No. 21-_____

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

PETITION FOR A WRIT OF CERTIORARI

Robert M. Loeb
Elizabeth R. Moulton
Sheila Baynes
Zachary Hennessee
ORRICK, HERRINGTON & SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005

E. Joshua Rosenkranz
Counsel of Record
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(212) 506-5000
jrosenkranz@orrick.com

Counsel for Petitioners

QUESTIONS PRESENTED

1. In *Puerto Rico v. Franklin California Tax-Free Trust*, this Court held that courts should "not invoke any presumption against pre-emption" when a "statute 'contains an express pre-emption clause.'" 136 S. Ct. 1938, 1946 (2016). Obeying that command, four circuits and a state supreme court no longer apply any such presumption to express pre-emption clauses. Four state supreme courts (now including the Mississippi Supreme Court) and two circuits, however, continue to apply the presumption to pre-emption provisions that they find ambiguous, or that touch on a state's historic police powers, or both.

Did the Mississippi Supreme Court err in narrowly construing an express preemption clause on the ground that a presumption against pre-emption applies here because it considered the pre-emption provision ambiguous and because the provision touches on historic state police powers?

2. The lower courts are divided over what types of agency actions can pre-empt state law. One circuit and the Mississippi Supreme Court hold that only notice-and-comment rulemaking qualifies as pre-emptive. In contrast, seven circuits and a state supreme court reject that line, giving pre-emptive force to final administrative actions that warrant *Chevron* deference or to any final agency action with the force of law.

Did the Mississippi Supreme Court err in holding that only notice-and-comment rulemaking can pre-empt state law?

PARTIES TO THE PROCEEDINGS

Petitioners Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) were defendants-appellants below.

Respondent Lynn Fitch, Attorney General of the State of Mississippi, ex rel. the State of Mississippi, was plaintiff-appellee below.

CORPORATE DISCLOSURE STATEMENT

1. Johnson & Johnson is a publicly held company. It has no parent corporation, and no publicly held company owns 10% or more of Johnson & Johnson's stock.

2. Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) is wholly owned by Janssen Pharmaceuticals, Inc. Janssen Pharmaceuticals, Inc. is wholly owned by DePuy Synthes, Inc. DePuy Synthes, Inc. is wholly owned by Johnson & Johnson International. Johnson & Johnson International is wholly owned by Johnson & Johnson.

RELATED PROCEEDINGS

Supreme Court of Mississippi:

Johnson & Johnson et al. v. Fitch ex rel. Mississippi, No. 2019-IA-00033-SCT (Miss. April 1, 2021)

Chancery Court of Hinds County:

State of Mississippi, ex rel. Jim Hood v. Johnson & Johnson et al., No. G-2014-1207 (Miss. Ch. Ct., Hinds Cty. Dec. 18, 2018)

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

U.S. Constitutional Provisions

Statutes & Regulations

Other Authorities

INTRODUCTION

The lower courts are making a hash out of pre-emption law in ways that dangerously flout both congressional commands and important federal policies. This case is the latest—and most extreme—illustration of the trend in judicial defiance and confusion regarding express pre-emption statutes.

The Food, Drug, and Cosmetic Act (FDCA) grants the Food and Drug Administration (FDA) broad authority to regulate cosmetic products and to decide when warning labels are necessary. In 2014, the FDA made a reasoned regulatory decision not to require talc products—like Johnson's Baby Powder—to bear warning labels stating that using talcum powder increases the risk of ovarian cancer. The decision came in the form of a final agency action that denied two citizen petitions. The FDA issued those rulings after considering a large body of scientific literature and public comments. The agency concluded that the evidence did not justify a warning. The FDA's decision was public, final, and appealable.

The Attorney General of Mississippi disagrees with the FDA's expert determination. Just months after the FDA announced its regulatory decision, the State AG filed this action contradicting the FDA. Wielding a state consumer protection statute, the State AG sued J&J[1] insisting that J&J was legally required to use an ovarian cancer warning label even though the FDA already rejected one. The State AG sought an injunction forcing J&J to affix that warning

[1] Petitioners are collectively referred to as "J&J."

label, plus a retroactive penalty of up to $10,000 for every bottle of baby powder sold in Mississippi for the last 50 years.

The State AG's effort to impose a cancer warning the FDA rejected runs headlong into an express pre-emption provision that prohibits a state from imposing "any requirement for labeling … that is different from or in addition to … a requirement specifically applicable to a particular cosmetic." 21 U.S.C. § 379s(a). In holding that the State AG's claim is not pre-empted, the Mississippi Supreme Court deepened two entrenched splits among the circuits and state supreme courts over two of this Court's commands—commands that seemed clear but have engendered profound confusion.

The first command is that when a "statute 'contains an express pre-emption clause,' [courts] 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.'" *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)). Yet, the Mississippi Supreme Court applied the presumption against pre-emption as justification for torturing the plain language of the FDCA's pre-emption provision. This holding took sides on a broad and acknowledged 6-5 split. Some courts apply this Court's command faithfully, but others carve out exceptions, as the court below did, for pre-emption provisions that the court considers unclear or that touch on subjects of traditional state police power.

The second command also seems clear, but likewise is not being followed. This Court has held that courts may 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). Again, without acknowledging this rule, the Mississippi Supreme Court held that "[i]n order to" pre-empt state law, "the Food and Drug Administration must follow the notice and comment rule making process." Pet. App. 15a.

That holding deepened another entrenched 7-2 split on what types of agency actions are capable of pre-empting state law. As Justice Thomas recently observed, the time has come for this Court to address that very question "in an appropriate case." *Lipschultz v. Charter Advanced Servs. (MN), LLC*, 140 S. Ct. 6, 7 (2019) (concurring in the denial of cert.). This is that case.

If the Mississippi Supreme Court's ruling stands, other state officials will join the fray, seeking their own paydays. Consumers will soon find drugstore shelves filled with products covered in conflicting warnings. Manufacturers will face the threat of huge retroactive penalties for failing to include labels the FDA rejected as scientifically unsound, and will be forced to defend their labels before juries who will second-guess the FDA's expert judgment. More broadly, rulings like this will undermine dozens of express pre-emption provisions and nullify the pre-emptive effect of innumerable federal agency actions, subjecting a

wide range of federally regulated industries to confusing and contradictory state and local requirements.

This Court should grant certiorari to resolve both enduring and important splits.

OPINIONS AND ORDERS BELOW

The opinion of the Mississippi Supreme Court is reported at 315 So. 3d 1017, and reprinted at Pet. App. 1a-17a. The decision of the Chancery Court of Hinds County is not reported, and is reprinted at Pet. App. 18a-22a.

JURISDICTION

The Mississippi Supreme Court issued its decision on April 1, 2021. Pet. App. 2a. This petition is timely under this Court's March 19, 2020 order extending the deadline to petition for a writ of certiorari to 150 days.

This Court has jurisdiction under 28 U.S.C. § 1257(a). The Mississippi Supreme Court finally decided the federal pre-emption issues raised in this petition when it affirmed the denial of J&J's motion for summary judgment. *See Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975). If this case proceeds to trial, J&J may "prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court." *Id.* at 482. The matter is final under § 1257(a) because "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action." *Id.* at 482-83. Moreover, "a refusal immediately to review

the state court decision might seriously erode" the federal policy of uniform nationwide labeling requirements for cosmetics. *Id.* at 483.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause, U.S. Const. art. VI, cl. 2, provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 379s provides:

> (a) In general
>
> Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair

Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

(1) protects an important public interest that would otherwise be unprotected;

(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

(3) would not unduly burden interstate commerce.

(c) Scope

For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this chapter for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

(d) No effect on product liability law

Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(e) State initiative

This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

STATEMENT OF THE CASE

The FDA Regulates Cosmetics Labels

Congress charged the FDA with ensuring that "cosmetics are safe and properly labeled." 21 U.S.C. § 393(b)(2)(D). The FDCA "establishe[s] a comprehensive regulatory scheme" governing cosmetics, including cosmetic talcum powder. *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35 (2d Cir. 2020). The FDCA prohibits "misbranded" cosmetics, and it empowers the FDA to inspect, sample, seize, and otherwise broadly regulate any cosmetic product. *See* 21 U.S.C. §§ 331(a)-(c), (g), 362, 371, 374(a)(1).

The FDA has developed detailed requirements governing the placement, size, and content of cosmetics labels. 21 C.F.R. §§ 701.1-701.13, 740.1-2. It requires all cosmetics "bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." *Id.* § 740.1(a). The FDA can require cosmetic

warning labels either on its own initiative or in response to a citizen petition from "any interested person." *Id.* § 740.1(b). When filed, citizen petitions are publicly docketed, *id.* § 10.20(j)(1)(i), and subject to public comment after the petition is published on regulations.gov, *id.* § 10.20(a). The FDA's decision on a citizen petition is a "final agency action" judicially reviewable under the Administrative Procedure Act. *Id.* § 10.45(d).

The FDCA includes an "expansive preemption provision" specific to cosmetics, which is designed to "ensure that these various federal requirements are not obstructed by state law." *Critcher*, 959 F.3d at 35 (citing 21 U.S.C. § 379s). Section 379s prohibits any state from "establish[ing] or continu[ing] in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under" the FDCA. 21 U.S.C. § 379s(a).

Three savings clauses (none of which applies here) cabin the scope of § 379s(a). First, § 379s(b) allows "a State or political subdivision thereof" to apply for an exemption. The Secretary of HHS "may by regulation, after notice and opportunity for written and oral presentation of views," grant the exemption to a "State or political subdivision requirement for labeling or packaging that—

> (1) protects an important public interest that would otherwise be unprotected;

> (2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and
>
> (3) would not unduly burden interstate commerce."

Id. § 379s(b). Second, § 379s(d) clarifies that product liability causes of action are not expressly preempted. Third, § 379s(e) exempts state requirements adopted by public initiative or referendum prior to September 1, 1997.

The FDA Denies Two Citizen Petitions Seeking To Place Warning Labels On Cosmetic Talc Products

Before the State AG commenced this action, the FDA actively studied whether a warning label was appropriate. The Cancer Prevention Coalition filed two citizen petitions requesting that all cosmetic talc products include an ovarian cancer warning on the label. The first petition, filed in 1994, asked the agency to mandate that all cosmetic talc products bear a warning stating that "[t]alcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." App'x 96.[2] The second petition, filed in 2008, similarly urged the FDA to "[i]mmediately require cosmetic talcum powder products to bear labels with a prominent warning such as: 'Frequent talc application in the female genital area is responsible for major

[2] The appendix before the Mississippi Supreme Court is cited as "App'x."

risks of ovarian cancer.'" App'x 102. Both petitions were publicly docketed and open to public comment.[3] The State did not submit any comment on either petition.

The FDA denied both petitions. App'x 88-93. The FDA explained that one of the principal studies on which the citizen petitions relied "lack[ed] convincing scientific support because of serious flaws in its design and conduct" and had "no relevance to human risk." App'x 90-91. Other studies had "biases in the study design," failed to "consider[] all the factors that potentially contribute to ovarian cancer," and "revealed no overall association" between talc use and ovarian cancer. App'x 91-92. The FDA's review included an "expanded literature search dating from the filing of the petition in 2008 through January 2014," and an "exploratory survey of … cosmetic products containing talc." App'x 90, 93. That investigation "failed to identify any new compelling literature data or new scientific evidence" supporting the petitions. App'x 93. Accordingly, the FDA concluded that the "evidence is insufficient" to warrant the warning requested. App'x 92. No one sought judicial review of that final FDA decision.

Mississippi Sues J&J For Failing To Give A Warning The FDA Rejected

Shortly after the FDA's decision denying a talc warning, the Mississippi Attorney General sued J&J in state court, asserting a single cause of action under

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[3] *See* FDA-2008-P-0309, https://tinyurl.com/djs996bx; FDA-1994-P-0067, https://tinyurl.com/44vx7dpe.

Mississippi's consumer protection act, Miss. Code § 75-24-5. The complaint alleges that J&J "should have warned the public … not to use its Talc Products perineally [sic] or in the alternative, at a minimum, should have informed the public that perineal use of talc-containing products causes an increased risk of ovarian cancer." App'x 61.

The State AG's consumer protection act complaint cites many of the same studies the FDA found insufficient to justify a warning label.[4] The complaint sought a wide array of relief: actual and punitive damages; disgorgement of "ill-gotten revenue"; an injunction requiring a warning and removal of nonconforming products; and a civil penalty of up to $10,000 for each sale of J&J's talc products since 1974. App'x 35-36.[5]

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[4] For instance, it relies heavily on a 1993 study published by the National Toxicology Program, App'x 24-25, which the FDA deemed to "lack[] convincing scientific support because of serious flaws in its design and conduct," App'x 90. Similarly, it features the Nurse's Health Study, which the FDA found to "reveal[] no overall association with … talc use and … ovarian cancer." App'x 92.

[5] In May 2020, J&J announced that it would cease selling its talc-based baby powder in the United States. *Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada*, Johnson & Johnson (May 19, 2020), https://tinyurl.com/dvymsfka (explaining that "[d]emand for talc-based Johnson's Baby Powder in North America has been declining due in large part to changes in consumer habits and fueled by misinformation around the safety of the product and a constant barrage of litigation advertising"). The State AG's claims for relief, other than injunctive relief, are still live.

The Mississippi Supreme Court Concludes That The State AG's Labeling Claim Is Not Pre-Empted

J&J moved for summary judgment, including on the ground that the FDCA pre-empts the State AG's claim. The trial court denied summary judgment, asserting that there were "genuine issues of material fact," but did not identify any disputed facts relevant to J&J's case-dispositive pre-emption argument. Pet. App. 20a.

The Mississippi Supreme Court affirmed. Pet. App. 17a. The court recognized that the State AG seeks to impose an ovarian cancer warning label that the FDA had rejected. Pet. App. 3a-4a, 13a-15a. But it held the action is not pre-empted.

The court gave two separate reasons—one relating to the limits on express pre-emption clauses and the other about what sorts of federal agency actions have pre-emptive force. As to the first, the court "start[ed] with 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 (second and third alterations in original) (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992)). It held, "courts 'have a duty to accept the reading that disfavors pre-emption.'" Pet. App. 15a (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

As to the second, the court opined that the only federal agency actions capable of pre-empting state law are regulations: "In order to be binding on the

public, the [FDA] must follow the notice and comment rule making process." Pet. App. 15a. The court accordingly narrowly construed § 379s's use of the term "requirement" to encompass only "positive expression[s] of regulation." Pet. App. 15-16a. Because the FDA had not "adopt[ed] any such regulation," the court held that the State AG's claim was not expressly pre-empted. *Id.*

The court rejected J&J's implied pre-emption argument for similar reasons. Because, in the court's view, the FDA had not "exercise[d] its regulatory authority" to set requirements for talc products through notice-and-comment rulemaking, the State AG had the "freedom to regulate cosmetics instead." Pet. App. 16a-17a.

REASONS FOR GRANTING THE WRIT

I. The Decision Below Deepens Two Important Splits.

The Mississippi Supreme Court deepened two entrenched splits on federal pre-emption. First, the court applied a presumption against pre-emption in interpreting the FDCA's express pre-emption provision for cosmetics. This compounds the lower courts' confusion over whether—and when—the presumption continues to apply to express pre-emption provisions. Second, the court held that no agency action can expressly or impliedly pre-empt state law except notice-and-comment rules, situating itself on the most anti-pre-emption end of a wide-ranging split among the lower courts as to what agency actions have pre-emptive force.

A. The decision below deepens a 6-5 split on whether, and when, a presumption against pre-emption applies to express pre-emption statutes.

Before *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938 (2016), there was some confusion as to whether the presumption against pre-emption applied to express pre-emption provisions. *Compare, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (applying the presumption to the express pre-emption provision of the Medical Device Amendments to the FDCA), *with Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-26 (2008) (finding that plaintiff's state-law claims were expressly pre-empted under the Medical Device Amendments without mentioning the presumption).

This Court attempted to lay any such doubt to rest in *Franklin*, holding that where a "statute 'contains an express pre-emption clause,' [courts] 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.'" 136 S. Ct. at 1946 (quoting *Whiting*, 563 U.S. at 594). Since *Franklin*, this Court has not applied the presumption to any express pre-emption provisions. *E.g.*, *Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1198-99 (2017).

Nonetheless, the circuits and state supreme courts continue to engage in "the great preemption presumption wars," *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 762 n.1. (4th Cir. 2018), and are split 6-

5 on whether, and when, the presumption applies to express pre-emption clauses.

1. Four state supreme courts and two circuits continue to apply the presumption to express pre-emption statutes.

On one side of the divide are the Supreme Courts of Mississippi, Indiana, California, and Michigan, and the Third and Ninth Circuits. These courts continue to believe that the presumption against pre-emption persists for express pre-emption provisions in either of two circumstances—both of which the Mississippi Supreme Court embraced here.

The first is where the federal law touches on an area of traditional state police powers. The Third Circuit has reasoned, for example, that "'the historic primacy of state regulation of matters of health and safety' requires us to apply the 'presumption against the pre-emption of state police power regulations.'" *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (quoting *Lohr*, 518 U.S. at 485). The court justified marginalizing *Franklin* on the ground that *Franklin* involved "a Bankruptcy Code provision" and "did not address claims involving areas historically regulated by states." *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 131 n.5 (3d Cir. 2018); *see also id.* at 131 (quoting *Bates*, 544 U.S. at 449); *Shuker*, 885 F.3d at 771 n.9.

The Mississippi Supreme Court here echoed that same line when it held that Congress must demonstrate a "clear and manifest purpose" to displace

"historic police powers of the States." Pet. App. 11a (quotation marks omitted).

The second is where the court finds a pre-emption provision ambiguous. The Indiana Supreme Court, for example, holds that *Franklin*'s instruction not to apply the presumption to express pre-emption clauses governs only when the words of the clause "are clear." *State v. Norfolk S. Ry. Co.*, 107 N.E.3d 468, 474 (Ind. 2018). The presumption continues to apply, the court holds, when the "words are ambiguous." *Id.* The Mississippi Supreme Court echoed that logic, reasoning that courts "have a duty to accept the reading that disfavors pre-emption." Pet. App. 15a (quoting *Bates*, 544 U.S. at 449). The California and Michigan Supreme Courts have drawn the same line (albeit pre-*Franklin*). *See Ter Beek v. City of Wyoming*, 846 N.W.2d 531, 536-37 (Mich. 2014); *Brown v. Mortensen*, 253 P.3d 522, 529 (Cal. 2011). None of these courts explains why this Court would have bothered rejecting "any presumption" when that prohibition applies only to clear statutory provisions for which a presumption would not matter. *Franklin*, 136 S. Ct. at 1946.

The Ninth Circuit sits on both sides of this fence. Sometimes, it continues to "presum[e] that Congress did not intend to preempt a law that is within a state's historical police powers." *Cal. Trucking Ass'n v. Bonta*, 996 F.3d 644, 654, 664 n.14 (9th Cir. 2021), *pet. for cert. filed*, No. 21-194 (Aug. 9, 2021); *see also Hardeman v. Monsanto Co.*, 997 F.3d 941, 958 (9th Cir.

2021).[6] Other times, the court has rejected arguments that "a presumption against preemption should … still apply," reasoning that "a state's traditional regulation in an area is not, standing alone, sufficient to defeat preemption in the face of an express preemption clause." *Int'l Bhd. of Teamsters, Loc. 2785 v. Fed. Motor Carrier Safety Admin.*, 986 F.3d 841, 853 (9th Cir. 2021), *pet. for cert. filed,* No. 20-1662 (May 28, 2021)); *see also Connell v. Lima Corp.*, 988 F.3d 1089, 1097 (9th Cir. 2021) (quoting *Franklin*, 136 S. Ct. at 1946. The Ninth Circuit has never explained what distinguishes the cases that warrant the presumption from those that do not.

2. Four circuits and one state supreme court faithfully decline to apply the presumption against pre-emption to express pre-emption statutes.

In contrast, the Fourth, Fifth, Eighth, and Tenth Circuits and the Arizona Supreme Court correctly recognize that *Franklin*'s directive applies to *all* express pre-emption clauses, regardless of the context of the state-law claim or the clarity of the provision. *Air Evac*, 910 F.3d at 761-62; *Dialysis Newco, Inc. v.*

[6] In *Hardeman*, the Ninth Circuit held that the express pre-emption provision of the Federal Insecticide, Fungicide, and Rodenticide Act, which is similar to § 379s, does not pre-empt failure-to-warn claims regarding glyphosate pesticides, even though the EPA had repeatedly rejected such a warning. A petition for certiorari in *Hardeman* is pending. Pet., *Monsanto Co. v. Hardeman*, No. 21-241 (Aug. 16, 2021). If the Court grants certiorari in *Hardeman*, it may want to hear that case together with this one. At a minimum, it should hold this petition pending its disposition of *Hardeman*, or vice versa.

Cmty. Health Sys. Grp. Health Plan, 938 F.3d 246, 257-59 (5th Cir. 2019); *Ferrell v. Air EVAC EMS, Inc.*, 900 F.3d 602, 606 (8th Cir. 2018); *Dirty Boyz Sanitation Serv., Inc. v. City of Rawlins*, 889 F.3d 1189, 1198 (10th Cir. 2018); *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 574 (Ariz. 2018).

As to the substantive areas to which *Franklin* applies, these courts have declined to apply any presumption to express pre-emption statutes even in cases involving traditional areas of state regulations. That includes health insurance contracts, *Dialysis Newco*, 938 F.3d 246, garbage collection, *Dirty Boyz Sanitation*, 889 F.3d 1189, deceptive trade practices, *Ferrell*, 900 F.3d 602, and common-law failure-to-warn claims against medical device manufacturers, *Conklin*, 431 P.3d 571.

Several of these courts have expressly acknowledged the split, and still have rejected the view that *Franklin*'s holding "appl[ies] only to bankruptcy cases" and does not apply to "claims historically regulated by the states." *Dialysis Newco*, 938 F.3d at 258, 259. The Fifth Circuit, for example, has opined: "[W]e do not read the clear language of *Franklin*'s holding on this point as being so limited." *Id.* at 258. And the Fourth Circuit has noted that the circuits "may not be in full accord" on this issue and concluded that the "best course is simply to follow … the wording of the express preemption provision, without applying a presumption," regardless of the substantive area being pre-empted. *Air Evac EMS*, 910 F.3d at 762 n.1.

These courts likewise decline to apply a presumption favoring a narrow reading of an express pre-

emption statute, even where the text is "not clear," *id.* at 766, is "ambiguous as to Congressional intent," *Dirty Boyz Sanitation*, 889 F.3d at 1199 (quotation marks omitted), or "does not mention the particular" issue "in question," *Dialysis Newco*, 938 F.3d at 259. They reason that, "[i]n [express pre-emption clause] case[s], our task is simply to interpret the words as they are written." *Air Evac EMS*, 910 F.3d at 762.

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In sum, express pre-emption provisions are now being interpreted differently based on the court considering the dispute, the type of state-law claim at issue, and the purported susceptibility of the text to multiple interpretations. The outcome of a case filed in Arizona or Mississippi will depend on whether it was filed in state or federal court. The split is acknowledged and entrenched. Only this Court can clear up the confusion.

B. The Mississippi Supreme Court deepened an 8-2 split regarding what sorts of agency actions can pre-empt state law.

The Mississippi Supreme Court's decision also deepens a split regarding what sorts of agency actions have pre-emptive force. This Court has repeatedly recognized that the FDA has multiple means to "communicate its disapproval of a warning" label, and any means that "carr[ies] the force of law" can be pre-emptive so long as the FDA is operating pursuant to its "congressionally delegated authority." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019);

see also Riegel, 552 U.S. at 322-23 (FDA premarket approval order pre-empted state law). This Court has further held that "[t]o insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be … to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended." *Geier*, 529 U.S. at 885.

Despite this guidance, the circuits and state supreme courts are hopelessly split, 8-2, on this question. Courts on both sides of the split have acknowledged, and rejected, the contrary view. *Compare Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 244 (3d Cir. 2008), *with Good v. Altria Grp., Inc.*, 501 F.3d 29, 51-53 (1st Cir. 2007), *aff'd on other grounds and remanded*, 555 U.S. 70 (2008). Noting this disarray, Justice Thomas has urged this Court to find "an appropriate case" to decide the type of federal agency action that is capable of pre-empting state law. *Lipschultz*, 140 S. Ct. at 7 (concurring in denial of cert.).

1. On one side of the split stand the Mississippi Supreme Court and the First Circuit. In this case, the Mississippi Supreme Court held that the FDA's denial of the citizen petitions requesting a warning on cosmetic talc did not bar the State AG from seeking to impose a warning that the FDA rejected. The court reached that result because it concluded that the FDA "must follow the notice and comment rule making process" to pre-empt state law. Pet. App. 15a. On this basis, the court held that the State AG's claim was not expressly pre-empted, because the term "requirement" in § 379s(a) is limited to a "positive expression of regulation." Pet. App. 16a. And it also held that the

action was not impliedly pre-empted, because "the Food and Drug Administration chose not to exercise its regulatory authority." Pet. App. 17a.

The First Circuit adopted the same line: "Limiting the preemptive power of federal agencies to exercises of formal rulemaking authority … ensures that the states will have enjoyed these protections before suffering the displacement of their laws." *Altria*, 501 F.3d at 51. The First Circuit acknowledges that its holding breaks with other circuits, which "have held that an agency can preempt state law through action short of [notice-and-comment] rulemaking." *Id.*

2. On the other side of the split are seven circuits and a state supreme court. They all recognize that agency actions "short of formal, notice and comment rulemaking may … have preemptive effect over state law." *Fellner*, 539 F.3d at 244. They reject the view that "the only regulatory process which can produce 'federal law' for purposes of the Supremacy Clause is formal, notice and comment rulemaking." *Id.* All of them would give pre-emptive force to the denial of a citizen petition—although they have adopted three different tests as to which agency actions have pre-emptive force.

The first test is the one the Second, Fourth, and Seventh Circuits and the California Supreme Court have adopted. These courts give pre-emptive force to any agency action that carries the "force of law"—that is, any final agency action taken pursuant to "'congressionally delegated authority.'" *City of N.Y. v. Permanent Mission of India to United Nations*, 618 F.3d 172, 187 (2d Cir. 2010) (quoting *City of N.Y. v. FCC*,

486 U.S. 57, 63-64 (1988)); *see also Feikema v. Texaco, Inc.*, 16 F.3d 1408, 1416 (4th Cir. 1994); *Dolin v. GlaxoSmithKline LLC*, 951 F.3d 882, 891 (7th Cir. 2020); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 9-11 (Cal. 2004). These courts ask simply whether the agency action is "sufficiently definite and authoritative" to pre-empt state law. *Dowhal*, 88 P.3d at 9.

The second test is the one the Third, Ninth, and Tenth Circuits have embraced: that an agency action has pre-emptive force so long as it "provides for a relatively formal administrative procedure tending to foster … fairness and deliberation." *Fellner*, 539 F.3d at 245 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)); *see also Hardeman*, 997 F.3d at 957; *Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015); *Utah Native Plant Soc'y v. U.S. Forest Serv.*, 923 F.3d 860, 868 n.5 (10th Cir. 2019). These courts give "preemptive effect" to any agency action so long as the action "should be afforded *Chevron* deference." *Fellner*, 539 F.3d at 245. As the Ninth Circuit puts it, "[c]reation of federal law should demand at least the same formality for purposes of preemption as it does for purposes of *Chevron* deference." *Reid*, 780 F.3d at 964.

A half-step further is the third test: The Eighth Circuit has held that a "federal policy of nonregulation" may have pre-emptive force. *See Charter Advanced Servs. (MN), LLC v. Lange*, 903 F.3d 715, 718 (8th Cir. 2018) (quoting *Minn. Pub. Utils. Comm'n v. FCC*, 483 F.3d 570, 580 (8th Cir. 2007)), *cert. denied sub nom.*, *Lipschultz*, 140 S. Ct. 6. This is the case in

which Justice Thomas noted the need for this Court to intervene. 140 S. Ct. at 7.

Regardless of the precise test, every one of the courts on this side of the split would give pre-emptive force to the denial of a citizen petition—and several have done exactly that. Applying the "force of law" test, the California Supreme Court and the Seventh and Tenth Circuits have concluded that the FDA's denial of a citizen petition was "sufficiently definite and authoritative" to pre-empt state law. *Dowhal*, 88 P.3d at 9; *see also Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010); *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017). The Third Circuit has done the same, applying the *Chevron* test. It reasoned that it was sufficient that the agency had "previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject [the requested] warnings." *Fellner*, 539 F.3d at 245 (discussing *Colacicco v. Apotex Inc.*, 521 F.3d 253, 271 (3d Cir. 2008)). Federal district courts, too, are aligned that the FDA's denial of a citizen petition is pre-emptive. *See In re: Zofran (Ondansetron) Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2021 WL 2209871, at *33 (D. Mass. June 1, 2021); *In re Incretin-Based Therapies Prods. Liab. Litig.*, --- F. Supp. 3d ---, 2021 WL 880316, at *16 (S.D. Cal. Mar. 9, 2021).

The divide between the courts requiring notice-and-comment-rules and those requiring something less is so stark, and so entrenched, that only this Court can resolve the split and restore clarity.

II. These Are Recurring Issues Of Exceptional Importance That Require This Court's Review.

A. The presumption against pre-emption affects the interpretation of dozens of federal statutes with express pre-emption provisions.

The split over whether courts should read express pre-emption statutes narrowly injects uncertainty into "most major industries, including drugs and medical devices, banking, air transportation, securities, automobile safety, and tobacco." Jay B. Sykes, et al. Cong. Rsch. Serv., R45825, *Federal Preemption: A Legal Primer* 1 (July 23, 2019), https://tinyurl.com/wp3mfu92. Unless this Court resolves the split, Congress will have no assurance that the words it enacts will be faithfully applied to pre-empt state law. States, in turn, will continue to encroach upon areas that Congress committed to uniform federal regulation. And the regulated community will be subject to the risk of contradictory rulings in different jurisdictions—with the potential to throw entire industries into disarray overnight.

As this Court recognized in *Franklin*, applying a presumption narrowing the language that Congress enacted in an express pre-emption statute necessarily fails to afford the plain text its natural meaning. 136 S. Ct. at 1946. That, in turn, dramatically limits the intended reach of dozens of federal statutes.

In the food and drug context alone, statutes with express pre-emption provisions govern the

nationwide regulation of meat, pesticides, poultry, pork advertising, medical devices, public health emergencies, and egg products, among other examples. *See, e.g.*, 21 U.S.C. § 678 (Federal Meat Inspection Act); 42 U.S.C. § 247d-6d(b)(8) (Public Readiness and Emergency Preparedness Act); 21 U.S.C. § 467e (Poultry Products Inspection Act); 7 U.S.C. § 4817(b) (Pork Promotion, Research, and Consumer Information Act); 21 U.S.C. § 360k(a) (Medical Device Regulation Act); 21 U.S.C. § 1052(b) (Egg Products Inspection Act). And the application of the presumption—and its limiting scope—reaches far beyond these industries, to employee pension plans, domestic air travel, and trucking. *See* 29 U.S.C. § 1144(a) (ERISA); 49 U.S.C. § 41713(b)(1) (Airline Deregulation Act); 49 U.S.C. § 14501(c)(1) (Federal Aviation Administration Authorization Act).

Applying a presumption against pre-emption to any of these express pre-emption statutes even in a single jurisdiction will have far-reaching consequences. Any time an express pre-emption clause permits an alternative, non-pre-emptive interpretation—even if that reading is not the ordinary plain language construction—Congress's intent to pre-empt state law and to create uniform rules on which that industry and the public rely will be thwarted. Congress's statutes should not be subjected to different interpretive criteria in different parts of the country.

The different approaches are typically outcome-determinative, as they are here. *Compare* Pet. App. 15a-16a (holding that § 379s is not pre-emptive after applying the presumption against pre-emption), *with Critcher*, 959 F.3d at 38 (pre-empting the state action

without applying any presumption disfavoring pre-emption, because of the "sweeping preemptive force" of § 379s, a "broad preemption clause"). And the split in authority over whether a presumption against pre-emption may apply to express pre-emption statutes is so wide and entrenched that these disruptive consequences will continue to arise with alarming frequency.

This case presents an especially dire threat, which requires this Court's intervention here and now. Congress charged the FDA with ensuring that "cosmetics are safe and properly labeled." 21 U.S.C. § 393(b)(2)(D). In doing so, Congress advanced the goal of "national uniformity" with respect to "requirements that relate to labeling … [and] warnings." H.R. Rep. No. 105-399, at 103 (1997) (Conf. Rep.). But the opinion below authorizes a state official to impose a labeling requirement even though the FDA has already carefully weighed and rejected one. This type of collateral attack on the FDA's decision not to require a warning undermines the FDA's authority and the ability of the cosmetics industry to rely upon decisions the expert agency rendered. The result will be exactly the opposite of the uniformity Congress sought when it enacted the pre-emption provision. Congress did not want to allow states to force manufacturers to print "50 different labels, driving consumers … crazy." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011).

If this Court does not step in to prevent the Mississippi Attorney General from seeking her own warnings—and recovering penalties of $10,000 for every single bottle of cosmetic talc sold in the state since

1974—her counterparts in other states, or plaintiffs' lawyers, will quickly jump in and seek similar jackpots under their own consumer protection statutes.

In addition to inviting a whole new wave of litigation, permitting this decision to stand will produce a cacophony of warning labels that will undermine the efficacy of those warning labels that are actually needed to protect the public. Consumers can become desensitized to legitimate warning labels and may end up ignoring them altogether. *See Cerveny*, 855 F.3d at 1102 (explaining that "the FDA views" unnecessary state warning requirements "as problematic because they can render the warnings useless").

There is no need to wait for further percolation before resolving this important conflict and avoiding the harms from allowing it to persist. When pre-emption is at issue, just one deviation can wreak havoc on a uniform national regulatory regime. But here the Court already has guidance from the 11 courts that have grappled with the issue and split right down the middle.

B. The power of agency action to pre-empt is dispositive in both the express and implied pre-emption contexts.

The issue of what types of agency action have pre-emptive force is also a recurring issue of exceptional importance—with ramifications far beyond express pre-emption. Agencies—and the regulated community—need to know in advance whether or not specific agency actions will have pre-emptive effect.

The decision below artificially curtails agencies' policy-making flexibility, effectively limiting agencies to notice-and-comment rulemaking if they want their decisions enforced nationwide. The decision below would strip pre-emptive force, for example, from the FDA's "rigorous" process of premarket approval for medical devices held to be pre-emptive in *Riegel*, 552 U.S. at 317-18 ("The FDA spends an average of 1,200 hours reviewing each application…."). The same would be true for Federal Energy Regulatory Commission orders governing cost allocation among energy companies—legally binding, published orders that are decided after proceedings in which all interested parties are able to participate. *See Entergy La., Inc. v. La. Pub. Serv. Comm'n*, 539 U.S. 39, 49-50 (2002) (holding that FERC order pre-empts state requirement); 16 U.S.C. §§ 824d, 824e. Such federal agency decisions carry the force of law, but would be deprived of any pre-emptive weight in some jurisdictions.

The issue, then, will have a profound effect on agencies' effectiveness. "It is well established that when developing law on a subject, an agency usually has a choice between the method of rulemaking and that of adjudication." *General Motors Corp. v. Abrams*, 897 F.2d 34, 39 (2d Cir. 1990). Agencies can properly determine that a problem is best resolved case by case, allowing the agency to closely consider individual circumstances and develop law incrementally. *See SEC v. Chenery Corp.*, 332 U.S. 194, 202-03 (1947). And an agency may follow a specialized decisionmaking procedure set out by Congress in its enabling statute that contains many of the hallmarks of rulemaking—such as public notice and opportunity to

submit comments—but was designed for the needs of that policy area. *E.g.*, 7 U.S.C. § 136d (procedure for suspension or cancellation of pesticide regulations). An agency may also preserve its limited resources for other policy priorities by tackling an issue through focused adjudications that apply narrowly to discrete entities.

None of those scenarios would result in a decision entitled to pre-emptive force in jurisdictions following Mississippi's approach. Even "where a comprehensive federal regulatory scheme authorized a process for the agency to apply a federal standard to concrete circumstances," and the agency "had utilized that process in a manner establishing a federal duty or policy," courts on this far side of the split would find the action incapable of pre-empting state law. *Fellner*, 539 F.3d at 244. This is so even when a decision legally binds one or more entities, as when an agency issues a decision following a "quasi-judicial" adjudication. *Id.* ("[B]oth agencies' quasi-legislative as well as their quasi-judicial powers 'have the binding force of federal law.'" (quoting *Abrams*, 897 F.2d at 39)). If this split endures, agencies that want to preserve uniformity at Congress's behest will have to think twice about taking any of these actions, which, in turn, will distort institutional decisionmaking and undermine federal policy.

The breadth and depth of the split in the circuits and state courts demonstrates that the issue will continue to crop up frequently. And it will have effects far beyond the express pre-emption context, to *all* pre-emption cases involving federal executive action.

Federal and state government actors—and the public—need to know what federal agency actions will be deemed pre-emptive. And they need a uniform answer that applies across the country. Such fundamental principles of our constitutional structure should not vary based on where (and in which court) the issue is raised.

III. This Case Provides An Excellent Vehicle For Resolving Both Issues.

Granting review in this case would provide a uniquely suitable vehicle for resolving both splits. Both questions presented were squarely raised and resolved below. The case presents the legal issues cleanly, without factual issues that could interfere with the Court's assessment of the questions presented. Notably, Mississippi does *not* contest that the FDA issued a final decision denying two citizen petitions that sought to require a warning label on talc products. Mississippi also acknowledges that its suit defies the FDA's decision that such a warning label is unwarranted.

Moreover, the Mississippi Supreme Court's decision was limited to the threshold federal pre-emption issue. That court recognized the fundamental, dispositive nature of the issue, and the importance of resolving it before permitting the case to move forward. The issue is no less pressing and fundamental now. And this Court's resolution of the questions presented would be outcome-determinative if this Court agrees that federal pre-emption bars the Mississippi Attorney General from collaterally challenging the FDA's decision.

The Mississippi Supreme Court presents these issues well for this Court's review. On the issue of whether a presumption against pre-emption requires express pre-emption provisions to be narrowly construed, the court invoked both contested lines of rationale for continuing to apply a narrow construction, even after this Court's ruling in *Franklin*: that the presumption applies where the pre-emption provision is unclear and that an express pre-emption provision must be read narrowly to the extent it addresses traditional state powers. Pet. App. 11a, 15a. Thus, granting review here would allow this Court to address both threads of the court cases seeking to limit *Franklin*.

Likewise, the decision of the Mississippi Supreme Court presents a clean vehicle for addressing when federal agency action has pre-emptive force. The court squarely held that only formal notice-and-comment rules are capable of pre-empting state law. Pet. App. 15a-17a. Moreover, the case arises in a context where the agency conducted a "careful review" of the available information, including public comments, and issued a reasoned decision that is acknowledged to be final and subject to judicial review. Pet. App. 4a, 14a-15a. This case, thus, presents the opportunity to clarify whether such final agency actions can have pre-emptive effect, or whether, as the Mississippi Supreme Court held, the only agency actions that are deemed pre-emptive must result from formal notice-and-comment rulemaking.

IV. The Mississippi Supreme Court's Decision Is Wrong.

The Mississippi Supreme Court's two central holdings were wrong—both its decision to apply a presumption against pre-emption and its view that only notice-and-comment regulations have pre-emptive force. Had the court correctly applied the law, it would have dismissed this action.

A. This Court spoke expansively when it held that courts "do not invoke any presumption against pre-emption" when a "statute 'contains an express pre-emption clause.'" *Franklin*, 136 S. Ct. at 1946 (quoting *Whiting*, 563 U.S. at 594). That holding and the rationale behind it are incompatible with both of the Mississippi Supreme Court's rationales for cabining this holding.

To start, *Franklin* leaves no doubt that its holding applies to pre-emption statutes whose meaning is unclear, because that was the situation in *Franklin*. This Court declined to apply the presumption even though there were multiple potential readings of the pre-emption clause at issue there. *See id.* at 1947-49 (rejecting the dissent's non-pre-emptive interpretation of the provision). The very notion of an exception for unclear statutes is absurd. It would swallow the rule. A presumption has effect *only* where a provision is unclear—i.e., where there is more than one way to read the provision. It would have made no sense for *Franklin* to declare that courts should "not invoke *any* presumption against pre-emption" when a "statute 'contains an express pre-emption clause,'" *id.* at 1946 (emphasis added), if it really meant that courts should

always invoke the presumption, but only when it matters.

Nor does anything in *Franklin* suggest that the holding depended on whether the pre-emption clause was in a bankruptcy statute as opposed to a statute governing health and safety. This Court cited cases involving traditional state powers in support of its holding that no presumption applies to express pre-emption statutes. *Id.* at 1946 (citing *Whiting*, 563 U.S. at 594 (addressing state business licenses), and *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 323-26 (2016) (addressing the "State's traditional power to regulate in the area of public health")). And the substantive context of the provision played no role in the Court's analysis.

Moreover, the rationale for rejecting the presumption applies with full force to all pre-emption clauses. This Court has held that congressional intent is the "ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Lohr*, 518 U.S. at 485). And in rejecting the presumption, this Court recognized that the "plain wording of" an express pre-emption clause "'necessarily contains the best evidence of Congress' pre-emptive intent.'" *Franklin*, 136 S. Ct. at 1946; *see also Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in part) (the presumption "dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself"). So the best way to discern Congress's intent is to find the best reading of the words it wrote, without a thumb on the scale in either direction. Anything else empowers judges to advance their own policy preferences. *See generally* Amy Coney Barrett,

Substantive Canons and Faithful Agency, 90 B.U. L. Rev. 109 (2010). None of that depends on the regulatory context of the statute.

Reading the statute faithfully is particularly important here. In drafting § 379s, Congress commanded that states not impose labeling requirements of the sort Mississippi seeks to enforce here: It did not want any "State or political subdivision" to "establish … any requirement for labeling" that is in any way "different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter." 21 U.S.C. § 379s(a). The statute leaves no room for a state to impose a "requirement for labeling" the FDA has flatly rejected.

Congress punctuated the point by refining the precise scope of pre-emption with three separate savings clauses. The first is particularly salient: It allows a state, such as Mississippi, to impose a warning even though the FDA has rejected one—but only with the FDA's permission. Congress prescribed a procedure for seeking and granting such exemptions from the pre-emptive force of the statute. 21 U.S.C. § 379s(b). Mississippi's decision to take matters into its own hands, without seeking any exception, negates this provision. And it is all the more inconsistent with Congress's objective, since Mississippi seeks to impose a cancer warning requirement that the FDA had just rejected as unwarranted—an exemption the FDA would surely have denied.

The other two savings provisions are inapplicable here: an exemption for product liability causes of

action (this is a consumer protection case), *id.* § 379s(d), and a grandfather clause for state requirements adopted by public initiative or referendum before September 1, 1997 (this consumer protection statute was enacted by a legislature), *id.* § 379s(e). They are relevant, though, because they further illustrate how carefully Congress considered the reach of the express pre-emption provision and made nuanced policy judgments to balance competing state interests against the federal regulatory interests. Courts cannot "presume[] that Congress" "cavalierly pre-empt[ed] state-law causes of action" given the careful carveouts in § 379s. *Lohr*, 518 U.S. at 485. To engraft onto the statute additional, atextual limitations would upset the careful balance Congress struck—which is exactly the opposite of what *Franklin* directed.

B. This Court was also expansive when it held that any "agency action carrying the force of law" and taken pursuant to "congressionally delegated authority" may pre-empt state law, *Albrecht*, 139 S. Ct. at 1679, and that it is wrong "[t]o insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking," *Geier*, 529 U.S. at 885; *see also New York v. FERC,* 535 U.S. 1, 18 (2002) ("[A] federal agency may pre-empt state law … if it is acting within the scope of its congressionally delegated authority …." (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986))); *Lohr*, 518 U.S. at 505 (Breyer, J., concurring in part) (observing that agencies possess "leeway to determine which rules, regulations, *or other administrative actions* will have pre-emptive effect" (emphasis added)). Indeed, this Court has routinely granted pre-emptive force to

agency actions that fall short of notice-and-comment rulemaking. *E.g.*, *Riegel*, 552 U.S. at 323 (FDA pre-market approval order pre-empted state law); *Entergy La.*, 539 U.S. at 49-50 (FERC order pre-empted state requirement); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 327 (1981) (agency's approval of carrier's application to abandon rail line was pre-emptive).

For good reason. Congress gives agencies a variety of tools by which to advance their missions because it recognizes that different tools fit different needs. The Supremacy Clause says that "the laws of the United States"—not just notice-and-comment regulations—"shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. If an agency action has the force of law, it pre-empts without regard to how that law was created. To privilege "notice-and-comment rulemaking" above all the other forms of agency lawmaking "would be … to tolerate conflicts that an agency, and therefore Congress, is most unlikely to have intended." *Geier*, 529 U.S. at 885.

That conclusion is especially apt here. The FDA issued its decision pursuant to its congressionally delegated authority over cosmetic labels. *See* 21 U.S.C. § 371(a); *see also id.* §§ 331, 362, 393(b). In response to citizen petitions seeking a warning on cosmetic talc, the FDA examined the evidence offered by both the citizen petitioners and other commenters, conducted its own "expanded literature search," and ultimately concluded that the evidence did not support the requested warning label. App'x 93. And, as the court below acknowledged, the FDA's denial of the citizen petitions "constitutes a final agency action that

is subject to judicial review." Pet. App. 14a. The FDA's regulations expressly say so, 21 C.F.R. § 10.45(d), and the decision denying the citizen petitions plainly "mark[s] the 'consummation' of the agency's decisionmaking process," determines "rights [and] obligations," and has "legal consequences," *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citations omitted). Thus, the FDA's decision denying the citizen petitions "carr[ies] the force of law," and has pre-emptive effect. *Albrecht*, 139 S. Ct. at 1679; *see id.* at 1683 (Thomas, J., concurring) ("final agency action with the force of law" is pre-emptive); *see also Dowhal*, 88 P.3d 1 at 9 (rejecting argument that the FDA's response to a citizen petition was "not sufficiently … authoritative" to pre-empt state law); *Fellner*, 539 F.3d at 244 (acknowledging that "quasi-judicial agency proceedings" with procedural protections like those involved in the FDA's citizen petition process "constitute 'federal law' under the Supremacy Clause").

C. Had the Mississippi Supreme Court not adopted these erroneous pre-emption carve-outs, it would have had to conclude that the State AG's labeling claim is both expressly and impliedly pre-empted.

The State AG's claim satisfies each of the elements of § 379s(a). She seeks to enforce a state "requirement," *i.e.*, a "state-law obligation," or "legal duty," *see Riegel*, 552 U.S. at 324, that is "for labeling," 21 U.S.C. § 379s(a). And, because she seeks to hold J&J liable for failing to include a warning label on its talc products that the FDA expressly rejected, the state requirement is "different from," "in addition to," and "not identical" to a federal "requirement

specifically applicable to a particular cosmetic or class of cosmetics." *Id.*

The FDA's denial of the citizen petitions is a federal "requirement" under § 379s(a)—i.e., a "rule of law that must be obeyed." *Bates*, 544 U.S. at 445. Far from being mere "inaction," Pet. App. 15a, the FDA's decision was an affirmative, final, and appealable administrative order, *see* 21 U.S.C § 10.45(d). The State AG's claim is therefore expressly pre-empted under 21 U.S.C. § 379s(a); *see Hardeman*, 997 F.3d at 957 (agency actions that follow "relatively formal administrative procedure[s] tending to foster … fairness and deliberation" "establish requirements that can preempt state law").

Even apart from the explicit pre-emption provision, the State AG's claim is also impliedly pre-empted because it poses an "actual conflict with a federal objective." *Geier*, 529 U.S. at 871. The conflict is stark: The Mississippi Attorney General seeks to impose a warning that the FDA rejected as unsupported by the available evidence. The FDA has "convey[ed] an 'authoritative' message of a federal policy" against the Attorney General's desired warning label. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002); *see also Albrecht*, 139 S. Ct. at 1684-85 (Alito, J., concurring in the judgment) (FDA's decision not to "require a label change despite having received and considered information regarding" the purported risk is "highly relevant to the pre-emption analysis"); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 637 (2011) (Sotomayor, J., dissenting) (state claim would be pre-empted where "FDA had itself considered whether to request enhanced warnings in light of the evidence on which a

plaintiff's claim rests but had decided to leave the warnings as is"). Federal agencies simply cannot operate effectively if states can freely reverse the decisions they reach after due deliberation.

It bears emphasizing that Congress granted the State multiple options to attempt to impose the warning label it now seeks. *See Kalo Brick*, 450 U.S. at 330-31 (action collaterally attacking agency's decision was "plainly contrary to" congressional intent, where plaintiff had multiple "avenues for relief" under federal law, but "chose[] not to" pursue any of these "express remedies"). Apart from seeking the exception mentioned above (at 34), the State AG could have participated in the citizen petitions or filed a new petition. *See* 21 C.F.R. § 10.20(a), (j). If, as the State AG now contends, the FDA's decision making process was infected by some far-reaching conspiracy between J&J and the FDA, judicial review was available. *See id.* § 10.45(d). The State AG did none of that.

What Congress did not allow—and the pre-emption provision explicitly rejects—is the route the State AG chose here: to collaterally attack the FDA's decision in her State's courts. The FDCA bars the State AG's efforts to retroactively impose a warning that the FDA rejected and to extract billions of dollars in penalties for failing to include such a warning.

CONCLUSION

The Court should grant the petition and reverse the Mississippi Supreme Court. Alternatively, the Court should hold this petition if it grants certiorari in *Hardeman*, No. 21-241.

Respectfully submitted,

Robert M. Loeb
Elizabeth R. Moulton
Sheila Baynes
Zachary Hennessee
ORRICK, HERRINGTON & SUTCLIFFE LLP
1152 15th Street, NW
Washington, DC 20005

E. Joshua Rosenkranz
Counsel of Record
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 West 52nd Street
New York, NY 10019
(212) 506-5000
jrosenkranz@orrick.com

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