**No. 09-3380**

# In the United States Court of Appeals for the Sixth Circuit

OLIVER WIMBUSH, ADMINISTRATOR OF THE ESTATE OF MARY BUCHANAN,
APPELLANT

*v.*

WYETH; WYETH-AYERST LABORATORIES CO.; WYETH PHARMACEUTICALS; WYETH PHARMACEUTICALS, INC.,
APPELLEES

*ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO (NO. 1:03-CV-2042) (THE HONORABLE SOLOMON OLIVER, JR., J.)*

## PETITION FOR PANEL REHEARING AND REHEARING EN BANC BY APPELLEES WYETH, WYETH-AYERST LABORATORIES CO., WYETH PHARMACEUTICALS, AND WYETH PHARMACEUTICALS, INC.

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## INTRODUCTION

This case presents an issue of exceptional importance—*viz.*, whether a claim that a drug manufacturer was negligent in the course of obtaining FDA approval to market a medicine is preempted by the Federal Food, Drug, and Cosmetic Act. The panel's decision is deeply flawed and cannot be squared either with the Supreme Court's decision in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), or with this Court's decisions in *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001), and *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005), cert. denied, 546 U.S. 935 (2005). That conflict merits rehearing.

The panel's erroneous decision, moreover, was entirely unnecessary. In its brief, Wyeth advanced two alternative arguments—firmly grounded in the district court's holdings—that would have easily disposed of plaintiff's claim on non-constitutional grounds. Mistakenly believing that they had not been asserted, the panel failed to consider those alternative arguments, which should have compelled a ruling in Wyeth's favor. As a result, rather than adhere to the longstanding doctrine of constitutional avoidance, the panel imprudently waded into the treacherous waters of federal preemption. The result is an ill-advised decision on a question of exceptional importance that departs from well-established precedent—a needless outcome that justifies rehearing.

## STATEMENT

Appellant Mary Buchanan filed an amended complaint against appellees Wyeth; Wyeth-Ayerst Laboratories Co.; Wyeth Pharmaceuticals; and Wyeth Pharmaceuticals, Inc. (collectively "Wyeth"), alleging, as is relevant here, product liability and negligence arising from her ingestion of the diet medicine Redux.[1] Wyeth moved for summary judgment based both on the lack of evidence of proximate causation and on preemption by the Federal Food, Drug, and Cosmetic Act (FDCA). The district court granted summary judgment to Wyeth. The panel affirmed except as to Buchanan's claim that Wyeth was negligent in bringing Redux to market; the panel reversed the district court's holding that the FDCA preempted that claim, and remanded the case for further proceedings.

1. Wyeth received FDA approval to market Redux in April 1996, began marketing it in June 1996, and removed it from the market in September 1997. Buchanan allegedly ingested Redux for several months during 1996 and 1997. She was allegedly diagnosed with primary pulmonary hypertension in 2001 and sued Wyeth in October 2003, claiming she had developed the condition as a result of having ingested Redux. Buchanan died in De-

[1] This case was originally filed by Buchanan; upon her death, the case was continued by her estate, represented first by Romona Longs and then by Oliver Wimbush. Like the panel decision, this petition refers to the plaintiff and appellant as "Buchanan." *See* Op. 3 n.2.

cember 2003. The amended complaint stated claims for (1) product liability under Ohio statute (encompassing both design defect and failure to warn); (2) common-law negligence; and (3) wrongful death. Buchanan sought economic, non-economic, and punitive damages. Buchanan later withdrew her failure-to-warn claim, leaving product liability (design defect) and common-law negligence as her only substantive claims against Wyeth. *Longs* v. *Wyeth*, 536 F. Supp. 2d 843, 845-846 (N.D. Ohio 2008) (*Longs I*); Op. 3-4.

Wyeth filed motions for summary judgment on Buchanan's claims, contending, as is relevant here, (1) that Buchanan had failed to adduce evidence demonstrating the requisite causal link between Wyeth's alleged acts or omissions and Buchanan's injury and (2) that the claims were in any event preempted by the FDCA. *Longs I*, 536 F. Supp. 2d at 845; Op. 4.

2. The district court granted summary judgment to Wyeth on all counts. On preemption, the district court concluded that, to the extent Buchanan's claims addressed conduct subsequent to FDA approval, the FDCA had no preemptive effect. Claims premised on Wyeth's conduct prior to FDA approval, however, were preempted because they "directly conflict[ed] with the FDA's authority to determine which drugs are sufficiently safe and effective to be marketed." *Longs I*, 536 F. Supp. 2d at 847-848.

Turning to Wyeth's motion on the merits, the district court then held that Buchanan had failed to present any evidence of inadequacy of the warn-

ings provided with Redux while Wyeth was marketing it. *Longs I*, 536 F. Supp. 2d at 851-854. As a result, the court granted summary judgment to Wyeth on Buchanan's product liability claim. As for Buchanan's negligence claim, the court deemed it "not clearly stated." *Id.* at 854. It reiterated that, to the extent Buchanan was pursuing claims for negligent misrepresentation to the FDA, negligent failure to investigate prior to FDA approval, or negligence in putting Redux on the market, those claims were preempted by the FDCA. *Id.* at 855. The court then held that, even if Buchanan's claim was more broadly understood as a "general negligence claim," it still would fail, because Buchanan had "not presented evidence showing that [Wyeth's] negligence proximately caused [her] injury or death." *Id.* As a result, the district court "grant[ed] summary judgment for [Wyeth] on [Buchanan's] negligence claim." *Id.* at 856.

Buchanan subsequently filed a motion to vacate the district court's order and judgment and to alter the judgment. The district court denied the motion. *Longs* v. *Wyeth*, 621 F. Supp. 2d 504 (N.D. Ohio 2009) (*Longs II*).

3. The panel reversed in pertinent part and remanded for further proceedings. At the outset, the panel agreed with the district court that Buchanan had "failed to point to any evidence creating a factual dispute as to the adequacy of" the warnings that had accompanied Redux during its time

on the market. Op. 8. Accordingly, the panel affirmed summary judgment as to the design-defect product liability claim. *Id.*

The panel further agreed with the district court that Buchanan's negligence claim was "unclear." Op. 10. It proceeded to divide Buchanan's claim into two separate claims: "claims regarding Wyeth's acts and omissions, prior to the FDA's approval, in bringing the drug to market" and "claims regarding Wyeth's acts and omissions subsequent to the FDA's approval." Op. 11. The panel agreed that summary judgment for Wyeth on the post-approval claims was justified, because "Buchanan failed to present evidence demonstrating proximate cause between Wyeth's alleged negligence after the FDA approved Redux and Buchanan's injury or death." Op. 11-12.

Rather than address the consequences of that ruling for Buchanan's *pre-approval* claims, however, the panel proceeded to address the legal question whether the FDCA *preempted* those claims—specifically, Buchanan's claim that Wyeth was negligent "for bringing Redux to market at all." Op. 12. Notably, the panel first assumed the existence of such a claim under Ohio law, stating that it was not determining "whether such a claim actually exists" but only "whether FDA approval would preempt such a claim if it does exist." Op. 12 n.6. Rather than determining whether the claim in fact existed, the panel proceeded to hold that a presumption against preemption

applied because Buchanan's claim was brought "under preexisting state products liability law." Op. 14 (internal quotation marks omitted).

The panel then disagreed with the district court's conclusion that negligent-bringing-to-market claims would conflict with the role of the FDA. Op. 15-16. The panel relied both on the presumption against preemption and on case law that, according to the panel, "support[ed] the conclusion that Congress did not intend to preempt state tort law claims when it passed the FDCA." Op. 16. "Allowing a state tort claim under the instant circumstances," the panel continued, "would not interfere with the methods by which the federal statute was designed to reach its goal." *Id.* (brackets and internal quotation marks omitted). In so holding, the panel also quoted at length from the Supreme Court's decision in *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009). Op. 17-18. The panel recognized, however, that "there is . . . no post-*Levine* court of appeals authority for the proposition that the *Levine* rationale extends beyond the realm of failure-to-warn claims to apply to all pre-approval state law claims." Op. 18. And it acknowledged that *Levine* "dealt solely with state tort inadequate warning claims versus FDA-approved labels, whereas this case pits state tort negligent-bringing-to-market claims against FDA approval to market." Op. 18 n.7 (citation omitted).

The panel observed that it was "not pass[ing] upon whether there may be alternative bases for adjudicating" Buchanan's negligent-bringing-to-

market claims prior to trial. Op. 18. The panel stated, erroneously, that "[n]either the parties nor the district court have asserted any such alternative, so the issue is not before us." *Id.*

## ARGUMENT

### A. The Panel's Decision Conflicts With Decisions Of The Supreme Court And This Court On A Question Of Exceptional Importance Concerning Federal Preemption

The panel affirmed summary judgment for Wyeth on Buchanan's product liability claim and on her claim for negligence relating to Wyeth's conduct after FDA approval of Redux. Accordingly, this petition solely addresses the viability of Buchanan's claim alleging Wyeth's negligence prior to FDA approval—that "Wyeth was negligent for bringing Redux to market at all." Op. 12. The panel held that such "negligent-bringing-to-market" claims, Op. 18 n.7, are not preempted by the FDCA. That conclusion cannot be squared with decisions either of the Supreme Court or of this Court.

1. In *Buckman Co.* v. *Plaintiffs' Legal Committee*, *supra*, the Supreme Court held that the FDCA preempts "fraud-on-the-FDA" claims. *Id.* at 344. Plaintiffs in that case had contended that, if the defendant had not made fraudulent representations to the FDA in the course of obtaining approval to market a medical device, the FDA would not have approved the device, and plaintiffs would not have been injured. *Id.* The Court rejected that contention and held that the plaintiffs' claims were preempted. As an initial

matter, it rejected a presumption against preemption because the manufacturer's "dealings with the FDA were prompted by" federal statute, and "the very subject matter of [the defendant's] statements were dictated by th[e] statute's provisions." *Id.* at 347-348. The Court then reviewed the "delicate balance of statutory objectives" the FDA is entrusted to carry out, concluding that this balance and the "comprehensive scheme" that the FDA employs to approve a product for the market would be "skewed" by permitting fraud-on-the-FDA claims to proceed. *Id.* at 348. The Court explained that such claims would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [agency], will later be judged insufficient in state court," leading to a "deluge" of information that the agency "neither wants nor needs." *Id.* at 351. In short, "this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Id.* at 353.

This Court has rejected fraud-on-the-FDA claims on similar grounds. In *Kemp* v. *Medtronic, Inc.*, *supra*, the Court observed that, in order to prevail on such a claim, a plaintiff would have to demonstrate that "but for the alleged misrepresentations made by the manufacturer, the FDA would have withheld approval of the device." *Id.* at 235. In order to do so, a plaintiff would be required to "adduce expert testimony from those familiar with FDA procedures, conduct discovery of FDA employees, and establish that the al-

leged misrepresentations rendered the device not safe and effective for its intended use." *Id.* "Effectively," the Court held, such claims "would allow individual juries to undertake a counterfactual FDA review, and conclude that the FDA would not have approved the device," even though "Congress allocated the FDA responsibility to design and manage a process" for evaluating medical items and "assigned the FDA the responsibility to approve or disapprove of applications to market" them. *Id.* (internal quotation marks and citation omitted). Accordingly, the Court concluded, fraud-on-the-FDA claims were preempted by federal law. *Id.* at 235-236.

Critically for present purposes, this Court has rejected efforts to circumvent *Buckman* and *Kemp* by restyling fraud-on-the-FDA claims as claims premised on a manufacturer's alleged negligence during the FDA approval process. In *Cupek* v. *Medtronic, Inc.*, *supra*, plaintiffs filed an amended complaint following the *Kemp* decision in an effort "to raise arguments that are distinguishable from the arguments made in *Kemp*." *Id.* at 422. One count of the amended complaint alleged the defendant's "negligence per se" in its "failure to comply with the [FDA's] conditions of approval." *Id.* The district court held that the claim was preempted, and this Court affirmed, stating that the claim was "a disguised fraud on the FDA claim." *Id.* at 424 (citations omitted).

2. The panel's holding that the FDCA does not preempt Buchanan's "negligent-bringing-to-market" claims—whether styled as "negligent misrepresentation or negligent failure to investigate or negligence in putting Redux on the market," *Longs I*, 536 F. Supp. 2d at 847, 855—conflicts with the foregoing precedent. As an initial matter, the panel's decision erroneously applied a presumption against preemption even though, as in the fraud-on-the-FDA context, Wyeth's "dealings with the FDA" during the pre-approval period "were prompted by" the FDCA, which prohibits a manufacturer from marketing a product absent FDA approval and dictates the procedures for obtaining that approval. *Buckman*, 531 U.S. at 347-348. That is, regardless whether Wyeth's conduct prior to FDA approval was negligent, Redux could not have been placed on the market, and Buchanan could not have ingested it, absent FDA approval—thus rendering the existence of federal law a "critical element" in Buchanan's claims and placing it outside the scope of the presumption against preemption. *Id.* at 353.

As in both *Buckman* and *Kemp*, moreover, Buchanan cannot prevail on a "negligent-bringing-to-market" claim without demonstrating a causal link between Wyeth's alleged conduct and her own injury. At a minimum, that requires a showing that, but for Wyeth's negligence, the FDA would not have approved Redux. But such a showing would necessitate a "'searching inquiry' of FDA internal procedures and personnel" that "runs counter to both

congressional intent and sound policy" committing approval decisions to the sound discretion of the FDA. *Kemp*, 231 F.3d at 235 (citation omitted). The FDA's "comprehensive scheme" for reviewing and approving medical products would undoubtedly be just as "skewed" by permitting claims of negligent representations to the FDA during the approval process to go forward as claims alleging fraudulent representations. *Buckman*, 531 U.S. at 348.

It is perhaps for those reasons that this Court has already repudiated attempts to restyle fraud-on-the-FDA claims as "pre-approval negligence" claims, *Cupek*, 405 F.3d at 422, 424; both causes of action undermine the FDA's critical role in approving medical products for release into the market. And, in fact, Buchanan's briefs to the panel reveal undercurrents of a fraud-on-the-FDA claim. *See, e.g.*, Buchanan Reply Br. 2 (alleging that Wyeth "dup[ed]" the FDA into approving Redux).

The panel's reliance on *Levine*, *supra*, is unavailing. As the panel itself acknowledged, *Levine* addressed a materially different scenario: "*Levine* dealt solely with state tort inadequate warning claims versus FDA-approved labels, whereas this case pits state tort negligent-bringing-to-market claims against FDA approval to market." Op. 18 n.7 (citation omitted). The panel deemed this to be a "distinction without a difference," since "[j]ust as state tort law on adequacy of warnings can be seen as complementary to the FDA's labeling regulation, so too can state law duties regarding the decision

to bring a product to market be seen as complementary to the FDA's function of approving a drug for market." *Id.* The panel further suggested that, "[i]f the manufacturer is negligent in [its] investigation, then the entire FDA approval process is tainted from the outset." *Id.* But those same points apply just as forcibly to claims alleging fraudulent conduct by a manufacturer during the pre-approval period. If they did not carry the day in *Buckman*—which *Levine* did not disturb—they cannot prevail here. This Court should grant rehearing to reconsider the panel's holding on an issue of exceptional importance not only to Wyeth, but to the entire pharmaceutical industry.

### B. The Panel's Failure to Decide the Appeal On Alternative Grounds Was Erroneous and Conflicts With the Canon of Constitutional Avoidance

The panel's determination that the FDCA does not preempt Buchanan's "negligent-bringing-to-market" claim is not only wrong and in conflict with Supreme Court and Sixth Circuit precedent; it is unnecessary. Wyeth provided the panel with two alternative, non-constitutional bases for affirming summary judgment as to that claim. The panel, however, not only failed to address either of these arguments, but erroneously stated that Wyeth had not asserted any alternative arguments *at all*. That conclusion is patently incorrect, and, in addressing only the preemption question, the panel violated the canon of constitutional avoidance repeatedly set forth by the Supreme Court and by this Court. See, *e.g.*, *Crook* v. *Baker*, 813 F.2d 88, 91 (6th Cir.

1987) (noting that, "prior to reaching any constitutional questions, federal courts must consider nonconstitutional ground[s] for decision").

In fact, Wyeth set forth two independent, non-constitutional, and logically antecedent bases for affirming the district court's grant of summary judgment on Buchanan's "negligent-bringing-to-market" claim. Wyeth first contended that no common-law claim for "negligent-bringing-to-market" has ever been recognized under Ohio law. *See* Wyeth Br. 38-40. That contention is plainly correct—so much so that Buchanan did not even attempt to answer it in her reply. As Wyeth explained in its brief before the panel, no Ohio court has ever recognized a claim premised solely on a manufacturer's alleged negligence in the period prior to approval by the FDA, much less identified the elements of or defenses to such a claim or elaborated upon the burden at summary judgment or trial for a plaintiff pursuing it. The absence of such a claim at common law is not surprising, given that it necessarily implicates FDA approval, a creature of federal statutory law. *See Buckman*, 531 U.S. at 353. The panel nevertheless ignored Wyeth's argument, and instead proceeded to "assume[] the viability of such a claim under the Ohio common law" for purposes of its preemption analysis. Op. 12 n.6.

Wyeth also contended that, even assuming the existence of a "negligent-bringing-to-market" claim, it was entitled to summary judgment on the merits because Buchanan had failed to adduce evidence supporting *any*

theory of negligence, even in the most broadly construed sense. *See* Wyeth Br. 17-19, 21-22, 34-37. Indeed, the district court itself repeatedly concluded that, quite apart from any preemptive force of the FDCA, Buchanan's "general negligence claim" failed because she did not "present evidence showing that [Wyeth's] negligence proximately caused [her] injury or death." *Longs I*, 536 F. Supp. 2d at 855; *see also id.* at 856 (granting "summary judgment for [Wyeth] on [Buchanan's] negligence claim"); *Longs II*, 621 F. Supp. 2d at 513 (noting that "[Buchanan's] failure to produce evidence regarding proximate cause was fatal to *any* claim of negligence" (emphasis added)). Given these holdings, the panel's contention that the district court—much less Wyeth—did not "assert[] any such alternative" grounds for disposing of the negligence claim, Op. 18, plainly resulted from a failure to recognize the ground expressly articulated in Wyeth's brief and relied on by the district court in granting summary judgment on Buchanan's entire negligence claim.

Moreover, Wyeth's contention that it was entitled to summary judgment on the entirety of Buchanan's negligence claim, including her claim of pre-approval negligence, was correct—as the panel's own decision confirms. The panel affirmed that the warnings accompanying Redux were at no time inadequate and that Buchanan failed to adduce evidence demonstrating proximate causation between Wyeth's alleged post-approval conduct and her injury. Op. 11-12. But if Wyeth was not negligent with respect to Buchanan

*after* Redux was approved, it cannot have been negligent *before* Redux was approved, given that the post-approval body of knowledge regarding Redux was necessarily greater than the pre-approval body of knowledge. That is, if Buchanan cannot prevail on a claim that Wyeth "fail[ed] to take the drug off of the market sooner," Op. 11, *a fortiori* she cannot prevail on a claim that Wyeth was negligent in bringing the drug to market in the first place. In addition, if Buchanan failed to adduce evidence establishing that Wyeth's post-approval conduct proximately caused her injury, she cannot logically establish proximate causation between Wyeth's pre-approval conduct—which occurred well before Buchanan could have possibly ingested Redux, and includes the intervening event of FDA approval—and her injury.

The panel erred when it failed to resolve the "negligent-bringing-to-market" claim on either of these non-constitutional grounds, contravening the canon of constitutional avoidance. It erroneously asserted that neither the district court nor Wyeth advanced any such alternative arguments. And it proceeded to render a constitutional ruling that conflicts with the decisions both of the Supreme Court and of this Court. Any one of those errors would justify rehearing. With respect, the existence of all three compels it.

## CONCLUSION

The petition for panel rehearing and rehearing en banc should be granted.

Respectfully submitted,

S/ *David R. Cooper*

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SEPTEMBER 15, 2010

## CERTIFICATE OF SERVICE

I, David R. Cooper, counsel for appellees and a member of the Bar of this Court, certify that, on September 15, 2010, a copy of the attached Petition for Panel Rehearing and Rehearing En Banc was filed electronically through the appellate CM/ECF system with the Clerk of the Court. I further certify that all parties required to be served have been served.

S/ *David R. Cooper*
DAVID R. COOPER

SEPTEMBER 15, 2010