No. 24-977

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORPORATION,

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 OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS 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.[2] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers and those in the supply chain. PLAC derives its perspective from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product litigation defense attorneys are sustaining (non-voting) members. Since 1983, PLAC has filed more than 1,200 briefs as *amicus curiae* in both state and federal courts, including this Court, on behalf of its

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[1] Pursuant to Supreme Court Rule 37.2, PLAC states that all parties' counsel of record received timely notice of PLAC's intent to file this brief. Pursuant to Supreme Court Rule 37.6, PLAC states that no counsel for a party wrote this brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than PLAC, its members or its counsel contributed money that was intended to fund preparing or submitting the brief. Merck Sharp & Dohme Corporation's parent company Merck & Co., Inc. is a member of PLAC but has made no monetary contribution to this brief except to the extent it has paid its annual dues.

[2] A complete list of PLAC's current membership is available at https://plac.com/PLAC/Membership/Corporate_Membership.aspx (last visited Apr. 4, 2025).

members, while presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

The issues raised by this appeal are of great concern to PLAC's members, many of whom are located in states within the Third Circuit. Product manufacturers frequently confront state law tort claims that conflict with governing federal statutory or regulatory schemes. This brief focuses on the Third Circuit's erroneous application of a "heavy" presumption against preemption to a question of implied "impossibility" conflict preemption. No such presumption applies in that context, and even when used in field preemption cases, it is not an evidentiary "presumption" to be applied in interpreting an agency record; rather, it is an interpretative "assumption" used to discern the applicable law.

PLAC's members and many other U.S. companies are regulated by numerous federal bodies, have extensive interaction with federal regulators, and are entitled to have regulators' decisions understood and interpreted in light of the actual regulatory record and "presumption of regularity" that regulators comply with their legal duties. Instead, at the first sign of purported ambiguity, the Third Circuit eschewed the district court's thorough analysis of the actual agency record, instead invoking a "heavy" presumption against preemption that no other circuit has read this Court's decision in *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019), or its earlier decisions to impose. This abandonment of facts leaves manufacturers in perpetual uncertainty

because they can no longer rely on what an agency actually did, and it further forces manufacturers into labeling practices that will necessarily lead to overwarning.

Many federally-regulated product manufacturers headquartered in or who sell products in the Third Circuit, including PLAC members, will be subject to the Third Circuit's anachronistic "heavy" presumption against preemption. The Court should correct the Third Circuit's error so this uncertainty and the resulting negative public policy consequences do not fester or spread.

SUMMARY OF ARGUMENT

The Third Circuit erroneously applied a "heavy" presumption against preemption. This led it to conclude that Plaintiffs' state law failure-to-warn claims are not preempted by the FDA's rejection of Merck's attempted label change for Fosamax that specifically addressed the exact risk Plaintiffs allegedly experienced. In so doing, the Third Circuit misconstrued this Court's earlier decision in this same litigation ("*Albrecht*"). *Albrecht* does not mention, let alone require, any "presumption" ("heavy" or otherwise) against preemption. Nothing in that decision requires a court to ignore the actual regulatory record whenever any ambiguity surfaces about the federal decision at issue. *Albrecht* established a simple two-part test for interpreting the preemptive force of agency action and emphasized that the ultimate result depends on whether state and federal law "irreconcilably conflict"—a process that neither requires (nor is aided by) application of a

presumption. 587 U.S. at 313–15. The Third Circuit is a glaring outlier in interpreting *Albrecht* to require such a presumption. Its disregard of this Court's clear direction in *Albrecht* merits intervention before the problem festers and recurs.

To the extent the presumption against preemption retains any relevance, it is as an interpretative "assumption" primarily in field preemption cases. This Court abolished any such presumption in express preemption cases in *Commonwealth of Puerto Rico v. Franklin-California Tax-Free Trust*, 579 U.S. 115, 125 (2016), which every circuit except the Third has acknowledged. In the implied conflict preemption context, consistent with the *non obstante* nature of the Supremacy Clause, at least since the Court's rejection of the presumption in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), this Court has never actually applied the presumption to resolve an implied preemption issue. In *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 621-23 (2011), a plurality of the Court necessarily rejected any anti-preemption presumption by recognizing the Supremacy Clause's "notwithstanding" language as a "*non obstante*" provision, so that courts "should not strain to find ways to reconcile federal law with seemingly conflicting state law." Even in field preemption cases, the "presumption" against preemption is only an "assumption" and a canon of statutory construction. It is *not* an evidentiary presumption, and certainly not one that overrides actual facts from an agency record as the Third Circuit applied it here.

Albrecht's repeated reliance on the FDA administrative record established that it is not only

proper, but necessary, to consider actual facts, such as "what information the FDA had before it," 587 U.S. at 317, surrounding an agency decision in deciding preemption. Moreover, agency actions are afforded a "presumption of regularity"—the only presumption that truly applies in this case. Under this presumption, absent clear contrary evidence, courts presume agency officials properly discharge their duties. Here, 21 U.S.C. §355(o)(4)(A) "impose[s] on the FDA a duty to initiate a label change" whenever it learns of "'new information, including any new safety information,'" that requires warnings. *Albrecht*, 587 U.S. at 324 (Alito, J., concurring) (quoting 21 U.S.C. §355(o)(4)(A)). Justice Alito, joined by the Chief Justice and Justice Kavanaugh, correctly pointed out that this duty is "highly relevant" because if the FDA declined any label change despite receiving and considering scientific information regarding a new risk, the "logical conclusion is that the FDA determined that a label change was unjustified." *Id.* Yet the Third Circuit used its "heavy" presumption to avoid §355(o)(4)(A), to ignore crucial extrinsic evidence, and to disregard the FDA's own explanation of its decision.

Equally erroneous is the Third Circuit's treatment of *Albrecht*'s second prong, examining whether the FDA disapproved the warning proposed by Merck. 587 U.S. at 313–16. The district court conducted a thorough analysis of the extrinsic evidence surrounding FDA's Complete Response Letter ("CRL") rejecting Merck's proposed warning and concluded the basis for the rejection was insufficient scientific evidence linking Fosamax to atypical femoral fractures. That conclusion was wholly

congruent with the FDA's statements in its *amicus* brief. Yet the Third Circuit held that the district court should not have even bothered to search for truth once the CRL was arguably ambiguous. Only the "heavy" presumption against preemption mattered, not the facts.

This Court's authority is implicated by the Third Circuit's disregard of this Court's clear decision in *Albrecht*. The Third Circuit's decision, if allowed to stand, also creates impossible choices for manufacturers not just of drugs, but a variety of federally-regulated products, who will face state-law liability despite taking all independent actions possible to comply with federal regulations. Manufacturers will face a perpetual state of uncertainty, no longer able to rely on agency decisions with preemptive power, as plaintiffs will always argue that some ambiguity exists that precludes review of what actually happened. The Third Circuit's decision broadly precludes review of relevant extrinsic evidence to resolve purported ambiguities. Third-Circuit forum-shopping will become the order of the day, not just for drug manufacturers like Merck, but for all manufacturers who sell their products there. The Third Circuit's decision also impels manufacturers towards labeling practices that will burden regulators with endless label change requests—creating a culture of overwarning and dilution of warnings based on legitimate scientific evidence.

Without this Court's action, the issue is bound to recur. This Court should grant Merck's Petition for Writ of Certiorari to correct the Third Circuit's

erroneous interpretation of applicable preemption law.

ARGUMENT

I. THE THIRD CIRCUIT ERRONEOUSLY APPLIED A PRESUMPTION AGAINST PREEMPTION NOT FOUND IN *ALBRECHT* AND UNSUPPORTED BY THE COURT'S PRECEDENT.

The Third Circuit erred when it applied a "heavy" presumption against preemption that it inaccurately attributed to this Court's decision in *Albrecht,* despite the fact that (1) *Albrecht* never mentioned a "presumption," and (2) the Court's other precedent establishes that the presumption against preemption does not apply in an impossibility preemption case but has been largely limited to field preemption cases. Further, when applied, it is not evidentiary but rather is an "assumption" to be used as an aid to statutory interpretation.

A. *Albrecht* Does Not Require Application of Any Presumption Against Preemption.

In *Albrecht*, the Court established a two-part test. In order to show "clear evidence" the FDA would not have approved a change to a drug's label: (1) the manufacturer must have fully informed the FDA of the justifications for the warning required by state law; and (2) the FDA, in turn, must have told the manufacturer it would not approve a labeling change to include that warning. *Albrecht,* 587 U.S. at 302. *Albrecht* does not mention, much less require, use of

a presumption against preemption or other means of biasing that test against finding a conflict with federal law. To the contrary, the Court explained that, in conflict preemption cases, "the judge must simply ask himself or herself whether the relevant federal and state laws irreconcilably conflict." *Id.* at 315 (internal quotation marks omitted).

The *Albrecht* court's failure even to mention a presumption in the context of impossibility preemption is consistent with the Court's overall treatment of the presumption in other cases since *Wyeth v. Levine*, 555 U.S. 555 (2009). And even in the narrow circumstances where a presumption has been applied (primarily field preemption), it is not an *evidentiary* presumption, and no circuit other than the Third has construed *Albrecht* to require any presumption at all, much less an evidentiary one.

In light of the above, there is no basis for the Third Circuit's application of a "heavy *Albrecht* presumption" or its claim that, in *Albrecht*, the Court "emphatically . . . directed [the Third Circuit]'s attention to the weight of that presumption." Pet.App.66a. That is not accurate.

B. To the Extent a Presumption Against Preemption Still Applies, It is Solely As an Interpretative "Assumption."

The Third Circuit's resurrection of a "presumption against preemption" in an impossibility conflict context not only runs counter to this Court's clear direction in *Albrecht* but defies the Court's steady pullback from application of a "presumption" that is

actually just an interpretative "assumption"—not evidentiary at all—applicable primarily in field preemption cases. Indeed, the "presumption" has been abolished in express preemption cases and has never been actually applied by the Court to resolve an implied conflict preemption issue.

i. The Presumption Against Preemption Has Been Abolished in Express Preemption Cases.

In the express preemption context, this Court has abolished the presumption against preemption altogether—a conclusion accepted by every circuit other than the Third. In *Commonwealth of Puerto Rico v. Franklin-California Tax-Free Trust*, 579 U.S. 115 (2016), the Court interpreted a preemption provision in the federal municipal bankruptcy code. In explaining its analysis, the Court stated:

> The plain text of the Bankruptcy Code begins and ends our analysis. Resolving [the question] for purposes of the pre-emption provision begins 'with the language of the statute itself,' and that 'is also where the inquiry should end,' for 'the statute's language is plain.' And because the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'

579 U.S. at 125 (quoting *U.S. v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 241 (1989) and *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)). Additionally, in *Coventry Health Care of Missouri, Inc. v. Nevils*, 581 U.S. 87, 95 (2017), the Court declined to apply a presumption even where the plaintiff's narrower interpretation of the express preemption provision was "plausible."

Since then, every circuit to address the question has understood and concluded that *Franklin* did broadly abolish any presumption in express preemption cases. *See, e.g.*, *Medicaid & Medicare Advantage Products Assn., Inc. v. Hernandez*, 58 F.4th 5, 11-12 & n.5 (1st Cir. 2023) ("[T]he Supreme Court's broad language in *Franklin* forecloses us from applying the presumption against preemption in interpreting the Medicare Advantage Act's express preemption clause."); *Ye v. GlobalTranz Enterprises, Inc.*, 74 F.4th 453, 465 (7th Cir. 2023) ("[R]eliance on the presumption against preemption . . . stood in direct conflict with the Supreme Court's instruction to 'focus on the plain wording of the clause' instead of 'invok[ing] any presumption against pre-emption.'"). This includes products liability cases. *See Carson v. Monsanto Co.*, 72 F.4th 1261, 1267 (11th Cir. 2023); *Buono v. Tyco Fire Products, LP*, 78 F.4th 490, 495 (2d Cir. 2023).

The only outlier is the Third Circuit. In *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760 (3d Cir. 2018), the court distinguished *Franklin* in a footnote as inapplicable because it did not involve product liability claims, 885 F.3d at 770-71 & n.9, ignoring the fact that this Court had already refused to apply the

presumption to the same preemption clause, 21 U.S.C. §360k(a), in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-330 (2008). It also ignored the rulings of its sister circuits. *See, e.g.*, *Watson v. Air Methods Corp.*, 870 F.3d 812, 817 (8th Cir. 2017) (relying on *Franklin* and refusing to apply a presumption).

ii. Consistent with the *Non Obstante* Nature of the Supremacy Clause, the Supreme Court Has Never Applied a Presumption to Resolve a Conflict Preemption Case.

Consistent with *Geier*, this Court has never since applied the presumption to resolve a conflict preemption case, and with good reason: a presumption in this context would conflict with the plain language, history, and purpose of the Supremacy Clause. In the conflict preemption context, the only issue is whether a conflict exists between state and federal law. *Albrecht*, 587 U.S. at 315.

A plurality of this Court in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 622 (2011), implicitly rejected any presumption against preemption in conflict preemption cases when it said that, "[t]he *non obstante* provision in the Supremacy Clause . . . suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." The Court further explained that "[t]he *non obstante* provision . . . indicates that a court need look no further than 'the ordinary meanin[g]' of federal law, and should not distort federal law to accommodate conflicting state law." *Id.* at 623 (quoting *Wyeth*, 555 U.S. at 588 (Thomas, J.,

concurring)). The *Mensing* plurality specifically rejected any "presumption" that would have a manufacturer defendant's "ability to comply with state law," and thus its ability to assert preemption, "depend[] on uncertain federal agency and third-party decisions[.]" *Id.*

Analyzing the origins of the anti-preemption presumption further illustrates its inapplicability to conflict preemption cases. The presumption originated as an "assumption" against preemption in a field preemption case. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (holding that where a federal statute covers a "field which the States have traditionally occupied," the Court would "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress"). *Rice* relied on two field preemption cases to support this assumption. *See Allen-Bradley v. Wisconsin Employment Relations Board*, 315 U.S. 740 (1942); *Napier v. Atlantic Coast Line Railroad Co.*, 272 U.S. 605 (1926).

Since *Rice*, the Court has invoked its "assumption," later phrased as an interpretive "presumption," in other field preemption cases and, until *Franklin*, in an occasional express preemption case. The Court made passing reference to the presumption in the implied preemption context, as noted by the majority in *Wyeth*, 555 U.S. at 565 n.3, but virtually all of the Court's post-*Rice* conflict preemption cases turn solely on the conflict issue, without regard to any supposed "presumption." *See, e.g.*, *Florida Lime & Avocado Growers, Inc. v. Paul*,

373 U.S. 132, 152-53 (1963) (impossibility); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 170 (1982) (obstacle).

In *Geier*, an obstacle preemption case, the Court explicitly rejected a presumption against implied preemption and any "special burden" on the implied preemption defense. 529 U.S. at 870-74. Instead, it addressed preemption under "ordinary pre-emption principles, grounded in longstanding precedent" and stated that "[t]he basic question . . . is whether a common-law 'no airbag' action like the one before us *actually conflicts* with [the governing federal regulations]." *Id.* at 874 (emphasis added).

Since *Geier*, while the Court has sporadically mentioned the presumption in conflict preemption decisions, it was never dispositive. The most prominent example is *Wyeth*, where the Court cited field and express preemption cases to support the applicability of the presumption. 555 U.S. at 565 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (express preemption), quoting *Rice*, 331 U.S. at 230 (field preemption)). But even in *Wyeth*, the majority did not rely on an anti-preemption presumption, finding instead that there was insufficient evidence FDA would have rejected the proposed label revision. *Id.* at 571-72.

Since *Wyeth*, the Court has not referenced or applied any presumption against preemption in a conflict preemption case. For example, in *Mutual Pharmaceutical Company v. Bartlett*, 570 U.S. 472, 486-493 (2013), the majority never mentioned any

anti-preemption presumption in its conflict analysis, despite the dissent's explicit contrary argument.

The Third Circuit ignored *Albrecht's* directive, which did not include application of any presumption, much less a "heavy" one, and failed to follow the Court's precedent regarding the inapplicability of a presumption against preemption in implied conflict preemption cases such as this one. That alone requires review.

iii. Even where applicable, the presumption is a canon of statutory interpretation—*not* an evidentiary presumption.

Even when applied in field preemption cases, as in *Rice*, the presumption has been viewed as an interpretative "assumption," *not* an evidentiary one. *Rice*, 331 U.S. at 230. Its purpose is to aid in statutory interpretation and understanding of congressional intent. *Id.* at 232-36.

The Third Circuit transformed the presumption into an evidentiary tool when it concluded that relevant extrinsic evidence that the district court used to resolve the purported ambiguity in the FDA's formal rejection was "swept away by the heavy *Albrecht* presumption." Pet.App.66a. Rather, in any "close case," actual evidence no longer mattered; only the "strong presumption" was "determinative." Pet.App.62a. Similarly to that court's prior creation of an erroneous "clear and convincing" evidence barrier to preemption, the decision below linked its "heavy" presumption to the *Albrecht* court's "clear-evidence standard" to justify discounting everything the FDA

actually did—including the agency's previous *amicus* brief to this Court—as immaterial "informal communications." *Id.* The Third Circuit's weaponization of the presumption as a tool to ignore undisputed facts flies in the face of the presumption's origins and this Court's precedent.

II. THE ONLY APPLICABLE PRESUMPTION IS THAT OF REGULARITY UNDER 21 U.S.C. §355(O)(4), WHICH, COMBINED WITH *ALBRECHT'S* DIRECTION TO CONSIDER THE ADMINISTRATIVE FACTS, DEMONSTRATES THE CLEAR ERROR IN THE THIRD CIRCUIT'S DECISION.

The Third Circuit failed to address the only presumption applicable in this case—the presumption of regularity. It also brushed off the FDA's obligation under 21 U.S.C. §355(o)(4) to update warnings whenever science so requires. Despite this Court's clear statements in *Albrecht* that it is necessary to consider facts related to the meaning and effect of an agency decision, the Third Circuit wiped out the fact-intensive analysis conducted by the district court with its newly invented "heavy" anti-preemption presumption. This Court should correct both of these fundamental errors.

A. The Presumption of Regularity of the FDA's Decision-Making Is the Only Applicable Presumption.

The only presumption applicable in this case is the "presumption of regularity" with respect to the FDA's intentional and well-informed decision not to permit

Merck to change the Fosamax labeling consistent with its obligations under §355(o)(4).

This Court has repeatedly recognized that "agencies are entitled to a presumption of regularity." *Food and Drug Admin. v. Wages and White Lion Investments, L.L.C.*, No. 23-1038, 2025 WL 978101, at *17 (U.S. Apr. 2, 2025). The Court has explained that the presumption of regularity serves as a "general working principle" that means courts will "insist on a meaningful evidentiary showing" before entertaining doubts about the integrity of official acts or documents. *National Archives & Records Admin. v. Favish*, 541 U.S. 157, 174-75 (2004); *see also Biden v. Texas*, 597 U.S. 785, 812-813 (2022) (referencing the "strong showing of bad faith or improper behavior" necessary to rebut the presumption of regularity) (internal quotation marks omitted); *United States v. Armstrong*, 517 U.S. 456, 464 (1996) ("'[I]n the absence of clear evidence to the contrary, courts presume that [Government agents] have properly discharged their official duties'") (quoting *United States v. Chemical Foundation, Inc.*, 272 U.S. 1, 14–15 (1926)).

As Justice Alito underscored in his *Albrecht* concurrence, §355(o)(4)(A) "impose[s] on the FDA a duty to initiate a label change" when it learns of "new information, including any new safety information," that requires warnings. 587 U.S. at 324. Justice Alito referred to that duty as "highly relevant" to the analysis because, in light of the presumption of regularity, "if the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical

conclusion is that the FDA determined that a label change was unjustified." *Id.* at 324-25. Justice Alito stated that, on remand, the Third Circuit should consider the effect of §355(o)(4)(A), *id.* at 325, and the district court certainly met this task head on.

Specifically, the district court correctly held that accepting Plaintiffs' position —that the FDA rejected Merck's proposed warning due to semantics surrounding use of the term "stress fracture," even though there was persuasive causal evidence linking bisphosphonates to atypical femoral fractures—would violate the presumption of regularity:

> [To accept Plaintiffs' position], one must assume that the FDA had reasonable evidence warranting a Precautions warning, but was so troubled by Defendant's use of the term 'stress fracture' that it rejected a warning without offering any suggestions or revisions. To make such an assumption would effectively overlook the FDA's *raison d'etre* to regulate drug safety, its independent legal duty to notify a manufacturer as soon as it 'becomes aware of new safety information that [it] believes should be included in the labeling of a drug' and 'initiate discussions to reach an agreement . . . on labeling,' 21 U.S.C. § 355(o)(4)(A), and the 'presumption of regularity' accompanying its actions.

Pet.App.150a.

If the FDA believed in May 2009 that the "new safety information" Merck submitted in 2008 "should

[have] be[en] included in [Fosamax's] labeling," the FDCA required that FDA "promptly notify" Merck and engage in expedited discussions to revise the labeling. 21 U.S.C §355(o)(4)(A)-(D). Instead, the FDA's CRL concluded that Merck's justification for an enhanced warning was insufficient. Pet.App.138a-142a. Indeed, nearly a year later, the FDA announced—after reviewing further data—that it had yet to find any "clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures." Pet.App.161a. It was only in October 2010—after an external task force had completed further scientific review—that the FDA changed its view and required a change in the warnings.

The district court's reasoning was sound, and the Third Circuit did not disagree with it. Rather, it invokes its "heavy presumption" to ignore all extrinsic evidence, including FDA communications and call notes, and the FDA's statements in its *amicus* brief. Replacing evidence with its presumption, the Third Circuit erroneously concluded that §355(o)(4) was inapplicable because the FDA had not "fully considered" the information submitted by Merck and "was not fully convinced of the link yet." Pet.App.70a-74a (emphasis removed). But as Merck's Petition points out, even if it were true that the FDA was "'not fully convinced" that the relevant risk existed when it rejected Merck's submission, then "Merck was barred from adding a warning until new evidence emerged." Pet. for Writ of Cert., at 18. That did not happen until October 2010. *Id.*

FDA made a decision in May 2009 not to permit the requested labeling alteration and seventeen months later made a different decision in the face of new evidence. The Third Circuit mistakenly portrays this as a failure to act when it was—and had to be under §355(o)(4)—actually an affirmative decision based on then-existing evidence.

Both Justice Alito and the district court correctly homed in on the key point here: given the presumption of regularity, if the FDA thought there was a causal link between Fosamax and atypical femoral fractures prior to October 2010 sufficient to warrant a warning in the Precautions section of Fosamax's label, it would have reached out and required Merck to act accordingly. The fact that it did not demonstrates it did not believe the evidence supported the label change.

B. *Albrecht* Mandated Consideration of the Extrinsic Evidence That the Third Circuit's Decision Ignores.

In ruling that preemption-related questions of agency action were matters of law for courts to decide, the Court in *Albrecht* explicitly contemplated the application of "legal skills to determine whether agency disapproval fits facts that are not in dispute." 587 U.S. at 316. The Court stated: "We understand that sometimes contested brute facts will prove relevant to a court's legal determination about the meaning and effect of an agency decision. . . . [W]e consider these factual questions to be subsumed within an already tightly circumscribed legal analysis." *Id.* at 317.

But in addressing the second prong of *Albrecht*, the Third Circuit improperly eschewed the district court's thorough analysis of the crucial extrinsic evidence, including the agency record, communications, and the FDA's own statements, in favor of a "heavy presumption" it erroneously ascribed to *Albrecht*. Pet.App.57a-69a. The Third Circuit required that if any reading the CRL could be considered ambiguous, the presumption is controlling, and no other "brute facts" this Court contemplated in *Albrecht* mattered. Pet.App.66a ("[E]xtrinsic evidence [that is, actual FDA administrative facts] . . . cannot be determinative in a case like this, where the ambiguities in the FDA's Complete Response Letter are swept away by the heavy *Albrecht* presumption").

The Third Circuit effectively "swept away" the very factual analysis that this Court mandated in *Albrecht*, using its purported "presumption against preemption" to ignore all actual facts and evidence underlying the FDA's rejection. It acknowledged that "[t]he outcome of this case [] largely depends on the interpretation of the Complete Response Letter" and that it was a "close case." Pet.App.57a, 62a. Yet, unlike the district court, it found error in any attempt to interpret the letter, instead concluding that because it could be construed as ambiguous, the presumption ends the analysis and precludes preemption. The district court's approach is the correct one. Courts should always try to find the correct meaning of any "written instrument." *Albrecht*, 587 U.S. at 317 (citation and quotation marks omitted). *Cf. Loper Bright Enterprises v.*

Raimondo, 603 U.S. 369, 400 (2024) (requiring use of "all relevant interpretive tools" to ascertain the "best reading" of a statute). In this case, that best reading is that the FDA complied with its statutory obligation under 21 U.S.C. §355(o)(4)(A) because its 2009 rejection of Merck's proposal was based on inadequate science.

The Third Circuit's disregard for truth-finding is most apparent in its failure to materially credit the FDA's *amicus* brief in *Albrecht* stating that the agency rejected label changes prior to October 2010 due to inadequate scientific evidence. The Third Circuit incorrectly reasoned that consideration of the FDA's brief was akin to "giv[ing] the FDA power to decide the pre-emption question [the court is] responsible to answer." Pet.App.66a-67a. Not so. Far from weighing in on the preemption question, the FDA supplied the reasons for the CLR's decision, which it was uniquely positioned to explain.

III. THE THIRD CIRCUIT'S DECISION NEGATIVELY AFFECTS MANUFACTURERS IN ALL FEDERALLY REGULATED INDUSTRIES AND WILL GIVE RISE TO FORUM-SHOPPING AND UNNECESSARY LITIGATION.

The Third Circuit is home to manufacturers of many federally-regulated products, including pharmaceuticals, medical devices, food products, consumer products, and many others. But any manufacturer who sells its products in the Third Circuit (which is to say, all nationwide manufacturers) now faces liability risks that do not

apply elsewhere. This will lead to forum-shopping because under the Third Circuit's ruling, state tort claims will be allowed to proceed despite manufacturers taking all available independent actions to comply with federal regulations.

As a result, manufacturers will be forced into an endless state of uncertainty since they can no longer rely on decisions made by agencies with preemptive power. Plaintiffs will always be able to argue that some sort of ambiguity exists in an agency's decisional documents, and the Third Circuit's decision precludes review of relevant extrinsic evidence to resolve the ambiguity. This is bad law and bad policy: manufacturers should be able to rely on the actual regulatory record so they can avoid liability if they do what the agency commanded them to. *Mensing* rejected any "presumption" that would leave a manufacturer's "ability to comply with state law," and thus its ability to assert preemption, "depend[ent] on uncertain federal agency and third-party decisions." 564 U.S. at 623. But the decision below revels in precisely that: "Whether it seems fair or not, the FDA can take its time, but [defendant] is responsible for the content of its label at all times." Pet.App.73a (citation and quotation marks omitted).

Further, consumers will be hurt because the ruling forces manufacturers into labeling practices that will necessarily lead to the very overwarning that this Court cautioned against in *Albrecht*. 587 U.S. at 304. The district court astutely framed the problems this can cause. Pet.App.167a-168a (addressing risks of overwarning). Uniquely, in the Third Circuit, manufacturers must warn about risks

even after federal regulators reject such a warning. When twenty-twenty hindsight substitutes for the actual basis for the federal decision, uncertainty reigns. Within the context of the CBE labeling-revision process, the Third Circuit's approach opens manufacturers to endless liability that can only be prevented by including warnings against every imaginable potential effect or danger, irrespective of how infinitesimal its likelihood may be.

As it currently stands, product manufacturers who reside in or sell products in states within the Third Circuit now have a duty to warn about risks despite federal regulators rejecting the very warning plaintiffs claim should have been given. The ensuing litigation will rise to this Court's attention again and again unless it corrects the Third Circuit's errors now.

CONCLUSION

For all the foregoing reasons, as well as those set forth in Merck's Petition, the Court should grant the Petition.

Respectfully submitted,

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