No. 17-290

IN THE Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

DORIS ALBRECHT, ET AL.,

Respondents.

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

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers. Its 84 corporate members make and sell a wide variety of products, including automobiles, trucks, aircraft, electronics, cigarettes, tires, chemicals, pharmaceuticals, and medical devices.[2] 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.

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three

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[1] All parties have filed blanket letters of consent with the Clerk. Pursuant to S. Ct. Rule 37.6, *amici* state 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 *amici curiae*, their members, or their counsel, has made a monetary contribution to this brief's preparation or submission.

[2] For a full list of PLAC's corporate members, see https://plac.com/PLAC/AboutPLACAmicus.

million companies and professional organizations of every size, in every industry sector, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. It presents an important question that has produced uncertainty and serious confusion in the lower courts involving the scope of implied conflict preemption in the aftermath of this Court's decision in *Wyeth* v. *Levine*, 555 U.S. 555 (2009). PLAC, the Chamber, and their members have a vital interest in the proper resolution of the question presented.

STATEMENT

1. *The Supremacy Clause and Implied Conflict Preemption*. Congress has the authority to specify the extent to which federal statutes preempt state and local law, and the United States Code contains many such "express" preemption provisions. Even in the absence of such specification, however, 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). Although this Court has referred to "impossibility," "obstacle" and ordinary "conflict" preemption as forms of implied preemption, these "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).

The Supremacy Clause serves a vital structural role in our Nation's government by protecting federal laws and programs against interference by subordinate governments. Like express preemption clauses, the Supremacy Clause also helps to create unified markets for nationally distributed goods and services by ensuring that uniform federal regulation – often the product of expert agency decision-making under authority delegated by Congress – is not undermined by state or local law, including state tort law as applied by lay juries. And the Supremacy Clause ensures that regulated individuals, businesses, and other entities are not placed in the impossible position of being compelled to obey directly conflicting obligations imposed by federal and state law. This case raises an important question concerning the Supremacy Clause's meaning in the context of prescription pharmaceuticals.

2. *Wyeth* v. *Levine*. In *Levine*, this Court addressed the preemptive effect of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, implementing regulations relating to drug labeling, and FDA regulatory oversight on state-law failure-to-warn claims against prescription-drug manufacturers. See Pet. Br. 2-6 (describing regulatory framework). Federal law, this Court explained, does not preempt such claims if applicable regulations would have allowed the manufacturer unilaterally to alter its previously approved labeling and FDA ultimately would have approved that change, but does preempt if FDA would have rejected

the change. 555 U.S. at 568, 570-71 (discussing "Changes Being Effected" (CBE) regulation), 21 C.F.R. § 314.70(c)). In *Levine*, the manufacturer had asserted both that FDA "intended to prohibit it from strengthening the warning" when the agency originally approved the drug and that FDA would have rejected the warning change proposed by plaintiff, but the Vermont courts rejected those contentions. This Court affirmed the Vermont Supreme Court's resulting no-preemption ruling, observing that the record lacked "clear evidence" supporting the manufacturer's contentions. *Id.* at 571-72 & nn.5-6. In fact, this Court explained, 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; emphasis added).

3. *The Decisions Below*. This case arises out of a multi-district litigation (MDL) involving more than a thousand state-law tort actions, including claims for failure to warn, brought against petitioner Merck Sharpe & Dohme Corp. (Merck), which manufactures the osteoporosis drug Fosamax. Among other things, plaintiffs claimed Merck should have provided a stronger warning concerning the risk of certain bone fractures.

Following a bellwether trial – and based on a painstaking analysis of "a complete record" (including extensive documentary and other evidence regarding FDA's oversight of the drug's labeling) – the district court concluded that "preemption is warranted because there is clear evidence that the FDA would not have approved a change to the Precautions section

of the Fosamax label prior to" plaintiff's injury. Pet. App. 164a, 168a, 169a-174a; see also *id.* at 156a-162a.

The Third Circuit vacated and remanded. Pet. App. 1a-95a. Parting company with other courts, it held that *Levine*'s unelaborated reference to "clear evidence" was meant to impose on defendant a heightened standard of proof akin to "clear and convincing evidence" under which defendant must prove that FDA would have rejected the proposed warning change. Breaking additional new ground, the court ruled that whether FDA would have rejected a warning is a question *for the jury*, even where, as here, the historical facts are undisputed. Under that approach, a manufacturer cannot prevail pre-trial, as a matter of law, unless there is a "smoking gun" FDA rejection letter from which a jury could only find the claim preempted. Pet. App. 36a-37a, 54a-55a. Based on those demanding standards, the Third Circuit opined that a reasonable jury "*could* conclude" that FDA would have allowed the labeling change sought by plaintiffs (even though FDA had in fact *rejected* proposed warning language concerning the very risk in question). *Id.* at 67a. The court remanded for juries in individual cases to decide, following a full trial, what FDA would have done.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises an important question of federal law – and the meaning of the Supremacy Clause – that has vexed the lower courts and is of paramount importance to the pharmaceutical industry. The central question turns on the meaning of certain language in *Wyeth* v. *Levine*, 555 U.S. 555 (2009) –

specifically, this Court's statement that an "impossibility" preemption defense was not available on the particular record developed there because there was not "clear evidence" that FDA would have rejected the warning sought by plaintiff. *Id.* at 571. In the decision below, the Third Circuit adopted a novel gloss on those two words in *Levine* and, in so doing, erected an exceedingly high – and unwarranted – barrier to pharmaceutical manufacturers' conflict preemption defenses.

I. The Third Circuit held that this Court's unelaborated reference to "clear evidence" was intended to impose on defendants the "clear and convincing" burden of proof. That is mistaken. Contrary to the Third Circuit's view, *Levine* did not adopt a heightened burden of proof for prescription pharmaceutical cases. Instead, this Court's reference to "clear evidence" merely reflects 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. So much is apparent from the authorities cited by this Court in *Levine*. 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"). Indeed, *Geier* specifically *rejected* as unworkable and unwieldy a proposal to impose on defendants a "special burden" to establish conflict preemption. It is implausible, to say the least, that this Court created exactly such a special burden in

Levine while citing and relying on *Geier*. Moreover, the parties neither briefed nor argued the burden-of-proof issue, which was unnecessary to decide anyway since there was *no* evidence FDA would have rejected the relevant warning.

In adopting the demanding "clear and convincing" standard of proof, the Third Circuit not only overlooked the origins of the "clear evidence" language in this Court's prior preemption cases but also relied on various *non-preemption* decisions that (as petitioner amply demonstrates) are all readily distinguishable. See Pet. Br. 45-46. The cited cases involve either instances where Congress has specified a higher standard or such standard is needed to protect a compelling interest, which is not true here. Notably, the Third Circuit also ignored the procedural posture of *Levine*, in which this Court could not have rejected any *factual* determinations of two state courts absent "extraordinary" circumstances, *i.e.*, "clear evidence" those determinations were erroneous.

As petitioner and the Solicitor General both explain, this Court could elect to reverse the Third Circuit's decision without addressing the meaning of "clear evidence" in *Levine*, simply by distinguishing that case (as not involving an FDA decision rejecting the proposed warning in question). But PLAC and the Chamber urge the Court not to rule so narrowly. Instead, this Court should treat the meaning of "clear evidence" in *Levine* as a threshold issue and clarify it. Doing so would go far toward dispelling the serious confusion – and conflicting results and approaches – that have plagued the lower-court decisions since *Levine*. And only this Court can clarify what it meant by "clear evidence."

More specifically, PLAC and the Chamber urge this Court to clarify that "clear evidence" means nothing more than it does in other conflict preemption cases: evidence of an actual, as opposed to a merely hypothetical, conflict between state and federal law. Nothing in *Levine* – where this Court, like both Vermont courts, resolved the preemption issue *as a matter of law* – was intended to adopt a standard of proof *for facts*, much less one different from the ordinary preponderance-of-the-evidence standard. Finally, this Court should leave to the lower courts the exploration, in the first instance, of additional arguments about how any burden of proof might be structured.

II. The Third Circuit also erred in concluding that the question whether FDA would have rejected a proposed warning is a *fact* question *for the jury*, even when (as in this case) the historical facts are undisputed. As petitioner and the Solicitor General demonstrate, it was wrong to apply that approach in this case which, unlike *Levine*, involved an *actual* decision by FDA to reject a warning concerning the risk that was at the center of respondents' claim. The meaning and effect of FDA's decision presents a *legal* question for the court, not a factual question for a jury.

Although this rationale would suffice to reverse the decision below, PLAC and the Chamber urge the Court to go further and make clear that in all cases involving prescription drug manufacturers, issues relating to conflict preemption – including counterfactual questions concerning whether FDA would have rejected a warning the manufacturer never proposed – are properly resolved by courts, not juries. The Third Circuit was wrong to believe that

the proper decisionmaker for such counterfactual issues was left open in *Levine*; in fact, both Vermont courts and this Court decided that issue for themselves without suggesting it was properly for a jury. That approach, which as the Third Circuit acknowledged has since been followed by many lower courts, fits comfortably within the traditional framework for resolving conflict preemption issues. It is also consistent with the history and form of the Supremacy Clause – the basis for conflict preemption – which expressly refers to "Judges" and is cast in the form of a *non obstante* clause specifically directed at judicial interpretation.

The Third Circuit believed it could tease out from the legal conflict preemption analysis the specific question of what the FDA would have done under counterfactual circumstances, because that question purportedly is one of fact, not law. But whether that issue is properly characterized as one of fact (unlikely) or law, or mixed law and fact, it plainly requires the decisionmaker to understand the complex backdrop of FDA's regulations and procedures, including the standards the agency applies to determine whether there is a sufficient scientific basis to provide additional warnings (or other cautionary statements) in various parts of the highly regulated drug labeling. It may also, as here, require the decisionmaker to understand how the agency deals with concerns regarding the appropriate wording of proposed labeling changes. See U.S. Inv. Br. 5-6, 19-22. In addition, the decisionmaker, again as here, may have to interpret FDA decisions and communications, which are properly "read in the context of [the manufacturer's] underlying labeling supplement and the surrounding regulatory framework and related

FDA actions." *Id.* at 15. As the government correctly notes, "[e]ven if disputed subsidiary factual questions were relevant to determining the meaning and effect of the agency's 2009 decision, the ultimate inquiry would remain a legal one." *Ibid.*

Finally, in other settings that call for predictive determinations about what other institutional actors *would have done* under circumstances that did not actually occur, courts have themselves often resolved the issue as a matter of law. Examples include harmless error analysis, which asks what the outcome of a court proceeding would have been if error had not occurred, and severability analysis, which asks whether Congress would have enacted the same statute if it had known that one or more portions would later be invalidated; see *Murphy* v. *National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1482 (2018). Accordingly, there is nothing unusual about courts rather than juries deciding counterfactual issues in the context of conflict preemption issues under *Levine*. And, of course, that approach would avoid the practical problems that flow from treating the counterfactual issues as factual questions for lay juries.

III. The Third Circuit should also be reversed – and its problematic reasoning expressly disapproved – because it ignored this Court's decisions establishing that conflict preemption may not be impaired or evaded altogether through tactics such as artful pleading by plaintiffs, *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 214 (2004), or resort to mere speculative possibilities, *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 623 (2011), or overbroad arguments that could be used to defeat preemption in essentially all

cases, *Mutual Pharmaceutical Co.* v. *Bartlett*, 570 U.S. 472, 514-15 (2013).

Unless corrected, the Third Circuit's decisions to (a) adopt the clear-and-convincing standard of proof, and (b) assign to juries, rather than courts, the authority to make decisions about what FDA would have done under counterfactual circumstances, will have predictably negative effects. Those rulings will deprive litigants of the recognized benefits of preemption as a dispositive issue that can be resolved before trial; create perverse incentives for manufacturers to burden FDA with constant proposed labeling changes for preemption purposes (an institutional burden this Court declared to be important in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)); and inhibit drug development by imposing massive additional litigation costs on drug manufacturers in the rising tide of product liability litigation against them. Unless corrected by this Court, the Third Circuit's flawed reasoning will also encourage litigants in other preemption settings both to argue for heightened burdens of proof and to attempt to shift the responsibility for policing violations of the Supremacy Clause to lay juries.

ARGUMENT

I. THIS COURT SHOULD CLARIFY *LEVINE*'S REFERENCE TO "CLEAR EVIDENCE," WHICH THE THIRD CIRCUIT MISINTERPRETED

As both petitioner and the Solicitor General demonstrate, this Court could reverse the Third

Circuit's flawed decision without addressing or clarifying the meaning of *Levine*'s ambiguous reference to "clear evidence." It could do so on the ground that this case, unlike *Levine*, turns on the meaning and effect of an *actual* FDA decision regarding a labeling supplement, not a purely hypothetical scenario. As both petitioner and the Solicitor General show, the Third Circuit failed to recognize that, in this setting, the conflict preemption issue raises a question of law for the court, not the jury – and that issue should have been resolved in favor of petitioner because FDA rejected the warning plaintiffs said should have been provided. Such a narrow resolution of this case, however, would leave unaddressed the lower courts' considerable confusion concerning what this Court meant in *Levine*. For that reason, and because only this Court can clarify what it meant in *Levine*, PLAC and the Chamber urge the Court to address and clarify *Levine*'s reference to "clear evidence." Doing so would both prevent the Third Circuit's flawed interpretation from creating any further mischief and bring greater uniformity to this important area of federal law.

A. There Is Serious Confusion In The Lower Courts Over The Meaning Of *Levine*

As the Third Circuit recognized (Pet. App. 33a-36a), there is rampant confusion in the lower courts over the meaning of *Levine*'s reference to "clear evidence." The court of appeals correctly noted that the meaning of this language, on its face, was "cryptic" and "lower courts have struggled to make it readily administrable." Pet. App. 28a. The Third Circuit also acknowledged that at least two different approaches

have been developed in the lower courts, one "more complex" than the other – and then proceeded to reject both in favor of yet a third reading. *Id.* at 33a-35a.

The confusion over the meaning of "clear evidence" extends well beyond that recognized by the Third Circuit. On the same record involving the same warning for Children's Motrin, the Seventh Circuit and Massachusetts Supreme Judicial Court (SJC) reached diametrically opposed conclusions regarding conflict preemption. Compare *Robinson* v. *McNeil Consumer Healthcare*, 615 F.3d 861, 869-70, 873 (7th Cir. 2010) (concluding there was "clear evidence" FDA would have rejected proposed warning change) with *Reckis* v. *Johnson & Johnson*, 28 N.E.3d 445, 457-60 (Mass. 2015) (reaching opposite conclusion). Such conflicting outcomes necessarily reflect divergent understandings of what is required by *Levine*.

Further, there are multiple tertiary disagreements – and much confusion – in the lower courts over precisely what qualifies as "clear evidence." Compare, *e.g.*, *Aaron* v. *Wyeth*, 2010 WL 653984, at *6 (W.D. Pa. Feb 19, 2010) (holding manufacturer's proposal to FDA to add warning and agency's rejection not "clear evidence" because manufacturer "did not press its position" but "acquiesced" in FDA 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 *Levine*."). In their *amicus* brief at the petition stage (at 10-12), PLAC and the Chamber documented this widespread confusion in the lower-court decisions. Commentators have also acknowledged it. See Thomas Ayala & Elizabeth Graham, *Overcome the*

Clear Evidence Defense, 52 Trial 32, 34 & nn. 13-16 (July 2016) (acknowledging split of authority and discussing additional cases); Michael Gallagher, *Clear Evidence of Impossibility Preemption After Wyeth v. Levine*, 51 GONZ. L. REV. 439, 440-42 (2015-2016) ("[c]ourts have issued divergent opinions").[3]

This Court should decide this case in a way that eliminates this confusion. The need for clarification is underscored by the large and growing body of federal product-liability litigation in which the issue typically arises.[4] The Court has discretion to resolve this case in any way it sees fit, and it would be perfectly sensible to address the meaning of *Levine*'s reference to "clear evidence" as a threshold legal issue (as, indeed, the Third Circuit did, see Pet. App. 28a-29a, 33a-37a). As next explained, the Third Circuit adopted an interpretation of *Levine* that was fundamentally flawed and in need of correction.

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[3] The misunderstanding of how the conflict preemption inquiry should be conducted is also reflected in the suggestion of various lower courts that preemption cannot be established unless a manufacturer *actually proposes* the allegedly missing warning, the FDA *actually rejects the manufacturer's proposal*, or both. Requiring such proof denies preemption in precisely those cases involving the most scientifically unfounded warnings, which *no* manufacturer would ever propose (and FDA *unquestionably* would reject). That cannot possibly be the law, nor can it be what this Court meant in *Levine*.

[4] The MDL proceedings in this case alone involve more than 1000 lawsuits. As PLAC and the Chamber showed in the petition-stage brief (at 23-24), in recent years there has been a sharp rise in the number of federal product liability lawsuits (and MDLs) against pharmaceutical manufacturers.

B. The Third Circuit Misunderstood *Levine*'s Reference To "Clear Evidence"

The Third Circuit concluded that this Court's unelaborated reference to "clear evidence" was intended to impose a special, heightened burden of proof – to require, in other words, more than the usual mere preponderance of the evidence.[5] Relying on that reading, the Third Circuit expressly adopted the "clear and convincing" standard, whereas other lower courts have used different formulations that may be more or less demanding. Pet. App. 35a, 37a. See, *e.g.*, *Mason* v. *Smithkline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010) (describing "clear evidence" as an "exacting" and "stringent" standard); *Forst* v. *SmithKline Beecham Corp.*, 639 F. Supp. 2d 948, 953 (E.D. Wis. 2009) (under *Levine* "a defendant drug manufacturer faces an exacting burden"). In concluding that by "clear evidence" this Court really meant "clear *and convincing*" proof, the Third Circuit also relied on various non-preemption decisions of this Court that, as petitioner demonstrates, are all readily distinguishable because they involve either instances where Congress has specified a higher standard or

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[5] As petitioner demonstrates (Br. 43-44), standards of proof apply to issues of *fact*; evidentiary standards such as "clear and convincing proof" do not apply to questions of law. See *Microsoft Corp.* v. *i4i Ltd. Partnership*, 564 U.S. 91, 100 n.4 (2011); *id.* at 114 (Breyer, J., concurring). As explained below, conflict preemption issues under *Levine* should be resolved by courts, rather than juries, not only in cases (such as this) where the issue turns on ascertaining the meaning and effect of an FDA labeling decision based on undisputed historical facts, but also in cases where there are disputes over what the FDA might have done in counterfactual circumstances.

such standard is needed to protect a compelling interest. See Pet. Br. 45-46; Pet. App. 36a-37. Here, in contrast, the important interest at stake is that underlying the Supremacy Clause – and it cuts *against* the higher burden invented by the Third Circuit.

The Third Circuit misread *Levine*. For starters, it is highly implausible to assume this Court adopted a heightened burden of proof without any briefing or mention by the parties of the burden-of-proof issue. That is all the more unlikely because in *Levine* the manufacturer had provided *no* evidence FDA would have rejected the relevant labeling change – so there was simply no need to the reach the question whether anything more than a preponderance of the evidence was required. See 555 U.S. at 572 (manufacturer "does not argue that it attempted to give the kind of warning required by the Vermont jury"); *ibid.* ("trial court found *no evidence* in this record that either the FDA or the manufacturer gave more than passing attention to the issue of IV-push versus IV-drip administration") (internal quotation marks omitted; emphasis added). The Third Circuit's interpretation ignores or disregards this context.

Nor is this the only way in which the Third Circuit ignored aspects of *Levine* that bear on the meaning of "clear evidence." In *Levine*, this Court was evaluating the drug manufacturer's preemption arguments in light of *factual findings on historical facts* made *by two lower state courts* concerning (1) whether other warnings the manufacturer proposed and FDA rejected were materially different from the allegedly defective warning that actually accompanied the product, and (2) whether FDA

intended to prohibit the manufacturer from strengthening its warning. See 555 U.S. at 572 & n.5. This Court's statement that there must be "clear evidence" was no doubt informed by this procedural posture and what would have been necessary to overcome the state courts' findings. See *324 Liquor Corp.* v. *Duffy*, 479 U.S. 335, 351 (1987) (this Court "customarily accept[s] the factual findings of state courts in the absence of exceptional circumstances"); see also David Geiger & Andrew London, *Wyeth's "Clear Evidence" Language: Clearly Misunderstood*, Law360 (Jan. 12, 2016) ("'clear evidence' language was necessitated by the fact that the preemption issue turned on factual findings made by the Vermont courts, which the Supreme Court could not ordinarily reverse absent exceptional circumstances"). The Third Circuit's reading of *Levine* ignores the case's procedural posture.

But the Third Circuit's interpretation is flawed for a more fundamental reason: it utterly fails to take account of the backdrop of this Court's own *conflict preemption* decisions, which repeatedly have alluded to the need for "clear evidence" to establish conflict preemption and on which this Court relied in *Levine*. Had the Third Circuit done so, it would have recognized that, far from announcing a heightened standard of proof, *Levine*'s reference to "clear evidence" merely reflects well-settled and longstanding principles governing conflict preemption.

Federal preemption is usually raised as an affirmative defense. And in civil actions, the ordinary standard of proof on issues of fact is by a

preponderance of the evidence.[6] Thus, a defendant ordinarily must prove any facts necessary for a preemption defense by a preponderance of the evidence.[7] In a long line of cases, this Court has made clear that ordinarily the proponent of conflict preemption must demonstrate an *actual* conflict

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[6] See also note 5, *supra*. 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 legal judgment whether the former conflicts with, or serves as an obstacle to, the latter. *Perez* v. *Campbell*, 402 U.S. 637, 644 (1971).

[7] Courts and commentators have suggested that, in prescription-drug failure-to-warn cases, the burden of proof ought to be structured differently and placed on plaintiff in whole or at least in part. See Geiger & London, *supra*, Law360 (arguing that, in light of federal regulatory scheme, plaintiff should bear burden to prove what constitutes an *exception* to the preemption that would otherwise exist once defendant proved it was using FDA-approved labeling); *Utts* v. *Bristol-Myers Squibb Co.*, 2017 WL 1906875, at *9, *19 (S.D.N.Y. May 8, 2007) (only after plaintiff "prove[s] the existence of newly acquired information" allowing a manufacturer to submit a CBE does burden shift to manufacturer to show that FDA would have rejected labeling change). And this Court has made clear that preemption is not always "in the nature of an affirmative defense." *Int'l Longshoremen's Ass'n* v. *Davis*, 476 U.S. 380, 381-82, 387-89 (1986) (involving so-called "*Garmon*" preemption under the National Labor Relations Act). Moreover, in cases (unlike this one) where the manufacturer has not proposed any warning because there is *no scientific basis* for the asserted risk, it might well make sense to place the initial burden on plaintiff to demonstrate that the claimed risk is real before requiring the manufacturer to show FDA would nevertheless have rejected the warning. This Court should resolve this case in a way that does not foreclose litigants from making arguments along these lines in the lower courts.

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. 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 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; internal quotation marks omitted). "Clear evidence" 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 explicitly referred to "clear evidence" in discussing conflict preemption. Specifically, this Court 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 discussion addressed whether a federal statute protecting whistleblower employees in the nuclear power industry against retaliation (and establishing and defining an administrative remedy in the Department of Labor) preempted a state-law tort claim for intentional infliction of emotional distress based on the same alleged retaliation. In arguing for preemption, the employer maintained that the

availability of a state remedy with a longer statute of limitations and the potential for recovery of exemplary damages would reduce the incentive for whistleblowers to utilize the federal administrative remedy and thus result in fewer safety violations being brought to federal regulators' attention – so that the safety of nuclear facilities would be diminished. Although this Court agreed there was "some force to this argument," it was insufficient to establish conflict preemption. The Court explained:

> First, many, if not most, retaliatory incidents come about as a response to safety complaints that employees register with federal regulatory agencies. The Federal Government thus is already aware of these safety violations, whether or not the employee invokes the [federal] remedial provision[] * * * . Also, we are not so sure as respondent seems to be that employees will forgo their [federal remedial] options and rely solely on state remedies for retaliation. *Such a prospect 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).

English, 496 U.S. at 90 (emphasis added). Notably, the manufacturer in *English* provided no data or other evidence to support its prediction that whistleblowers would abandon federal administrative remedies

merely because they could *also* use a more favorable state judicial remedy. See Resp. Br. 44-45, *English* v. *General Electric Co.* (1990) (No. 89-152), 1990 WL 505669.

As the foregoing makes clear, 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 potential, conflict between federal and state requirements. It is not enough for the proponent of a conflict preemption argument to predict (without supporting data or evidence) what future actions of third parties might be – that type of prediction is simply too "speculative" to establish the requisite conflict between federal and state law. Nothing in *Geier* and *English* remotely supports the establishment of a "clear and convincing" burden of proof.

What is more, if the Court in *Levine* had meant to require more than the "clear" evidence of a conflict required in *Geier* and *English* – if it had meant to create a special ("clear and convincing") standard of proof unique to prescription drug labeling cases – then it surely 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). As noted above, no one asked this Court in *Levine* to adopt a heightened standard of proof for conflict preemption – and, indeed, no such standard was necessary to resolve the case because the defendant there provided "no * * * evidence" FDA "would not have approved a [labeling]

change" that would have added "the kind of warning required by the Vermont jury." 555 U.S. at 571-72.

Finally, the Third Circuit's reading of *Levine* is especially implausible for an additional reason. In *Geier* itself, the Court expressly *rejected* an argument that a defendant must shoulder a "special burden" in certain subcategories of implied preemption cases. 529 U.S. at 870-74. Such a "special burden," the Court explained in words that are equally applicable to the Third Circuit's holding, "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 holding, *Geier*'s reference to "clear evidence" obviously did not alter the ordinary burden of persuasion in establishing conflict preemption. Nor is it plausible to conclude that this Court in *Levine* intended to adopt the very kind of "special burden" rejected in *Geier* (and without even mentioning this aspect of that decision).

In reversing the decision below, this Court should make clear that its reference to "clear evidence" in *Levine* was *not* intended to adopt a heightened burden of proof. Instead, the Court should explain that it was merely declaring, as it has done in past conflict-preemption cases, that preemption requires demonstrating an actual, as opposed to merely a potential or hypothetical, collision between federal and state law. In this setting, that translates into the requirement of a showing that it is more likely than not FDA would have rejected the warning the plaintiff claims should have been given. Such clarification would send a strong signal to the lower courts that there is no need to create special, complicated rules

for different categories of evidence (*e.g.*, warnings proposed by citizen petitions versus by manufacturers). Instead, *any* type of proof demonstrating that FDA would have rejected a warning suffices to establish preemption.

II. THE QUESTION WHETHER FEDERAL LAW PRECLUDED A PRESCRIPTION DRUG MANUFACTURER FROM ALTERING ITS LABELING IS PROPERLY RESOLVED BY THE COURT, NOT BY A JURY

Not only did the Third Circuit misread *Levine* in imposing on pharmaceutical manufacturers an unwarranted "clear and convincing evidence" burden of proof. Equally problematically, it also held that whether FDA would have rejected a proposed warning is a *fact* question *for the jury*, even when (as in this case) the historical facts are undisputed. Pet. App. 36a-37a, 46a-47a n.122, 54a-55a. Under that approach, issues of conflict preemption in cases involving prescription drugs would routinely be relegated to a jury even where the regulatory record clearly shows it is more likely than not FDA would have rejected the proposed warning. See Pet. i, 28; Pet. App. 59a-60a. The Third Circuit erred in holding that this issue was for the jury, not the court.

As petitioner and the Solicitor General demonstrate, the Third Circuit was clearly wrong to apply that approach in this case. Unlike in *Levine*, this case involved an *actual* FDA decision to reject a warning concerning the risk at the center of respondents' claim. As petitioner and the Solicitor General show, the meaning and effect of FDA's

decision to reject the proposed labeling presents a *legal* question for the court, not a factual question for a jury. Pet. Br. 22-24, 42-45; U.S. Inv. Br. 13-16. The question is "properly determined as a matter of law from FDA's Complete Response Letter, read in the context of petitioner's underlying labeling supplement and the surrounding regulatory framework and related FDA actions." U.S. Inv. Br. 15. And "[e]ven if disputed subsidiary factual questions were relevant to determining the meaning and effect of the agency's 2009 decision, the ultimate inquiry would remain a legal one." *Ibid*.

Although this rationale would suffice to reverse the decision below, PLAC and the Chamber urge the Court to go further and make clear that in all cases involving prescription drug manufacturers, issues of conflict preemption – including questions concerning whether the FDA would have rejected a warning the manufacturer never proposed – are issues that should be resolved by courts, not juries.

In concluding otherwise, the Third Circuit took the view that the proper decisionmaker with respect to such "counterfactual" scenarios was somehow left open in *Levine*. Pet. App 39a-40a & n.102. In fact, the Vermont trial court unambiguously held that "[p]reemption is an issue *for the Court*, not the jury" – and it relied on that holding in making its own findings and resolving defendant's post-trial motion for judgment based on new documentary evidence (correspondence with FDA) not presented at trial. *Levine* v. *American Home Products*, 2004 WL 5456809 (Vt. Super. Ct. July 30, 2004) (emphasis added). In affirming, the Vermont Supreme Court in no way questioned that holding, and indeed both the majority

and dissent treated the preemption issue (including the embedded question of what the FDA would have done) as one for the court. Thus, both state courts resolved the issue for themselves, without relying on any jury finding or requiring that the issue be resolved by a jury. And so, too, did this Court, as the Third Circuit was constrained to admit. See Pet. App. 39a-40a (acknowledging that this Court "did decide that the evidence presented in [*Levine*] was not sufficient to pass the clear evidence test").

Thus, every court involved in *Levine* treated the question of whether the FDA would have approved the warning sought by plaintiff as one for the court to resolve. And, not surprisingly, in the decade since *Levine* was decided, "[m]any other circuits have followed this approach" in resolving the conflict preemption issue in prescription drug cases. Pet. App. 40a. *Levine* itself thus strongly supports treating the embedded issue of what FDA would have done as one properly resolved by courts, not juries.

This approach also fits comfortably within the traditional framework for resolving conflict-preemption issues. As this Court has long made clear, conflict preemption flows directly from the text of the Supremacy Clause, which provides: "This Constitution, and the Laws of the United States * * * and all Treaties * * * 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. See *Brown* v. *Hotel & Restaurant Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984) (state and local laws that conflict with federal law are preempted "by direct

operation of the Supremacy Clause"). This Court's general methodology in resolving conflict preemption issues is well settled: "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." *Perez* v. *Campbell*, 402 U.S. 637, 644 (1971). See also note 6, *supra*. Plainly, each of these steps in the overall conflict-preemption analysis involves the determination of an issue of law.

The appropriateness of *judicial* resolution of issues relating to conflict preemption is confirmed by both the history and form of the Supremacy Clause. During the Convention, the Framers considered "three mechanisms for resolving conflicts between federal and state law." Bradford Clark, *Separation of Powers As a Safeguard of Federalism*, 79 TEX. L. REV. 1321, 1348 (2001). The two primary options were (1) a "congressional negative," included in the Virginia Plan, which would have expressly authorized Congress to nullify state laws that, in Congress's judgment, were contrary to the Constitution (or, in a later version, "improper" for any reason), and (2) the Supremacy Clause, included in the New Jersey Plan, which assigned *to the courts* in the first instance the duty to ensure that state laws that were inconsistent with federal laws would be accorded no effect (and preempted). See Bradford Clark, *Unitary Judicial Review*, 72 GEO. WASH. L. REV. 319, 325-27 (2003); Viet Dinh, *Reassessing The Law of Preemption*, 88 GEO. L.J. 2085, 2089-90 (2000); see also Amicus Br. of the U.S. Chamber of Commerce, *Wyeth* v. *Levine*, 2008 WL 2322235 (2008) (No. 06-1249), at *14-*18

(discussing genesis of Supremacy Clause). Moreover, the text and structure of the Supremacy Clause – with its second clause expressly directed at "Judges" and its third clause in the form of a *non obstante* provision (which was widely understood as a directive governing judicial interpretation) – confirm the appropriateness of conflict preemption issues being resolved by judges, not juries. See *PLIVA* v. *Mensing*, 131 S. Ct. 2567, 2579-80 (2011) (plurality); see also Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 232, 235-44, 292-303 (2000).

Despite a setting that clearly points toward *judicial* resolution of the Supremacy Clause's meaning, and the resolution by all three courts in *Levine* of the conflict preemption issue without any suggestion that it was properly for the jury, the Third Circuit took pains to tease out and isolate the "counterfactual" question of what "the FDA would have done" from its context and concluded that, viewed in isolation, that question presented an issue of "fact" for the jury. See Pet. App. 38a-55a.[8] The

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[8] Compare Robert Strassfeld, *If . . . : Counterfactuals in the Law*, 60 GEO. WASH. L. REV. 339, 340-41 (1992) ("[W]hen we talk about what might have been but did not happen, we leave the domain of facts * * * . Whatever status we give to these imaginative creations, we are certain that they differ in kind from facts."); Amy Burns, *Counterfactual Contradictions: Interpretive Error in The Analysis of AEDPA*, 65 STAN L. REV. 203, 211 (2013) ("[Counterfactuals] are commonplace *legal* questions without which adjudication as we know it would not be possible. Courts do this day in and day out * * * [T]he practice sweeps across divergent areas of the law.") (emphasis added); Gerald Magliocca, *Introduction: "What if" Counterfactuals in Constitutional History*, 45 IND. L. REV. 1, 1 (2011) ("Counterfactual reasoning is a staple of legal analysis.").

Third Circuit acknowledged that this supposedly factual issue did not involve any question of *historical* fact but rather called for a prediction about what the expert federal agency, FDA, would have done under circumstances that never actually occurred. In the Third Circuit's view, however, that prediction raised an issue of fact requiring an "evaluative inference" that was "based on correspondence, agency statements, contemporaneous medical literature, the requirements of the CBE regulation, and *whatever intuitions the factfinder may have about administrative inertia and agency decision-making processes*." Pet. App. 54a (emphasis added). "This assessment," the Third Circuit opined, "is certainly complex, but it does not require any special legal competence or training." *Ibid*.

This analysis is flawed. Whether this issue is properly characterized as one of fact, law or something else entirely (or a mixed question of law and fact), it plainly calls upon the decisionmaker to understand the complex backdrop of FDA's regulations and procedures, including the standards the agency applies to determine whether there is a sufficient scientific basis to provide additional warnings (and other cautionary statements) in various parts of the highly regulated drug labeling. It may also, as here, require the decisionmaker to understand how the agency addresses concerns regarding the appropriate wording of proposed labeling changes. See U.S. Inv. Br. 5-6, 19-22. In addition, the decisionmaker, again as in this case, may have to interpret FDA decisions and communications, which are properly "read in the context of [the manufacturer's] underlying labeling supplement and the surrounding regulatory framework and related FDA actions." *Id.* at 15. And

yet, as the Solicitor General explains, "[e]ven if disputed subsidiary factual questions were relevant to determining the meaning and effect of the agency's 2009 decision, the ultimate inquiry would remain a legal one." *Ibid*.

In other settings that call for predictive determinations about what other institutional decisionmakers *would have done* under circumstances that did not actually occur, courts have themselves often determined the answer as a matter of law. This is true even in legal settings that do not so clearly call for judicial decision-making as does applying the Supremacy Clause to issues of implied conflict preemption. For example, "[w]hen appellate courts review an error in a criminal trial to determine if it was harmless, they must pretend that the error never happened and ask themselves if the jury would have acquitted the defendant." Magliocca, *supra*, 45 IND. L. REV. at 1. Similarly, when courts conduct a severability analysis, they ask whether Congress would have enacted the same statute if it knew that one or more portions would be invalidated. See *Murphy* v. *National Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1482 (2018); see also *id.* at 1485 (Thomas, J., concurring) ("The Court must make this severability determination by asking a counterfactual question: "Would Congress still have passed the valid sections had it known about the constitutional invalidity of the other portions of the statute?") (internal quotation marks omitted). Accordingly, there is nothing unusual about judges, rather than juries, deciding counterfactual issues in the context of preemption issues under *Levine*. And, of course, that approach would avoid the host of potential practical problems – in particular, the risk of non-uniform outcomes not

susceptible to appellate correction and reconciliation – that would flow from treating the counterfactual issue as a factual question for lay juries.

III. THE THIRD CIRCUIT'S REASONING ALSO IGNORES THIS COURT'S PRE-EMPTION TEACHINGS AND, IF LEFT UNCORRECTED, WILL CREATE HARMFUL CONSEQUENCES

There are several additional reasons why this Court should reverse and, in so doing, expressly reject the Third Circuit's analysis (rather than resolving the case on narrower grounds that might leave the decision below intact for other types of pharmaceutical cases). Under the decision below, a manufacturer cannot prevail on the preemption argument pre-trial, as a matter of law, unless there is a "smoking gun" rejection letter from FDA that would leave a jury no choice but to find the claim preempted. Moreover, so long as a plaintiff can conjure up some variation between the wording of the warning rejected by FDA and the wording plaintiff says should have been proposed, preemption can be defeated or at least delayed until trial (where it will be decided by a jury). These outcomes strip the constitutional preemption defense of much of its practical utility and render it susceptible to being circumvented or effectively rendered meaningless. The Third Circuit's highly restrictive two-part gloss on *Levine* ignores this Court's teachings in several cases and, if affirmed, will have multiple negative effects.

a. *Preemption's Value as a Threshold Legal Issue*. In most settings, courts treat preemption as an issue capable of resolution on purely legal grounds at the

threshold of or early in litigation (typically on a motion to dismiss or for summary judgment). Much of the practical benefit of the doctrine stems from its capacity to ensure that litigants are not forced to endure lengthy and costly discovery proceedings, and even trial, defending against state-law claims that violate the Supremacy Clause.

This Court has recognized the need to preserve this salutary function of preemption – and to prevent the defense from being circumvented through artful pleading. Thus, where preemption hinges on the allegations of a complaint, the Court has repeatedly stated that plaintiffs may not avoid preemption through artful pleading. See, *e.g.*, *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would 'elevate form over substance and allow parties to evade' the pre-emptive scope of ERISA simply 'by relabeling their contract claims as claims for tortious breach of contract.'") (quoting *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 211 (1985)); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading."). To hold otherwise would deprive a defendant of the right to obtain the dismissal of preempted claims at the pleading stage.

The Third Circuit's decision similarly allows a plaintiff to avoid both dismissal and summary judgment merely by arguing FDA's decision rejecting a warning about the risk in question *might* have been different if the warning had been worded only slightly differently. But it is no more difficult to conjure up

hypothetical alternative wordings for a warning than it is to use artful pleading in a complaint. The Third Circuit's flawed approach also forces a trial in many if not all cases where no warning was ever sought to be added by a defendant (because, for example, the risk was totally unsubstantiated). Taken together, the "clear and convincing" standard of proof and the jury aspects of the Third Circuit's decision will allow plaintiffs to evade preemption through artful rephrasing of warnings and will deprive the constitutional defense of most of its value at the dismissal and summary judgment stages in pharmaceutical cases.

b. *This Court's Teachings in* PLIVA *and* Bartlett. In other settings, the Court has not hesitated to make clear that preemption is an important constitutional defense that may not be defeated by mere speculative possibilities or by arguments that could be made in every case. Thus, in *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604 (2011), 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 FDA to change both its own and the brand-name label, and such a request might ultimately have resulted in FDA's permitting the change. *Id.* at 618-22. Because the manufacturer had not even *tried* to persuade FDA to do so, plaintiffs 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.*

Similarly, in *Mutual Pharmaceutical Co.* v. *Bartlett*, 570 U.S. 472 (2013), the Court rejected 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. Accepting that argument, which could be made in virtually every case, the Court explained, would render impossibility preemption "meaningless." *Id.* at 488. The Third Circuit did not explain how its decision to relegate to *the jury* an equally speculative hypothetical scenario, based on alternative wording for a warning that virtually any plaintiff could claim, can be squared with *PLIVA* and *Bartlett*. In fact, it cannot.

c. *Burdens on the FDA.* The Third Circuit's flawed approach would likely also burden the federal regulatory process governing drug labeling. The decision creates powerful incentives for drug manufacturers to constantly propose labeling changes to FDA to ensure that plaintiffs cannot defeat preemption by invoking hypothetical alternative language.

In *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that fraud-on-the-FDA claims are impliedly preempted, this Court emphasized the need to avoid such unwarranted burdens on FDA's regulatory processes. Specifically, the Court explained the negative impact such claims would have on the agency's approval of certain categories of medical devices:

> [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 [approval] process could encounter delays * * * .

531 U.S. at 351. In much the same way, the Third Circuit's flawed approach to conflict preemption, if affirmed, would multiply the burdens on FDA's oversight of drug labeling.

d. *Effects on Drug Development and the Rising Tide of Pharmaceutical Litigation.* Developing drugs is very expensive. See, *e.g.*, J.A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, at 5 (Nov. 18, 2014) (estimated average industry cost of new prescription drug approval, including failures and capital costs, is $2.59 billion). A manufacturer will not invest the vast sums necessary to develop a drug unless it believes it can recoup its investment. Allowing failure-to-warn claims to proceed under the varying tort laws of the fifty states despite a preponderance of the evidence that FDA would not have approved the proposed warnings would impose significant and unpredictable defense and liability costs on manufacturers, and thereby reduce their willingness to invest in drug development. See *Caplinger* v. *Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) (Gorsuch, J.) (discussing medical devices). The Third Circuit's approach, if affirmed, would increase the costs and uncertainty of litigation faced by manufacturers by requiring more trials and placing the preemption issue in the hands of lay juries. Given the rapid

expansion in recent years of federal litigation against pharmaceutical companies (see note 4, *supra*), this is no idle concern.

CONCLUSION

For the foregoing reasons, the judgment should be reversed.

Respectfully submitted.

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