respondents' non-failure-to-warn claims. App. 74a. The petition does not challenge either of those rulings. *See* Pet. 13 n.1 (Adverse Reactions ruling "not at issue here"). In fact, petitioner fails to acknowledge the non-failure-to-warn claims that the Third Circuit held were erroneously dismissed. Pet. 11.

REASONS FOR DENYING THE PETITION

I. THERE IS NO CIRCUIT COURT CONFLICT, AND LOWER COURTS HAVE FAITHFULLY APPLIED *WYETH V. LEVINE*

Petitioner admits that no circuit split exists regarding the conflict preemption issue presented here. Pet. 14 (arguing that this Court should grant review "even absent any circuit conflict"). Rightly so. Since *Wyeth v. Levine*, 555 U.S. 555 (2009), lower courts have consistently understood and applied the basic framework laid out by this Court: failure-to-warn claims generally are not preempted because they pose no obstacle to Congress's purposes and because federal law expressly allows brand-name drug manufacturers to add a warning to the label. *See id.* at 568-81. The manufacturer can, however, establish a preemption defense if it meets its burden to show "clear evidence that the FDA would not have approved" a label change. *Id.* at 571.[2] No federal court of appeals or state court of last resort has reached a conclusion contrary to the Third Circuit's

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[2] *Compare*, *e.g.*, *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098-99 (10th Cir. 2017) ("we must apply the 'clear evidence' test set forth in *Levine*," under which claims are preempted if defendant "presented clear evidence that the FDA would have disapproved of the warnings suggested by [plaintiffs]"); *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385 (6th Cir. 2017) ("'[A] court cannot order a drug company to place on a label a warning if there is "clear evidence" that the FDA would not approve it.'") (quoting *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010)); *and Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 460 (Mass. 2015) (claims preempted if there is "clear evidence that the FDA would not have approved a warning" sought by plaintiffs), *cert. denied*, 136 S. Ct. 896 (2016)), *with* App. 37a ("under *Wyeth*, the factfinder must conclude that it is highly probable that the FDA would not have approved a change to the drug's label" to support a preemption defense).

either on the allocation of decision making between the judge and the jury for factual issues underlying the preemption inquiry or on the standard of proof for preemption under *Levine*.

In the absence of a split, petitioner argues that all lower courts are getting it wrong, contending that "lower courts have defied [this Court's] directive," in a "trend" of decisions that are "quite wrong." Pet. 15. Petitioner claims that the lower courts have erred in two ways: (1) misinterpreting *Levine*, and (2) "gutt[ing]" the impossibility preemption defense to make it "impossible for brand-name drug manufacturers to establish preemption." Pet. 15, 18-19 (capitalization omitted). In both respects, petitioner mischaracterizes the lower court cases. Lower courts have carefully applied *Levine*'s anti-preemption rule and clear-evidence exception to the facts of each case, in ways that have resulted in both approval and rejection of preemption defenses.

First, the petition itself disproves petitioner's argument that lower courts have misinterpreted *Levine*. Petitioner bizarrely claims that lower courts have defied this Court by applying the preemption standard exactly as this Court articulated it, requiring "clear evidence" that the FDA would reject a label change to support a preemption defense. Pet. 19 (citing cases). Petitioner's real argument is that this Court did not mean what it said in *Levine*. But this Court's holding that failure-to-warn claims are not preempted absent clear evidence that it would have been impossible to add a warning was no "offhand, solitary reference," as petitioner argues (at 19); it followed from this Court's lengthy analysis of the federal regulatory scheme, which showed that the "premise" of the Federal Food, Drug, and Cosmetic Act is "that manufacturers, not the FDA, bear primary

responsibility for their drug labeling at all times." *Levine*, 555 U.S. at 579.

Second, the contention (at 18) that lower courts "have made proving impossibility preemption under *Levine* next to impossible" is demonstrably incorrect, disproven by the many lower court cases upholding that defense. *See*, *e.g.*, *Robinson*, 615 F.3d at 873; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 43 (1st Cir. 2015); *Cerveny*, 855 F.3d at 1105; *Rheinfrank*, 680 F. App'x at 385; *Reckis*, 28 N.E.3d at 458 (finding claims partially preempted); *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1280 (W.D. Okla. 2011); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1120-23 (S.D. Cal. 2015), *appeal pending*, No. 15-56997 (9th Cir.). The outcome of this case resulted from petitioner's own failure of proof, not any barrier to preemption erected by the lower courts.

No reason exists to depart from this Court's general practice of "permitting several courts of appeals to explore" an issue and "waiting for a conflict to develop" before granting review. *United States v. Mendoza*, 464 U.S. 154, 160 (1984). That practice is especially appropriate here because conflict preemption issues continue to percolate in the lower courts. For example, in a pending appeal involving diabetes drugs, *Adams v. Merck Sharp & Dohme Corp.*, No. 15-56997 (9th Cir. argued Oct. 3, 2017), the Ninth Circuit is reviewing the district court's grant of summary judgment to defendants (including petitioner) on preemption grounds. Before oral argument, the court issued an order for the parties to be prepared to address the Third Circuit's decision. Order, *Adams*, No. 15-56997, Dkt. 115 (Sept. 15, 2017). If a later circuit court decision disagrees with the decision

below, the Court can consider taking up the issue then. No circuit split warranted this Court's review when it denied certiorari in *Reckis*, 136 S. Ct. 896 (2016), and petitioner concedes that none has developed since.[3]

II. THE THIRD CIRCUIT'S DECISION WAS CORRECT

The Third Circuit correctly determined that petitioner had not established that the FDA would have rejected "a properly-worded warning" of atypical femoral fractures. App. 5a. The FDA's Complete Response to petitioner's proposed warning cited only one reason for the rejection: language that described incorrectly, and minimized the seriousness of, these fractures by referring to them as "stress fractures." Petitioner's theory — that the FDA issued a false Complete Response and that the real reason was insufficient scientific evidence to support any warning — hinged primarily on an ambiguous, self-serving

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[3] *Amici* argue that lower courts are "sharply divided" and "have reached conflicting outcomes on virtually identical regulatory records." PLAC/Chamber Br. 6. This Court should not grant certiorari based on a supposed split identified by *amici* that petitioner concedes does not exist. In any event, *amici* are incorrect. Application of the *Levine* standard is fact-specific, hinging on the drug at issue, the evidence of causation, the FDA's regulatory actions with respect to the drug, and the nature of the plaintiff's legal theories. *See Reckis*, 28 N.E.3d at 457; *Cerveny*, 855 F.3d at 1104. *Amici*'s discussion of the case law (at 9-12) does not show a split warranting this Court's review, but instead reveals courts applying the same legal standard to different facts and legal claims and coming to different results based on the specific circumstances of each case. Moreover, the only so-called splits identified by *amici* involve purported conflicts between *other* decisions. *Amici* point to no decision that conflicts with *this* decision, making this case a poor vehicle to address the issues raised in those other cases.

memorandum by petitioner's employee of a telephone call with an FDA official. Moreover, the FDA *mandated* a proper warning less than 18 months after rejecting petitioner's inaccurate and misleading proposed warning, so it is undisputed that sufficient scientific evidence exists that Fosamax causes atypical femoral fractures to justify a warning. In light of the weakness of petitioner's evidence, the Third Circuit was charitable to petitioner by allowing further proceedings on the preemption defense rather than rejecting it outright.

Petitioner argues for a sweeping rule that, when the FDA rejects *any* proposed warning relating to *any* medical risk, *all* failure-to-warn claims regarding *all* arguably similar risks are preempted, even if the FDA explains that it rejected the warning because the manufacturer's description of the risk was inaccurate and misleading. Pet. 29-30. According to petitioner, it is the FDA's obligation to propose specific warning language, and, in the absence of the FDA mandating a warning, claims that the manufacturer should have added a warning are preempted. Pet. 24. That argument ignores *Levine*'s fundamental teaching that, under federal law, "the manufacturer bears responsibility for the content of its label at all times." 555 U.S. at 570-71.

A. The Third Circuit Correctly Determined That Factual Disputes Existed Regarding Whether The FDA Would Have Rejected A Properly Worded Femur-Fracture Warning

1. The Third Circuit correctly denied summary judgment to petitioner because petitioner failed to proffer clear evidence that the FDA would have rejected a properly worded warning of atypical femoral fractures. There is no dispute that reason-

able evidence exists that Fosamax causes atypical femoral fractures; petitioner agreed as such when it added an atypical femoral fracture warning to the Warnings and Precautions section in January 2011. App. 23a; C.A.App. 1070.

There is ample evidence that petitioner could have added an atypical femoral fracture warning much earlier than that. By 2002, the proliferation of previously rare atypical femoral fractures among Fosamax patients was so extreme that leading orthopedic surgeons began to call them "Fosamax Fracture[s]." C.A.App. 875-76, 1254, 1261. Surveying the scholarly literature and petitioner's adverse event reports, respondents' experts (whose admissibility and qualifications were not challenged) opined that sufficient evidence existed to justify a warning by 2005, if not sooner. C.A.App. 878, 1015. And the FDA stated in 2008 that it was "concerned" about the relationship between bisphosphonates and atypical femoral fractures. C.A.App. 1145.

Petitioner's preemption defense is based on the FDA's rejection of proposed language to warn of "stress fractures." App. 15a-16a (proposed language). But the FDA's "Complete Response" letter explained that the rejection was because "[i]dentification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature." App. 18a; C.A.App. 1500.

In its Complete Response, the FDA was required by its own regulations to "describe *all* of the specific deficiencies that the agency has identified in an application." 21 C.F.R. § 314.110(a)(1) (emphasis added). Yet the Complete Response said nothing regarding what petitioner contended was the real reason for the rejection: a supposed deficiency in

the scientific evidence that Fosamax causes atypical femoral fractures. App. 59a.[4] Petitioner repeatedly (but erroneously) contends that denying preemption would require "conjecture," "speculation," or "psycho-analysis" about "some 'hypothetical' reason" that the FDA rejected petitioner's proposed language. Pet. i, 2, 14, 23, 25, 28, 29, 30. The FDA told petitioner exactly why it rejected the language in its official Complete Response. Petitioner just does not like the answer.

If there were any doubt that the FDA disapproved of petitioner's inaccurate and misleading conflation of atypical femoral fractures with stress fractures, that doubt was dispelled the next year. In 2010, after the FDA mandated a warning of atypical femoral fractures, petitioner again proposed language referring to the fractures as stress fractures. App. 22a. The FDA struck every instance of the term "stress fracture" from petitioner's proposed language, explaining that "the term 'stress fracture' was considered and was not accepted" because, "for most practitioners, the term 'stress fracture' represents a minor fracture and this would contradict the seriousness of the atypical femoral fractures associated with bisphosphonate use." App. 22a-23a; C.A.App. 1540, 1557. One need only glance at a gruesome x-ray of someone who has suffered an atypical femoral fracture, C.A.App. 1226, to understand that the term "stress fracture" does not adequately convey the risk to physicians or patients.

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[4] To the contrary, the FDA approved an atypical femoral fracture warning in the Adverse Reactions section, C.A.App. 1500, which required the FDA to conclude there was "some basis to believe there is a causal relationship between" Fosamax and atypical femoral fractures. 21 C.F.R. § 201.57(c)(7).

2. Petitioner argued that the real reason for the FDA's rejection was one nowhere stated in the Complete Response — that scientific evidence of causal association was insufficient to justify any warning. App. 59a. This argument depends on the premise that the FDA violated its own regulations and submitted a misleading Complete Response. The evidence put forward by petitioner to support this theory was at best speculative.

As an initial matter, petitioner distorts the record by misleadingly citing the Third Circuit's rehash of petitioner's legal arguments as a representation of the undisputed facts. *See* Pet. 24 (citing App. 59a-61a). The Third Circuit summarized both sides' glosses on the evidence, *see* App. 59a-62a (petitioner); App. 63a-67a (respondents), before concluding that, based on the evidence, a reasonable factfinder could find for either side, App. 67a-68a. Contrary to petitioner's representation (at 24), the Third Circuit never characterized as "bizarre" the idea that the FDA would have accepted a properly worded atypical femoral fracture warning after rejecting an inaccurate and misleading warning. In fact, the Third Circuit held that "Plaintiffs have produced sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly-worded warning about the risk of thigh fractures." App. 5a.

Petitioner stated below that its "single best piece of evidence" for its theory was a memorandum by petitioner's employee, Ms. Merritt, of a telephone conversation she had with Dr. Monroe, the FDA official who wrote the Complete Response. App. 49a n.125; C.A.App. 1970; *see* Pet. i, 9 (quoting this memorandum). As the Third Circuit correctly noted, a decisionmaker would need to resolve a host of factual

disputes to "gauge the import" of the memorandum, including to:

> (1) make a credibility determination regarding the Merck employee who drafted the notes; (2) determine the veracity and accuracy of the notes; (3) determine the semantic meaning of Dr. Monroe's statements; (4) infer Dr. Monroe's intent and state of mind when making the statements; and (5) weigh that inference against whatever competing inferences can be drawn from Dr. Monroe's subsequent letter rejecting Merck's proposed warning.

App. 49a n.125. These factual issues precluded the grant of summary judgment to petitioner.

Another document relied on heavily by petitioner is the FDA's email to petitioner stating it would like to "work with . . . [petitioner] to decide on language for a W&P [Warnings and Precautions] atypical fracture language, if it is warranted." C.A.App. 1498; *see* Pet. 9, 24 (quoting this document). That document in fact supports respondents. It shows that the FDA wanted petitioner to come forward with alternative warning language and that the agency was open to approving such language. If, as petitioner contends, the FDA had come to a definitive conclusion that it would reject any atypical femoral fracture warning because of insufficient scientific evidence, that outreach would have been illogical.

In sum, the evidence shows that the FDA would have welcomed a properly worded warning about atypical femoral fractures. Petitioner fell far short of meeting its burden on summary judgment to show clear evidence that the FDA would have rejected such a warning.

B. Petitioner's Arguments Are Inconsistent With This Court's Precedents

The Third Circuit faithfully followed *Levine*. Petitioner's attacks on the decision below are actually attacks on *Levine*, but *Levine* was correctly decided and forecloses petitioner's arguments.

1. Petitioner asks for a bright-line rule that *any* FDA rejection of proposed warning language relating to a medical risk "should suffice — as a matter of law — to preempt state tort liability" for all failure-to-warn claims relating to such a risk. Pet. 30. As a threshold matter, this case provides no opportunity to adopt such a rule because the warning that petitioner proposed and the FDA rejected related to a different risk (stress fractures) than respondents experienced (atypical femoral fractures).

In addition, petitioner's theory ignores the reality that, when the FDA rejects an inaccurate and misleading warning and specifically cites the inaccurate and misleading nature of the warning in its official rejection letter, the FDA would not necessarily reject a properly worded warning of the actual medical risk at issue. As *Levine* noted, a failure-to-warn claim requires showing only that the existing "warning was insufficient." 555 U.S. at 565. Thus, a preemption defense requires "clear evidence that the FDA would not have approved a change to [a drug's] label," *id.* at 571, not just evidence that a specific, misleading formulation of a different warning had been rejected. To adopt petitioner's bright-line rule would deprive the FDA of flexibility to do just what it did here: reject an inaccurate and misleading warning and invite the manufacturer to submit an appropriate warning.

2. Petitioner contends that the fact that the FDA did not immediately *mandate* alternative warning

language means that it would have *rejected* any alternative language proposed by petitioner. Pet. 24. According to petitioner, if there is sufficient scientific evidence to support a warning, it is the FDA's "statutory obligation[]" to mandate such language, so failure-to-warn claims should be preempted absent such a mandate. Pet. 24, 29. That argument misreads the federal drug laws and ignores the central lesson of *Levine*.

Petitioner is incorrect to assert that the FDA has a "statutory obligation[]" to mandate a warning whenever the regulatory standard for a warning is satisfied. Pet. 24; *see also* Pet. 13. The decision whether to mandate such a change is wholly discretionary, hinging on whether the "Secretary [of Health and Human Services] believes" that a label should be changed. 21 U.S.C. § 355(*o*)(4)(A).[5] Moreover, when Congress empowered the FDA to mandate warnings, "it adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels." *Levine*, 555 U.S. at 567-68.

Thus, the Third Circuit correctly followed this Court's holding that, "[a]s a matter of law, . . . the burden and the responsibility to correct a drug label rests with the manufacturer, not the FDA." App. 67a & n.162 (citing *Levine*, 555 U.S. at 570-71; 21 U.S.C.

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[5] According to FDA guidance, "FDA does not anticipate that all labeling changes that may be related to safety will be required and reviewed under [21 U.S.C. § 355(*o*)(4)]. For other labeling changes, application holders may continue to submit labeling supplements using standard procedures," including the CBE regulation. FDA, *Guidance for Industry Safety Labeling Changes — Implementation of Section 505(o)(4) of the FD&C Act* 5-6 (July 2013), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM250783.pdf.

§ 355(*o*)(4)(I)). "Once the FDA rejected [petitioner's] proposal, the ball was back in [petitioner's] court to submit a revised, corrected proposal," App. 67a, particularly because the FDA repeatedly invited petitioner to do so. *See supra* p. 8. The record therefore supported the inference "that it was [petitioner's] failure to re-submit a revised CBE or PAS without stress-fracture language, rather than the FDA's supposedly intransigent stance on the science, that prevented the FDA from approving a label change." App. 67a.

3. Contrary to petitioner's argument (at 25-28), the Third Circuit faithfully interpreted *Levine* in holding that the "clear evidence" standard imposed a heightened standard of proof akin to the "clear and convincing evidence" standard. App. 33a-37a. As the Third Circuit noted, this Court has traditionally used the phrase "clear evidence" as equivalent to "clear and convincing evidence," a standard of proof higher than "mere preponderance of evidence." *E.g.*, *Oriel v. Russell*, 278 U.S. 358, 362-63 (1929); *Ramsey v. United Mine Workers*, 401 U.S. 302, 307-09, 311 (1971) (interpreting statute requiring "clear proof" as requiring "clear and convincing evidence"); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 97, 113-14 (2011) (equating Federal Circuit's "clear evidence" standard for patent invalidity with a "clear-and-convincing-evidence standard").

Petitioner contends (at 27) that this Court imposes a clear-and-convincing-evidence standard only "for good reason." But the majority and concurring opinions in *Levine* identified multiple good reasons for a heightened standard of proof. As the majority explained, because "a central premise of federal drug regulation" is "that the manufacturer bears responsi-

bility for the content of its label at all times," it is "difficult to accept" the idea that the FDA would punish a manufacturer "for strengthening a warning." 555 U.S. at 570-71. As Justice Thomas noted, preemption of failure-to-warn claims against brand-name drug manufacturers goes beyond traditional impossibility preemption because the CBE regulation makes it "physically possible" for a manufacturer "to comply with a state-law requirement to provide stronger warnings . . . while continuing to market [a drug] in compliance with federal law." *Id.* at 591-92 (Thomas, J., concurring in the judgment). Because such preemption arguments rest on speculation that a federal agency *might have* blocked a manufacturer if it complied with state law (rather than a contention that compliance with state law was impossible in the first instance), this Court properly imposed a heightened burden to advance "clear evidence" to support such a defense.

In any event, application of a preponderance standard would have made no difference in the outcome of this case. That is because, regardless of the standard of proof, "[s]ummary judgment is appropriate only if 'the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law.' In making that determination, a court must view the evidence 'in the light most favorable to the opposing party.'" *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam) (quoting Fed. R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970)). Given the summary-judgment standard, the weakness of petitioner's evidence, and the factual disputes raised by petitioner's reliance on Ms. Merritt's memorandum, petitioner could not have won summary judgment under any standard of proof.

4. Nor was it error, under the circumstances of this case, to hold that the preemption inquiry involved disputed factual issues for the factfinder. The Third Circuit concluded that, while "*most* preemption cases present purely legal questions[,] . . . it is equally clear that preemption can be, and sometimes must be, a fact question for the jury." App. 42a. That conclusion was consistent with and compelled by this Court's holding in *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988), that, in the context of a government contractor preemption defense, "whether the facts establish the conditions for the defense is a question for the jury." *Id.* at 514.

Here, petitioner's efforts to contradict the official regulatory record with self-serving hearsay evidence of informal communications with the FDA provided no basis for granting summary judgment in petitioner's favor. The official regulatory record did not support petitioner's preemption defense, because the FDA's Complete Response listed the inaccurate and misleading stress-fracture language as the only deficiency in petitioner's proposed warning application. C.A.App. 1500-01. However, petitioner supported its preemption defense by citing a memorandum written by one of petitioner's employees regarding a telephone conversation she had with the same FDA official who wrote the Complete Response, which (under petitioner's reading of the memorandum) supported a contradictory inference about why the FDA rejected petitioner's proposed warning. As the Third Circuit concluded, assessing such evidence requires "precisely the types of personal evaluations and weight-of-the-evidence assessments" that are typically reserved for the trier of fact. App. 49a n.125.

III. THIS CASE PRESENTS A POOR VEHICLE TO ADDRESS THE SCOPE OF CONFLICT PREEMPTION

Even if the Court wished to address the scope of conflict preemption of failure-to-warn claims, this case is a poor vehicle to do so in many respects.

1. This case does not implicate the policy concerns that petitioner and *amici* contend warrant review. Petitioner asserts that review is necessary because state tort law can "undermine[] the FDA's expert judgment" about what warnings are necessary, leading to overwarning where "the FDA would have made" a different "policy decision" from the jury. Pet. 31-32. Similarly, *amici* warn that state tort lawsuits can upset the "balance" of what warnings should be included on the label and lead to "warnings that are not grounded in science." PhRMA Br. 6.

At the outset, this Court rejected those policy arguments in *Levine*. There, as here, the drug manufacturer contended that FDA regulation "establishes both a floor and a ceiling for drug regulation." 555 U.S. at 573. This Court disagreed, explaining that "all evidence of Congress' purposes is to the contrary." *Id.* at 574. The policy arguments of petitioner and its *amici* cannot be reconciled with this Court's rejection of the same arguments in *Levine*.

In any event, petitioner's and *amici*'s policy concerns are entirely inapplicable here, because the FDA has in fact determined that Fosamax's label should include a warning about atypical femoral fractures. In October 2010, the FDA required all bisphosphonate manufacturers to add an atypical femoral fracture warning, based on its scientific judgment that "'these atypical fractures may be related to long-term . . . bisphosphonate use.'" App.

20a (quoting C.A.App. 1118) (alteration in original). Accordingly, in January 2011, petitioner added a warning of "Atypical Subtrochanteric and Diaphyseal Femoral Fractures" to the Fosamax label. C.A.App. 1070-71. Thus, the FDA has already made an "expert judgment" and a "policy decision" that an atypical femoral fracture warning *is* appropriate. In agreeing to add an atypical femoral fracture warning (rather than challenging the FDA's scientific determination), petitioner has forfeited any argument that such a warning is "not grounded in science."

These cases are thus different from the typical failure-to-warn case where the parties dispute the necessity of a warning. Here, petitioner and the FDA *agree* with respondents that a warning is necessary. These cases cannot result in a situation in which the manufacturer would need to add a warning to avoid liability, because that warning was added to the label more than six years ago (albeit too late to prevent respondents' injuries). Accordingly, any concerns that state tort lawsuits encourage over-warning or upset the FDA's judgments are wholly inapplicable here.

2. This case is also a poor vehicle because the district court's violations of respondents' procedural rights may prevent, and will at least hinder, the Court from considering the question presented. As noted above, the district court held that respondents' claims were preempted on the basis of its preemption opinion in *Glynn v. Merck Sharp & Dohme Corp.*, a case to which *none* of the respondents was a party. On the basis of that opinion, the court ordered every respondent to show cause why their claims were not preempted, giving each respondent just 45 days to summon evidence in opposition to preemption. C.A.App. 769. Although respondents did the best they

could under the circumstances, they argued to the court that it would be procedurally improper to apply the ruling in the *Glynn* case (to which they were not parties) against them through a show-cause procedure that did not give them an adequate opportunity to develop evidence. Dist. Ct. Dkt. 2995-3.

In dismissing respondents' claims, the district court held that, on the basis of the *Glynn* ruling, "the burden [wa]s therefore shifted to [respondents]" to disprove preemption, App. 132a, in violation of the controlling summary-judgment standard. The court then applied its *Glynn* ruling to respondents, with minimal additional analysis. App. 150a-152a. Respondents argued on appeal that "[i]t was procedurally improper for the district court to shift the burden to [respondents] as a result of the preemption opinion in *Glynn*." Plaintiffs-Appellants C.A. Br. 67. Although the Third Circuit did not need to reach respondents' procedural objections because it held that petitioner was not entitled to summary judgment, it did note that "a deeper problem lurking" in the district court's analysis was its inability to acknowledge that "[a] mass tort MDL is not a class action," but "is a collection of separate lawsuits that are coordinated for pretrial proceedings — and *only* pretrial proceedings," and that "the District Court's understandable desire to streamline proceedings cannot override the Plaintiffs' basic trial rights." App. 72a-73a.

If this Court grants certiorari, respondents may raise the district court's violations of their procedural rights as an alternative and independent ground for affirming the Third Circuit's ruling that petitioner was not entitled to summary judgment. *See United States v. Tinklenberg*, 563 U.S. 647, 661-63 (2011) (affirming based on "alternative grounds"). Should this

Court agree with respondents' procedural arguments, it will not be able to reach the question presented by the petition.

At the very least, the district court's cursory procedure led to an underdeveloped factual record. For example, petitioner's "single best piece of evidence," App. 49a n.125, was Ms. Merritt's memorandum purporting to summarize her telephone conversation with Dr. Monroe. But Ms. Merritt has not been deposed. Moreover, the district court's decision to dismiss more than 500 lawsuits in one fell swoop with no analysis of the specific circumstances of any case may hinder this Court's review, should this Court determine that plaintiff-specific facts (such as the timing of respondents' injuries or the state law that applies to their claims) are relevant to the analysis. If this Court wishes to consider the scope of conflict preemption, it should do so in the context of a fully developed factual record, not in a circumstance in which the district court's unorthodox use of a show-cause order forced the parties to scramble to gather evidence in 45 days.

3. Even if petitioner prevails on the question presented, it will have limited impact (and may have no impact) on these cases. Petitioner concedes (albeit buried in a footnote) that respondents' failure-to-warn claims *are not preempted* insofar as they are based on the theory that petitioner should have added a warning of atypical femoral fractures to the Adverse Reactions section of the label before June 2009. Pet. 13 n.1.[6] Thus, even if this Court rules

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[6] As the Third Circuit recognized, even respondents injured after June 2009 can assert that their injuries were caused by Fosamax usage before the Adverse Reactions label change. App. 70a n.165.

for petitioner, respondents' failure-to-warn claims will survive. They would merely be narrowed from two sections of the Fosamax label (Adverse Reactions, and Warnings and Precautions) to one (Adverse Reactions).[7]

Moreover, petitioner does not challenge the Third Circuit's separate holding that none of respondents' non-failure-to-warn claims are preempted. App. 74a. As the Third Circuit noted, many of respondents' complaints include claims for design defect, negligence, fraud, breach of warranty, deceptive trade practices, and other claims. App. 24a.[8] Petitioner does not even mention these claims in its petition. These claims, like the Adverse Reactions aspect of the failure-to-warn claims, will survive regardless of this Court's ruling.

Even as to the Warnings and Precautions aspect of respondents' failure-to-warn claims, the Third Circuit did not reject petitioner's preemption defense but merely denied summary judgment. App. 67a-68a. Nothing justifies the extraordinary step of granting review in this interlocutory posture. Petitioner may yet prevail on remand, either on its preemption defense or on some other ground. And petitioner has identified nothing that would prevent this Court

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[7] Petitioner's description (at 13 n.1) of the Adverse Reactions theory as a "distinct failure-to-warn claim" is inaccurate. As the Third Circuit explained, respondents "alleg[ed] generally that the Fosamax label did not adequately warn patients and doctors of the fracture risk," and these general allegations encompassed both "the Warnings and Precautions theory" and "the Adverse Reactions theory." App. 71a.

[8] *See* C.A.App. 2252-80, 2304-06, 2311-15, 2331-33, 2335-47 (examples of non-failure-to-warn claims in respondents' complaints).

from reviewing the preemption issue on appeal from a final judgment, in the event petitioner does not prevail.

4. Finally, petitioner's argument (at 34) that this case provides "an excellent vehicle for putting another stake in the ground . . . to illustrate facts that *prove* preemption" has no merit. For several reasons described in greater detail above, petitioner's preemption evidence is weak:

(1) It is undisputed that sufficient scientific evidence exists to justify an atypical femoral fracture warning.

(2) The FDA mandated an atypical femoral fracture warning many years ago.

(3) The first time petitioner proposed any warning, the FDA approved a warning on one section of the Fosamax label.

(4) The FDA's only reason given in its Complete Response for rejecting the proposed language on the other section of the Fosamax label was that petitioner's language mischaracterized the risk, and the FDA later confirmed that this proposed language "contradict[ed] the seriousness" of the risk and would confuse physicians by making serious atypical femoral fractures seem like a "minor fracture."

(5) Petitioner's "single best piece of evidence" to support preemption was a self-serving memorandum written by one of petitioner's employees purporting to describe a phone call she had with an FDA official.

If the Court wants to review a case involving unassailable evidence of preemption in order to plant a "stake in the ground," it should look elsewhere.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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