No. 21-348

IN THE

Supreme Court of the United States

JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.,

Petitioners,

v.

LYNN FITCH, Attorney General of the State of Mississippi, ex rel. THE STATE OF MISSISSIPPI,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE MISSISSIPPI SUPREME COURT

REPLY BRIEF FOR THE PETITIONERS

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INTRODUCTION

J&J's petition identifies two persistent, acknowledged, and cross-cutting splits on important issues of pre-emption and the Supremacy Clause. First, the circuit and state supreme courts are split 6-5 on whether a presumption against pre-emption applies to express pre-emption clauses. Pet. 14-19. Second, the courts are split 8-2 regarding what types of agency actions can pre-empt state law. Pet. 19-23. The State AG cannot (and makes no effort to) refute that showing. Nor does the State AG dispute the significance of the two questions presented.

The State AG instead attempts to elide these critical issues by arguing that the Mississippi Supreme Court did not address them. That cannot be squared with the Court's opinion, which turned on the application of the presumption and the belief that only notice-and-comment rulemaking can trigger pre-emption. And the State AG's baseless accusations of undue delay do not support denial of review on these important questions.

The State AG also criticizes Petitioners' filing of a notice of the application of the automatic bankruptcy stay. As the bankruptcy court has held, however, the stay applies to talc claims against both Petitioners. There was nothing improper about the notice. To the extent the State AG claims the stay should not apply to this or similar actions, those issues can and will be raised and litigated in the bankruptcy court. In the meantime, this matter should be stayed.

ARGUMENT

I. The Mississippi Supreme Court's Decision Directly Presents Both Important Questions On Which The Lower Courts Are Split.

The Mississippi Supreme Court committed two errors when it held that the FDCA does not pre-empt the State AG's suit. As detailed in the petition (12-13, 15-16, 20-21, 32-39), the court (1) erroneously applied the presumption against pre-emption; and (2) in applying the presumption, narrowly read the term "requirement" in 21 U.S.C. § 379s(a) as being limited to notice-and-comment rulemakings. This errant two-step—first assuming that a presumption against pre-emption must apply, and then implementing the presumption by adopting an extremely cramped interpretation of the term "requirement"—formed the basis for the court's construction of § 379s and its ultimate holding that there was no pre-emption: Because the FDA had "deci[ded] not to adopt any … regulation" governing talc labeling, its "decision not to act cannot be deemed to be a requirement for purposes of § 379s(a)." Pet. App. 16a; *see* Pet. App. 17a (FDA's citizen petition denial likewise did not impliedly pre-empt AG's claim because "the [FDA] chose not to exercise its regulatory authority").

Unable to refute that both issues are the subject of deep, well-developed splits of exceptional importance, the State AG attacks the suitability of the Mississippi Supreme Court's opinion as a vehicle for resolving them. Opp. 6, 8-9, 11. The State AG claims that the court did not decide either issue, and the "actual basis" of the Mississippi Supreme Court's

decision was its ultimate holding: that "the denial of two citizen petitions falls outside" § 379s(a). Opp. 8. The two predicate errors were, however, central to the court's opinion and crucial to the result reached.

A. The court applied the presumption against pre-emption.

Five years ago, this Court seemingly called off one front of "the great preemption presumption wars," *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 762 n.1 (4th Cir. 2018), when it declared unequivocally that where a "statute 'contains an express pre-emption clause,' [courts] do not invoke any presumption against pre-emption," *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)). And yet the battle rages on in the state and lower courts. The Fourth, Fifth, Eighth, and Tenth Circuits and the Arizona Supreme Court, heeding *Franklin*'s pronouncement, decline to apply the presumption to express pre-emption provisions, even in the context of traditional areas of state regulation. Pet. 17-19. In contrast, the Third and Ninth Circuits, along with the Supreme Courts of California, Michigan, Indiana, and now Mississippi, stubbornly continue to apply a presumption against pre-emption when the pre-emption provision is ambiguous or touches on the historic police powers of the states. Pet. 15-17.

The State AG does not deny this intractable split. Nor does the State AG contest the importance of the issue to regulators, businesses, consumers, and the public interest. As the U.S. Chamber of Commerce

highlighted in its amicus brief, this split—where some courts adhere strictly to the statutory text while others give priority to "extratextual considerations"—imposes "severe" penalties on producers and consumers of valuable goods and services like medical devices and vaccines for childhood diseases. Chamber Br. at 6, 15-16. The patchwork of different regulations not only inflates the prices of goods and services, but precludes some from being brought to market at all. *Id.* at 15-16.

Unable to dispute the deep split or its importance, the State AG tries to cast the Mississippi Supreme Court as not employing the presumption here. But that is just wishful thinking. The Mississippi Supreme Court twice stated that it was applying a presumption against pre-emption. The court began its discussion of pre-emption by expressly employing the "assumption that the historic police powers of the States [are] not to be superseded by … Federal Act unless that [is] the clear and manifest purpose of Congress." Pet. App. 11a (alterations in original) (quotation marks omitted). The court cited and quoted pre-*Franklin* cases to support its invocation of the presumption against pre-emption for express pre-emption provisions. Pet. App. 11a-12a. The court made clear that, given the presumption, it needed to look beyond the plain language of the express pre-emption provision to understand Congress's "purpose." Pet. App. 12a. And then the court declared that it must accept a plausible reading of the statute that "disfavors pre-emption," Pet. App. 15a, again citing pre-*Franklin* cases. In short, the court's invocation and application of the presumption could not have been clearer.

After declaring it had a "duty" to choose the reading that disfavors pre-emption, the Mississippi Supreme Court did just that. Pet. App. 15a-16a. The court's approach surely comes as no surprise to the State AG. It is exactly what the AG urged the court to do in the briefing below: "Ultimately, courts have a duty to accept the reading that disfavors pre-emption." Br. of Appellee 42 (quotation marks omitted). The court, quoting the very same language, accepted that invitation to apply the presumption against pre-emption.

B. The court held that only formal regulations issued through notice-and-comment rulemaking pre-empt state law.

This Court has stressed that any agency action taken pursuant to "congressionally delegated authority" may "carry[] the force of law" under the Supremacy Clause, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019), and that courts should not "insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking," because to do so "would be … to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended," *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000).

As explained in the petition (19-23), despite this guidance, lower courts remain intractably split as to whether agencies must undergo burdensome notice-and-comment rulemaking for their actions to be given pre-emptive effect. Two courts hold that only notice-and-comment rulemaking is pre-emptive. Eight

courts give pre-emptive effect to less formal agency actions, although they disagree as to the proper analysis. The issue arises in both implied pre-emption cases, *e.g.*, *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237 (3d Cir. 2008), and cases involving express pre-emption clauses like § 379s, which ask whether an agency action procedurally establishes a "requirement," *i.e.*, a "rule of law that must be obeyed," *Hardeman v. Monsanto Co.*, 997 F.3d 941, 956 (9th Cir. 2021) (quotation marks omitted), *pet. for cert. filed*, No. 21-241 (Aug. 16, 2021).

This Court's input on this important question is vitally needed. As eight former high-level FDA officials explained in their amicus brief, the Mississippi Supreme Court's ruling that only notice-and-comment rulemaking is pre-emptive "hobbles the agency's flexibility, forcing it to choose between rigid rulemaking that is often logistically impossible or having its expert judgments lost in a sea of contradictory state-required labels." Br. of Former FDA Officials 18. The court's restrictive ruling likewise risks subjecting manufacturers "to years of uncertainty regarding the FDA's position on proposed labeling while the agency finalizes … notice-and-comment rule[s]," PhRMA Br. 19, and spawning confusing and potentially dangerous "overwarning" for consumer products, Br. of Product Liability Advisory Council 7-21.

The State AG again cannot dispute the split and its importance. Instead, the State AG assiduously tries to avoid all of this, asserting only that "this case does not present" the question of the types of agency actions capable of pre-empting state law. Opp. 13. But

that cannot be squared with the Mississippi Supreme Court's opinion.

The Mississippi Supreme Court held that the FDA's denial of the citizen petitions was not pre-emptive because it "does not follow the notice and comment rule making process." Pet. App. 15a. Agency actions that do not follow this process, the court reasoned, are "deemed inaction." *Id.* (citing *Fellner*, 539 F.3d at 253). Based on this narrow, anti-pre-emption driven interpretation of what is required for agency action to pre-empt state law, the court interpreted the phrase "requirement" in § 379s(a) to mean only a "positive expression of regulation applicable to a specific product." Pet. App. 16a. The court concluded, therefore, that the FDA's "decision not to act"—*i.e.*, its "decision not to adopt any such regulation"—"cannot be deemed to be a requirement for purposes of § 379s(a)." Pet. App. 16a.

Again, the court's limiting pre-emption to notice-and-comment rulemaking should come as no surprise to the State AG. In that court, the State AG emphatically argued that "*only* formal FDA notice-and-comment rulemaking has pre-emptive effect." Br. of Appellee at 42.

The State AG also misses the mark in contending, Opp. 11-14, that the Mississippi court's reasoning is limited only to the pre-emptive effect of FDA actions. The court's logic extends equally to any agency action

and any express pre-emption provision that uses the term "requirement."[1]

The State AG's argument regarding the limited nature of the ruling here is belied by the court's reliance on the Third Circuit's decision in *Fellner*—a leading case analyzing the pre-emptive force of various agency actions that expressly acknowledges a circuit split on the issue. *See Fellner*, 539 F.3d at 244-45. The court's reliance on that case in support of its conclusion that agency actions short of notice-and-comment rulemaking are "deemed inaction" for pre-emption purposes, Pet. App. 15a, demonstrates that its reasoning is not limited to the FDA context.

The State AG mistakenly contends that the Mississippi court's invocation of *Fellner* shows that the court discerned a distinction between agency action in general (which need not involve notice-and-comment rulemaking to pre-empt) and the FDA's actions in particular (which must). Opp. 12-13. Neither *Fellner* nor the decision below recognizes such a distinction. *Fellner* specifically opines that "federal agency action

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[1] The court's single citation to a 1997 FDA guidance document does not change this fact. *See* Pet. App. 15a (citing 62 Fed. Reg. 8961 (Feb. 27, 1997)). The court's reasoning was in no way limited to the FDA's non-binding guidance document, which does not address § 379s or pre-emption at all. The document—which sought to clarify the effect of guidance documents such as itself—specifically states that it "cannot legally bind FDA or the public." 62 Fed. Reg. at 8963. Notably, the court also cited both non-FDA specific authorities and the presumption against pre-emption in arriving at its conclusion that the FDA must undergo notice-and-comment rulemaking to establish pre-emptive requirements. Pet. App. 15a-16a.

taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking"—including "FDA's actions"—"may also have preemptive effect over state law." 539 F.3d at 244-45. The Mississippi court simply misread another passage of *Fellner* as supporting its contrary conclusion; it did not adopt a nuance in that case that does not exist.

The State AG fares no better in invoking 21 C.F.R. § 740.1(b), which provides that the FDA may establish regulations prescribing warning labels for cosmetics. That provision says nothing about the pre-emptive effect of the FDA's decision to deny a citizen petition. The FDA does have regulations governing the denial of citizen petitions, however, and those rules specifically provide that a denial is a "final agency action" judicially reviewable under the Administrative Procedure Act. 21 C.F.R. § 10.45(d). "[F]inal agency action" may be "'Law' with pre-emptive effect." *Albrecht*, 139 S. Ct. at 1683 (Thomas, J., concurring); *see id.* at 1679 (majority op.).

Finally, the State AG is incorrect in distinguishing the numerous cases that have granted pre-emptive effect to the FDA's denial of a citizen petition as being limited to the drug pre-approval context. Opp. 14-15. The pre-emptive effect of the FDA's actions in those cases hinges on the same analysis here—whether the action "lie[s] within the scope of the authority Congress has lawfully delegated," such that it "carr[ies] the force of law." *Albrecht*, 139 S. Ct. at 1679; *cf. Hardeman*, 997 F.3d at 957 (employing identical analysis to determine whether agency action was a pre-emptive "requirement[]" under express pre-emption provision). In concluding that the FDA's

citizen petitions are pre-emptive, courts in drug pre-approval cases have specifically held that the FDA's "formal rejection of [a] Citizen Petition falls within the scope of the FDA's congressionally delegated authority" and "carr[ies] the force of law." *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1029-33 (S.D. Cal. 2021), *appeal filed sub nom. In re Adams v. Novo Nordisk,* No. 21-55342 (9th Cir. Apr. 9, 2021); *see* PhRMA Br. 13-14 (collecting cases).

In short, the Mississippi Supreme Court directly ruled on both questions presented, deepening two entrenched, acknowledged circuit splits that go to the heart of federalism.

C. The State AG's assertions that this petition was improperly brought for the purpose of delay are without merit.

The State AG asks this Court to deny the petition because Petitioners have "sought delay." Opp. 16. Petitioners, however, have pursued this Court's review diligently. When filing their certiorari petition, Petitioners did not ask this Court for a stay of the mandate. Nor have Petitioners sought any extensions for filing—unlike the State AG.

And seeking review of these important issues is hardly improper. Indeed, the Mississippi Supreme Court itself recognized the pressing importance of review on these issues. Thus, the claim that this petition was brought for some improper purpose is baseless.

II. Consideration Of The Petition Should Be Stayed.

On October 18, 2021, Petitioners filed a notice of the bankruptcy filing by LTL Management LLC (the entity now responsible for talc claims against Johnson & Johnson Consumer Inc.). The notice cited the automatic bankruptcy stay, 11 U.S.C. § 362, and explained that all talc-related claims against LTL and other related entities (including Petitioners) are subject to the automatic stay. Such notices are routine after a bankruptcy filing. Petitioners filed similar notices, with the same substantive language, in thousands of other cases involving talc-related claims.

The State AG argues that the notice was inappropriate, that the bankruptcy filing by LTL was irrelevant to this case, and that the automatic bankruptcy stay has no application here. Opp. 16. But the bankruptcy court has now held that the automatic stay in the LTL bankruptcy applies to talc claims against both Petitioners here and that the stay applies to alter ego claims asserted by talc claimants. *See* Order Granting Prelim. Inj. at 2, 7, *In re LTL Mgmt. LLC*, No. 21-30589 (Bankr. W.D.N.C. Nov. 15, 2021), Dkt. No. 102 (PI Order).[2] Thus, it was hardly improper to provide this Court the notice of bankruptcy filing by LTL and the applicability of the automatic stay.

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[2] Because the bankruptcy court also transferred the case to the District of New Jersey, it limited the effect of its ruling as to J&J to last for 60 days to permit the newly assigned bankruptcy judge to look at the issue afresh if it so chooses. PI Order at 7.

The State AG invokes the police powers exception to the automatic stay, 11 U.S.C. § 362(b)(4). But the State AG is not seeking to stop the sale of a dangerous product. Rather, the State AG is seeking to collect money based on past conduct (up to $10,000 for every cosmetic talc bottle sold by Petitioners in the past 47 years, which the State AG now claims were mislabeled). Compl. p. 31. In any event, the police powers exception has no application here, where the State AG is asserting an alter ego claim. *See* Compl. p. 5 (alleging that Defendants are alter egos of one another). Such a claim is considered an asset of the bankruptcy estate, *In re Tronox*, 855 F.3d 84, 104 (2d Cir. 2017); *In re Emoral, Inc.*, 740 F.3d 875 (3d Cir. 2014); *Steyr-Daimler Puch of Am. Corp. v. Pappas*, 852 F.2d 132, 135 (4th Cir. 1988); *S.I. Acquisition, Inc. v. Eastway Delivery Serv., Inc.*, 817 F.2d 1142, 1152-53 (5th Cir. 1987), and "does not fit within the police powers exception to the statute," *Wharton v. Virginia*, 993 F.2d 1541 (table), 1993 WL 192515, at *3 (4th Cir. 1993). Consistent with that authority, the bankruptcy court's recent order expressly includes "alter ego" theories. PI Order at 7.

To the extent the State AG claims the stay should not apply to this action, those issues can be raised and litigated in the bankruptcy court. The State AG has not raised the issue to date in that forum, choosing instead to unilaterally declare that the stay does not apply. Petitioners, however, will seek resolution of the issue by the bankruptcy court. In the meantime, this matter should be stayed.

CONCLUSION

Consideration of the petition should be stayed. When the Court does consider the petition, however, it should grant the petition and reverse the Mississippi Supreme Court or, alternatively, hold this petition if it grants certiorari in *Hardeman*, No. 21-241.

Respectfully submitted,

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