In The

United States Court of Appeals

for the

Third Circuit

06-3107

JOSEPH C. COLACICCO, INDIVIDUALLY AND AS EXECUTOR OF THE ESTATE OF LOIS ANN COLACICCO, DECEASED,

Plaintiff-Appellant

v.

APOTEX INC; APOTEX CORP, AS SUBSIDIARY OF APOTEX. INC.; SMITHKLINE BEECHAM, d/b/a Glaxosmithkline,

Defendant-Appellee

06-5148

BETH ANN MCNELLIS, on behalf of the Estate of Theodore DeAngelis, Deceased and In Her Own Right,

Appellee

v.

PFIZER INC.; JOHN DOES 1-5; ABC DOE CORP.; DEF DOE CORP.; GHI DOE CORP.

Pfizer Inc.,

Appellant

Appeal from an Order entered from the United States District Court for the Eastern District of Pennsylvania

PETITION FOR REHEARING *EN BANC*

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I express a belief, based on a reasoned and studied professional judgment, that this proceeding involves a question of exceptional importance: whether a federal agency's inaction can rise to the level of federal law sufficient to create an implied conflict with a State common law tort claim and warrant preemption of that claim. Furthermore, the panel decision directly conflicts with the Supreme Court's decision in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), by equating the Food & Drug Administration's (FDA) failure to require a stronger drug warning as tantamount to an "authoritative message of federal policy" sufficient to warrant the abrogation of State law. *Compare Sprietsma*, 537 U.S. at 64-67, *with* Slip op. at 28-34.

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PRELIMINARY STATEMENT

Petitioners urge this Court to grant their joint petition for rehearing *en banc* because the majority's decision threatens the vitality of State tort law and the historic co-existence of federal prescription drug safety standards and common-law remedies for injuries arising from prescription drugs. Petitioners believe that Judge Ambro undertook the right analysis in his dissenting opinion, and that his view should prevail.

The majority committed several errors in reaching its conclusion. Notably, the majority eviscerated the force of the settled presumption against preemption, relying, among other things, on *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). As Judge Ambro explained, *Geier* **confirms** that the presumption applies in the implied conflict preemption context. The presumption should have been given more than mere lip-service by the majority.

The majority erred further in finding an actual conflict between Petitioners' tort claims and federal law. Slip op. at 28. The majority reached this view notwithstanding the lack of any Congressional intent to preempt; notwithstanding the traditional presumption against preemption; and notwithstanding the absence of any concrete law from Congress or the FDA that might be frustrated by a state-law tort suit. The majority instead viewed the FDA's "scientific conclusions" concerning the warnings addressed by Petitioners' lawsuits and the agency's

"public announcements" of those conclusions as amounting to "federal law" entitled to preemptive force. *Id.* at 28-29, 40. These actions by the FDA do not rise to a level that warrants preemption. There is no actual conflict under the circumstances presented, pursuant to *Sprietsma*.

Although purportedly narrow in scope, the majority's opinion is exceedingly broad because it allows a federal agency's **failure** to act to rise to the level of "federal law" sufficient to warrant the abrogation of State law. The Panel majority's holding will allow product manufacturers to skirt common-law accountability for an injurious product simply because the federal entity regulating that product has failed to mandate the safety measure implicated by a tort suit. The holding threatens the "harmony" between state tort law and FDA regulation and threatens bedrock principles of federalism. For these reasons, as further explained below, Petitioners request rehearing *en banc*.

FACTUAL AND PROCEDURAL BACKGROUND

Petitioners' lawsuits arose from the deaths of two people who committed suicide after taking a prescription antidepressant from the class of drugs known as selective serotonin reuptake inhibitors ("SSRIs"). The issue raised by the defendant drug manufacturer in each case was whether FDA requirements for prescription drug labeling preempt State common law tort claims based on a negligent failure to warn. In *McNellis*, the district court rejected the

manufacturer's insistence that the lawsuit was preempted by federal law and denied its motion for summary judgment. In *Colacicco*, the district court deferred to the FDA's position that the lawsuit was impliedly preempted by federal law and granted the manufacturers' motions to dismiss.

The cases were consolidated for argument and the Panel, consisting of Circuit Judges Sloviter and Ambro and Judge Restani of the Court of International Trade, issued a consolidated opinion on April 8, 2008. The majority opinion held that Petitioners' lawsuits are preempted by federal law. Judge Ambro dissented.

The majority's opinion set forth the relevant background that served as the foundation for its preemption analysis as follows:

> In 1991, after considering whether antidepressants caused or intensified suicidal thoughts, the FDA's Psychopharmacological Drugs Advisory Committee concluded that no such warning should be added to Prozac (an SSRI similar to Paxil and Zoloft) or other antidepressants. The FDA specifically rejected citizen petitions in 1991, 1992, and 1997 which sought to either withdraw approval of Prozac as a result of its asserted association with suicide or to include a suicide warning on the labeling of that drug. In each instance, the FDA concluded that there was insufficient evidence to take the actions requested.
>
> [Petitioner's Decedent] DeAngelis committed suicide on January 22, 2003. The FDA approved the Zoloft suicide precaution seven separate times before and after that date, in each instance requiring Pfizer to market the drug with the precise labeling approved. Further, just months before DeAngelis' death, the FDA filed an amicus brief in an action before the Court of Appeals for the Ninth Circuit, stating that it had concluded that there was no scientific basis for a warning suggesting that Zoloft causes suicidality.

> The FDA also repeatedly approved the Paxil labeling in effect at the time of [Petitioner's Decedent] Lois Colacicco's prescription of Paxil on October 6, 2003, and her death on October 28, 2003, approving it for a new indication, the treatment of generalized anxiety disorder, just a year before those events. The FDA approved Apotex's application to market generic paroxetine on June 30, 2003, concluding that the "the drug is safe and effective for use as recommended in the submitted labeling," which included the suicide precaution ... rather than a warning. Significantly, on June 19, 2003, the FDA issued a public statement to address reports associating the pediatric use of Paxil with suicidality, in which it stated: "There is no evidence that Paxil is associated with an increased risk of suicidal thinking in adults.
>
> On October 27, 2003, the FDA issued a Public Health Advisory regarding increased suicidality in pediatric users of antidepressants. This advisory was limited to pediatric patients; a warning for adult patients was not issued. In that advisory, the FDA announced that it would continue to research the reports of suicidality in pediatric patients treated with antidepressants, explaining that "[s]uch reports are very difficult to interpret, in the absence of a control group, as these events also occur in untreated patients with depression."

Slip op. at 29-32. To the extent the majority's recitation of the regulatory history suggests that there is no evidence of an association between adult suicidality and either of the antidepressants at issue here, that suggestion is belied by the record in Petitioner Colacicco's case, which makes clear that in 2006 GSK warned physicians directly of the link it had observed between Paxil and suicidality for **adults of all ages.** *See Colacicco* Record A1069 (Dear Healthcare Professional letter).

REASONS WHY THIS PETITION FOR EN BANC HEARING SHOULD BE GRANTED

I. The Majority Failed to Properly Apply the Presumption Against Preemption.

The Panel majority's first error is its failure to meaningfully apply the time-honored presumption against preemption.

Congressional intent is the "ultimate touchstone of pre-emption analysis," *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), and, in ascertaining that intent, the Supreme Court's preemption jurisprudence has repeatedly applied a presumption *against* preemption. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005); *Medtronic v. Lohr*, 518 U.S., 470, 485 (1996); *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707 (1985). Contrary to the Panel majority's statement that there is some "tension" between the presumption and the notion of implied conflict preemption, the Supreme Court has always held fast to the presumption, **especially** in implied preemption cases. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000); *Hillsborough County*, 471 U.S. at 716. The rationale for that practice is clear: the presumption **against** preemption – and **in favor** of the sovereign State – is at its strongest when Congress has not explicitly trumped that sovereignty. *See* Slip op. at 44 (Ambro, J. dissenting) (reasoning that lack of express Congressional preemption "should push us to hold

the presumption against preemption in place, as we lack the best kind of evidence of congressional intent: statutory text.").

Here, as Judge Ambro explained, the majority opinion "under-emphasizes congressional intent as the 'ultimate touchstone of pre-emption analysis'," *id.* at 43 (quoting *Cipollone*, 505 U.S. 516), and misapprehends the language of *Geier* as somehow creating a "counter-presumption in favor of preemption" in the implied conflict preemption arena. *Id.* at 46. *Geier* should not be interpreted to "muddy the presumption," because it explicitly recognized that "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." *Id.* (quoting *Geier*, at 885). Judge Ambro explains further:

> The Plaintiffs' failure-to-warn claims stand near the heart of the states' police powers over matters of health and safety. And the existence and detailed nature of the federal scheme does not change our imperative to require clear congressional intent ... to preempt state tort law.

Id. at 47.

In sum, the majority allowed the presumption against preemption to perform "virtually no analytical work." *See id.* at 46 n.24. This error negatively affected the panel's reasoning from the outset, warranting rehearing en banc.

II. The Majority Erred in Finding an Actual Conflict.

At the outset of its conflict analysis, the majority acknowledged the true nature of the regulatory facts in these cases – the "FDA's **failure to require** a

warning," *id.* at 28 – and resisted the drug manufacturers' invitation to couch what happened here as the FDA's **"rejection"** of stronger drug warnings. The majority then failed to appreciate the implications of that finding: it had a clear path to concluding that there is simply no federal "law" with which Petitioners' lawsuits possibly could conflict. As Judge Ambro properly found, no federal statutory or regulatory text was frustrated by the operation of tort principles that would hold a drug manufacturer liable for a failure to adequately warn. Indeed, the FDA's regulatory scheme **requires** manufacturers to strengthen drug warnings when they have basis for doing so. *See* 21 C.F.R. §§ 314.70(c), 201.57(e).

Notwithstanding the absence of any tangible conflict, the majority reasoned that the FDA's monitoring of SSRIs over a period of time, coupled with the agency's repeated public announcement of its conclusions as to the suicide risk posed by SSRIs, was sufficient to constitute federal "law" that would have preemptive effect. *Id.* at 28-32. This "monitoring" and these "public announcements," the majority said, created an actual conflict with Petitioners' failure to warn claims. *Id.* at 34 ("[W]e reject the notion that, in order to rise to the level of a conflict in this situation, the FDA's rejection must be imbued with the formality proposed by the plaintiffs."). The majority's opinion thus reverts to the vocabulary urged by the drug manufacturers in finding that the FDA "rejected"

stronger warnings, elevating agency **inaction** to an undefined form of affirmative conduct.[1] *Id.* at 40.

The majority erred here as well. As Judge Ambro correctly explained, the majority improperly found an actual conflict between the FDA's regulations and the State tort claims in question where (1) "[n]one of the drug manufacturers in these cases attempted to enhance a warning and received an FDA sanction in response," *id.* at 52; (2) "drug manufacturers have authority to strengthen warnings without advance permission from the FDA," *id.*; and (3) neither the drug manufacturers nor the FDA point to one example of the FDA having punished a manufacturer for "over-warning." *Id.* at 53.

Judge Ambro also grasped what the majority did not: the conflict urged by the drug manufacturers and the FDA here is both hypothetical and unconvincing.

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[1] Practicality requires concrete federal law as a prerequisite for a finding of implied preemption. If the preemption question in this or any case can be said to turn on a federal agency's subjective understanding of the current state of science in the field that it regulates, preemption is reduced to a fact-finding inquiry as to what is going on in the heads of federal regulators. Predicating preemption only on positive federal law – statutory or regulatory law – preserves judicial focus on proper place: Congressional intent measured against State sovereignty.

Moreover, because science is not static, but evolves with each passing day, preemption becomes an arbitrary exercise when it is contingent upon the understanding of science that the agency happens to have at the time a lawsuit arises. This risk is evident in Petitioner Colacicco's case, where the record demonstrates that, in 2006, after Lois Colacicco's death, GSK directly warned physicians about Paxil's link to suicidality for adults of all ages. *See Colacicco* Record A1069 (May 2006 Dear Healthcare Professional letter).

Responding to the majority's suggestion that the FDA's authority under the Food Drug & Cosmetic Act to render a drug "misbranded" dictates preemption because the agency **would have** exercised that authority if any of the SSRI manufacturers had acted to strengthen their warnings, Judge Ambro replied: "I find it hard to believe that, if a drug manufacturer augmented its warning in response to or in anticipation of a state tort lawsuit, the FDA would sanction the manufacturer for over-warning consumers." *Id.* at 52. Judge Ambro's view was hardly speculation: at oral argument, the FDA could not recall a single such instance in its history. *See* Oral Argument Tr. 82, Dec. 10, 2007.

The majority opinion also conflicts with the Supreme Court's decision in *Sprietsma*, 537 U.S. at 51. There, the plaintiff's alleged that the defendant boat-motor manufacturer sold its boats in an unreasonably dangerous condition because they were not equipped with protective propeller guards. In holding that the plaintiff's state-law claims were impliedly preempted by the Federal Boat Safety Act ("FBSA"), the Illinois Supreme Court found that the U.S. Coast Guard had explicitly considered and rejected the adoption of a regulation requiring propeller guards. The state court thus concluded that "the Coast Guard's failure to promulgate a propeller guard requirement ... equates to a ruling that no such regulation is appropriate pursuant to the policy of the FBSA." *Id.* at 66 (quoting *Sprietsma v. Mercury Marine*, 757 N.E.2d 75, 85 (Ill. 2001)).

The Supreme Court reversed, holding that the plaintiff's claims were neither expressly nor impliedly preempted by the FBSA. At the very outset of its analysis, the Court rejected the rationale of the Illinois court, commenting that it was "quite wrong" to view the Coast Guard's rejection of the protective measure in question as "the functional equivalent of a regulation prohibiting all States … from adopting such a regulation." *Id.* at 65. Rather, the recommendation by the Coast Guard's subcommittee not to adopt the regulation "left the law applicable to propeller guards exactly the same as it had been before the subcommittee began its investigation." *Id.*

Here, the FDA's conduct underlying its regulatory inaction closely parallels the agency's conduct underlying the regulatory inaction in *Sprietsma*, where the Supreme Court rejected implied preemption. In *Sprietsma*, the agency had long been examining the safety and feasibility of requiring the measure in question. *See id.* at 60-62. Here as well, the FDA has "monitored" SSRIs since the early 1990s. Also as in *Sprietsma*, the FDA came to conclusions regarding the science of the subject-matter being regulated, and its decision not to require manufacturers to do more in the way of safety was "intentional and carefully considered." *Id.* at 67. *Sprietsma* mandates that such intentional and careful consideration does not

convey an "'authoritative' message of federal policy against" the safety measure in dispute, and the majority erred in concluding otherwise. *Id.* [2]

III. The Majority Erred in the Level of Deference It Gave to the FDA.

Judge Ambro was also correct in his criticism of the level of deference the majority afforded to the FDA's position on preemption. Slip op. at 47-51. As the majority notes, "[t]he FDA has taken the position, both in the preamble to the 2006 amendments revising the drug labeling regulations and in its amicus brief in the *Colacicco* case, that plaintiffs' claims are preempted ...." *Id.* at 37. That preamble – which is itself not a regulation and was not even subject to notice-and-comment rulemaking – announces the FDA's belief that a tort lawsuit for a drug manufacturer's failure to warn is preempted where the warning urged by the lawsuit had not been required by the FDA. *Id.* at 38 (citing 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006)). Cautioning that it would "ordinarily be leery of an agency's

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[2] The majority's reliance on *Geier* for setting the implied conflict preemption bar so low is misplaced. Here, no federal positive law conflicts with Petitioners' tort theories. In *Geier*, the tort claims at issue conflicted with specific federal law in the form of a duly promulgated regulation. *Geier* also held that a suit premised on a failure to install airbags was an obstacle to the accomplishment of federal regulatory objectives because the agency had considered requiring airbags alone, but ultimately decided that automakers should have the flexibility to choose from a variety of passive restraints in a Federal Motor Vehicle Safety Standard, published after notice-and-comment rulemaking in the Code of Federal Regulations. *See id.* at 874-75. The implied preemption analysis in *Geier* thus turned on at least two features that are lacking here: (1) positive law, and (2) formal federal agency action.

view of what is essentially a legal issue," *id.*, the Panel majority nonetheless explained why the FDA should be entitled to "some degree of deference" here under the guidelines of *Skidmore* and *Mead*. *Id.* at 40.

Judge Ambro agreed with the majority's finding that the analytical framework guiding the deference inquiry is set forth in *Skidmore* and *Mead*. But he disagreed with the majority's application of that framework to the regulatory facts. Under *Mead*, Judge Ambro would have afforded a "relatively low level of deference" because (1) the FDA's position has been inconsistent; (2) the FDA is not an expert on federalism concerns; (3) there is no evidence of any degree of formality; and (4) the FDA's position is unpersuasive. *Id.* at 48-50. Judge Ambro described the better rule; the majority erred to the extent it deferred to the FDA's views.

IV. The Majority Erred in Failing to Appreciate the "Harmony Between Tort Law and FDA Regulation."

Judge Ambro pointed out a consistent feature of prescription drug regulation since its inception: federal regulations concerning prescription drug labeling work in tandem with State common law tort regimes. As he explained:

> In reaching its holding of conflict preemption, the majority focuses on the hypothetical scenario of differing (and presumably conflicting) results of the FDA regulatory process and state tort lawsuits. Because we are dealing with hypothetical situations, however, **I would focus on the essential harmony of the standards applied by the FDA and state courts rather than the disharmony conjured about the results. Both institutions seek to balance safety and efficacy.** If it

> turns out those results actually conflict, then it is time for Congress to step in or at least for the FDA to propose a rule followed by public comment before proclaiming preemption.

Slip op. at 54-55 (emphasis added). Judge Ambro continued:

> Allowing multiple institutions to investigate the difficult question of how strong to make a warning can have important benefits. **State courts provide a check on agency power.** ... Discovery in state tort lawsuits provides a different way for third parties to raise questions about new and existing drugs. Given this context, I would not eliminate the potentially valuable information-gathering tools of state tort law.
>
> To make all this real, I would point out that the regulatory process at the FDA, even if it allows for submission of citizen petitions, does not compensate the families of alleged victims like Lois Colacicco and Theodore DeAngelis. ... **[T]he prospect of paying damages can sharpen drug manufacturers' incentives to place appropriate weight on safety as they strike the safety-efficacy balance. We should not lightly assume this balance now preempted – and by a single recently adopted preamble at that.**

Id. at 55 (emphasis added).[3] The majority ignored these concerns in its analysis, providing another reason for rehearing en banc.

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[3] The Supreme Court has indicated that "tort suits can serve as a catalyst in this process" of keeping warnings up-to-date and should not be preempted:

> [A] state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides... [the] EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits.

Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 449 (2005)(quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541-42 (C.A.D.C. 1984).

V. The United States Supreme Court's Grant of *Certiorari* in *Levine v. Wyeth* Supports Rehearing En Banc.

The exceptional importance of the issue at bar is underscored by the United States Supreme Court's grant of *certiorari* in *Levine v. Wyeth*, --- A.2d ---, 2006 WL 3041078 (Vt. 2006), *cert. granted,* 128 S. Ct. 1118 (2008). In *Levine*, a prescription drug failure-to-warn case, the Vermont Supreme Court rejected a preemption argument virtually identical to the argument advanced here. The Supreme Court is expected to hear argument in *Levine* in October.[1]

Yet another reason to grant re-hearing is to allow this Court the opportunity to have the benefit of the *Levine* decision in consideration of this matter.

CONCLUSION

Petitioners respectfully request that this Honorable Court rehear the instant matter *en banc* and reverse the order and opinion of the Panel majority in this case.

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[1] The majority incorrectly states that *Levine* is distinguishable from the instant cases. *See* Slip op. at 33, n.17. The Vermont Supreme Court's reasoning and holding is in line with the result reached by the district court here in *McNellis v. Pfizer*. Put otherwise, had the majority followed the reasoning of the Vermont Supreme Court, it would have ruled in favor of petitioners.

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CERTIFICATE OF SERVICE

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