No. 21-348

In The
Supreme Court of the United States

JOHNSON & JOHNSON AND
JOHNSON & JOHNSON CONSUMER 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
From The Mississippi Supreme Court**

AMICUS CURIAE BRIEF OF THE FEDERATION OF DEFENSE & CORPORATE COUNSEL IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST[1]

The Federation of Defense & Corporate Counsel (FDCC) is a not-for-profit corporation with national and international membership of 1,400 defense and corporate counsel working in private practice, as in-house counsel, and as insurance claims representatives. A significant number of FDCC members practice in the trial and appellate courts of the United States both at the federal and state level. The FDCC constantly strives to protect the American system of justice. Its members have established a strong legacy of representing the interests of civil defendants, including publicly and privately owned businesses, public entities, and individual defendants. The FDCC seeks to assist courts in addressing issues of importance to its membership that concern the fair and predictable administration of justice.

A touchstone of a fair judicial system is one with predictable procedural safeguards to all litigants no matter the court, the state, or the judge. This case presents issues of vital interest concerning how the courts should decide preemption cases so that there is predictability in the law. The FDCC's membership is able to provide scholarly and practical insights into the

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[1] Pursuant to Rule 37, *Amicus Curiae* certifies that no counsel for a party offered this brief, in whole or in part, and that no person or entity, other than *amicus*, its members, or its counsel has made a monetary contribution to the preparation or submission of this brief. Both parties have given their blanket consent to the filing of *amicus* briefs and received notice of the FDCC's intention to file this brief.

issue of preemption and its impact on consumers and businesses. Through its broad membership and nationwide perspective, the FDCC is well-positioned to address the important legal, constitutional, and public policy questions posed in this case.

Accordingly, the FDCC supports the positions of Petitioners. The FDCC urges the Court to grant the Petition and resolve the splits in the lower courts that threaten to impede national uniformity of the law. Reversing the order below is necessary to an effective and predictable operation of preemption.

SUMMARY OF ARGUMENT

This case is not confined to what labels the cosmetics industry is required to place on its products. Rather, this case has far-reaching ramifications for consumers and businesses alike—well beyond any single business sector. The Mississippi Supreme Court's opinion undermines express preemption, creating an environment which the plain language codified by Congress varies depending on where one is on the map. Consumers will be flooded with multiple instructions and warnings, including contradictory ones. Such a flooding of the market undermines the effectiveness of the warnings, placing consumers at a heightened public health risk. Consumers in one state may have remedies that consumers in another state do not, thus encouraging forum shopping. Such a patchwork approach increases the economic costs to

consumers, according to empirical research. Manufacturers will be forced to either comply with a multitude of conflicting and burdensome state laws and federal agencies or risk being subjected to expensive lawsuits and inconsistent jury verdicts. Preemption reduces costs incurred by manufacturers in trying to comply with a multitude of conflicting requirements. *Franklin* requires that courts take their thumbs off the scales when deciding preemption and instead of presuming *against* preemption, simply apply the plain language spoken by Congress.

ARGUMENT

I. THIS COURT SHOULD GRANT CERTIORARI TO RESOLVE MULTIPLE LOWER COURT SPLITS THAT UNDERMINE PREDICTABILITY IN THE LAW.

Pursuant to the Supremacy Clause of the United States Constitution, Congress may preempt state statutory or common law through federal legislation. *See* U.S. Const. art. VI, cl. 2. At issue here is whether the FDA's actions through 21 U.S.C. § 379s preempts the Mississippi Attorney General's lawsuit. The statute 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.

Two lower court splits undermine this Court's precedent and warrant review. Without intervention, the lack of uniformity and predictability of when state law is preempted will grow exponentially.

A. Presumptions Against Express Preemption Are Prohibited By *Franklin*.

First, the Mississippi Supreme Court added its state to a lower court split involving whether a presumption against preemption could be applied to express preemption clauses. Before 2016, questions abounded as to whether an express preemption clause was subject to a presumption ***against*** that

Congressionally mandated preemption. *See, e.g.*, Jay B. Sykes, Nicole Vanatko, *Federal Preemption: A Legal Primer*, CONGRESSIONAL RESEARCH SERVICE, Summary, https://crsreports.congress.gov (last visited Sept. 13, 2021) (noting that courts have "applied the presumption somewhat inconsistently, raising questions about its current scope and effect.").

However, in 2016, this Court was clear in *Puerto Rico v. Franklin Cal. Tax-Free Tr.* that where the statute contains an express preemption clause, "we do not invoke any presumption against preemption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." 136 S.Ct. 1938, 1946 (2016). Accordingly, the analysis begins and ends here with the plain language of 21 U.S.C. § 379s. The language either preempts the Mississippi Attorney General's lawsuit or it does not. There is no room for carving out exceptions not recognized in *Franklin*. The language of Congress should apply—regardless of geographical location.

This Court has not applied a presumption against preemption to any express preemption clause in the five subsequent years since *Franklin. See* Pet. 14. Despite this fact, a lower court split on the issue continues. It is important to have clear and uniform standards on how preemption will be applied because, as one commentator has noted, "where [the presumption against preemption] rears its heads, its effect is seemingly outcome determinative." Catherine M. Sharkey, *Products Liability Preemption: An Institutional*

Approach, 76 George Washington L. Rev. 449, 506 (2008).

Four state supreme courts (Mississippi, Indiana, California, and Michigan) and two U.S. Circuit Courts of Appeals (Third and Ninth) continue to apply a presumption to an express preemption clause where either the federal statute is found to implicate the state police powers or to be ambiguous. *See, e.g.*, *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); *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018); *State v. Norfolk S. Ry. Co.*, 107 N.E.3d 468, 474 (Ind. 2018); *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); *Pet*. at 15–17.

Four U.S. Circuit Courts of Appeals (Fourth, Fifth, Eighth, and Tenth) and the Arizona Supreme Court apply *Franklin* to all express preemption clauses without the exceptions made by the Mississippi Supreme Court. *Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan*, 938 F.3d 246, 257-59 (5th Cir. 2019); *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 761-62 (4th Cir. 2018); *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); *Pet*. at 17–19.

B. The Split Over What Type of Agency Action Carries Preemptive Force.

Second, there is a lower court split as to what type of federal agency action can preempt state law. This is despite opinions from this Court recognizing that federal agencies, such as the FDA, can preempt state law in multiple ways. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1679 (2019); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). Justice Thomas has recognized that the Court must find "an appropriate case" to decide this very issue. *Lipschultz v. Charter Advances Svs. (MN), LLC*, 140 S.Ct. 6, 7 (2019) (Thomas, J., concurring in denial of cert.). "Understanding the proper basis and limits of judicial deference to agency interpretations is vital for a simple reason: in the modern administrative state, most statutory interpretations are done by agencies." Eliner Elhauge, *Statutory Default Rules: How to Interpret Unclear Legislation*, 79 (Harvard Pub. 2008).

The Mississippi Supreme Court and the First Circuit Court of Appeals would deny preemptive effect to the FDA action under the facts of this case. *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); *Pet.* at 20.

On the other hand, six U.S. Circuit Courts of Appeals (Second, Third, Fourth, Seventh, Eighth, Ninth, and Tenth) recognize the preemptive effect to the denial of a citizen petition, although they apply different tests to determine which agency actions carry

preemptive force. *Dolin v. GlaxoSmithKline LLC*, 951 F.3d 882, 891 (7th Cir. 2020); *Utah Native Plant Soc'y v. U.S. Forest Serv.*, 923 F.3d 860, 868 n.5 (10th Cir. 2019); *Charter Advanced Servs. (MN), LLC v. Lange*, 903 F.3d 715, 718 (8th Cir. 2018); *Reid v. Johnson & Johnson*, 780 F.3d 952, 964 (9th Cir. 2015); *City of N.Y. v. Permanent Mission of India to United Nations*, 618 F.3d 172, 187 (2d Cir. 2010); *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 245 (3d Cir. 2008); *Feikema v. Texaco, Inc.*, 16 F.3d 1408, 1416 (4th Cir. 1994).

Finally, this case presents an opportunity for this Court to further address how the FDA's administrative review process arising from citizen petitions may establish federal preemption.[2] The citizen petition process found in 21 C.F.R. §§ 10.30(a), (e)(1-3) was followed twice here—first in 1994 and again in 2008.

Both citizen petitions requested the FDA to require a cancer warning. That failure to warn theory is the underlying premise for the State of Mississippi's lawsuit under its Consumer Protection Act. Ultimately, the FDA concluded the requested warning was not warranted based on the scientific evidence it examined. The final decision issued by the FDA in 2014 was subject to judicial review. 21 C.F.R. § 10.45. However, the FDA's final agency action was not challenged.[3] As a result, the Court has before it a case suited to provide

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[2] Mississippi Supreme Court opinion at paragraphs 22-26. *See* Petitioners' App. A, pgs. 13a-15a.

[3] The two citizen petitions were denied in the same final decision in 2014.

guidance to lower courts concerning FDA regulatory action, taken in response to citizen petitions, and when it may preempt state-based lawsuits.

C. Certiorari Is an Appropriate Mechanism to Resolve the Doctrinal Chaos Found In the Lower Courts.

Presumptions against federal preemption or against the preemptive effect of agency actions will impact more than just warning labels in cosmetics cases. "[P]reemptive federal statutes shape the regulatory environment for most major industries, including drugs and medical devices, banking, air transportation, securities, automobile safety, and tobacco." Jay B. Sykes, Nicole Vanatko, *Federal Preemption: A Legal Primer,* CONGRESSIONAL RESEARCH SERVICE, p.1, https://crsreports.congress.gov (last visited Sept. 13, 2021).[4]

Thus, this case implicates policy decisions on every level of every industry, not just the very substantial issues of public health and interstate commerce in the cosmetics industry specifically raised by the Petition. Given the significant splits in the lower courts, review is warranted. Without review, the inconsistent interpretation of express preemption

[4] See the petition for certiorari currently pending before this Court in *Monsanto Co. v. Hardeman* No. 21-241, filed August 16, 2021, raising similar preemption issues concerning pesticide label warnings.

clauses will upend any predictability of the law for consumers and manufacturers.

II. PRESUMPTIONS AGAINST PREEMPTION WEAKEN NATIONAL UNIFORMITY, REPLACING CONFIDENCE WITH CHAOS.

Congressional intent behind the FDA includes national uniformity of labelling and warning requirements. *See* H.R. Rep. No. 105-399, 103 (1997) (Conf. Rep.); 21 U.S.C. §§ 361-62, 371, 374(a)(1), 379s. National uniformity in product labelling protects consumers and manufacturers alike.

1. Uniform standards protect the consumer by increasing the effectiveness of any given warning. The more warnings given in varying language, the more watered down any one of them becomes. This Court has cautioned (albeit in the context of financial disclosures) that "[m]eaningful disclosure does not mean more disclosure. Rather, it describes a balance between . . . complete disclosure . . . and the need to avoid informational overload." *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 558 (1980) (citations and quotations omitted). The Seventh Circuit Court of Appeals has recognized,

> It is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50

> different labels, driving consumers who buy good products in more than one state crazy.

Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011). *See also Thompson v. County of Alameda*, 614 P.2d 728, 735 (Cal. 1980) (multiple warnings "produce a cacophony . . . that by reason of their sheer volume would add little to the effective protection of the public."); W. Page Keeton, *et al.*, *Prosser & Keeton on the Law of Torts* § 96, at 686 (5th ed. 1984) (cautioning that too much detail in a warning can be "counter-productive").

The warnings themselves can become useless, including to the medical professionals advising the consumer. Indeed, the FDA has warned that flooding the market with conflicting warnings can harm the consumers because additional warnings "can erode and disrupt careful and truthful representation of benefits and risk that prescribers need to make appropriate judgments about drug use." 71 Fed. Reg. at 3935. "[L]abelling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'" *Id.*; *see also* Lars Noah, "*The Imperative to Warn: Disentangling the 'Right to Know' from the 'Need to Know' About Consumer Product Hazards*," 11 Yale J. Reg. 293, 382-83 (1994) ("In the event that labeling included warnings of all possible side effects, the cacophony of risk information could undermine a doctor's ability to appreciate warnings about meaningful hazards"). The flooding of warnings in the market results in chaos and public health suffers.

Even truthful warnings can sometimes fail to communicate in an effective way. In *Finn v. G.D. Searle Co.* (Cal. 1984), the California Supreme Court observed: "[E]xperience suggest[s] that if every report of a possible risk, no matter how speculative, conjectural or tentative imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given." 677 P.2d 1147, 1153.

2. Further, chaos does not create an environment where the consumer is protected economically, as documented by empirical research. Economists researching state consumer protection laws have opined that preemption reduces the costs to the consumer, relying on case studies involving the wine and wireless industries before and after uniform regulatory standards. In the wine industry,

> [s]everal states erected barriers to out-of-state wineries directly shipping their goods ordered online or over the phone to consumers without similar restrictions for in-state wineries; these barriers were overturned by the Supreme Court in 2005, creating what economists call a "natural experiment" designed to test the consumer-welfare effects of the state regulations. Economic research reveals that, soon after states' discriminatory regulations were repealed, wine prices at brick-and-mortar stores declined up to 40% relative to prices offered by online retailers.

Joseph R. Mason, Robert Kulick, and Hal J. Singer, *The Economic Impact of Eliminating Preemption of State Consumer Protection Laws*, 12 Bus. L. J. 781, 783 (2010). The reason for the decline was due to both "facilitating entry by out-of-state sellers. but also by placing competitive pressure on the in-state sellers." *Id*. at 801. (citations omitted)

> Similarly, in the wireless industry,
>
> > [b]efore 1994, states and the federal government had concurrent power to regulate wireless services; in 1994, the Federal Communications Commission preempted the state laws regulating wireless telephony. Once again, economic research demonstrated that the change in regulatory oversight toward uniform, national standards increased economic efficiency. Before deregulation, consumers in states that regulated wireless telephony, such as California and New York, paid more. Furthermore, state regulations discouraged wireless providers from entering the market and slowed consumer adoption of cellular phones. Just as balkanized state laws hindered the growth of wireless networks and raised cellular prices for everyone, balkanized state branching laws inhibited the growth of ATM networks and bank branches, raising the cost of credit and banking services for consumers.

Id. Accordingly, the economists conclude that "[w]hen preemption is considered from an economic efficiency standpoint, its merits become apparent." *Id.* at 782.

See also Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 George Washington L. Rev. 449, 483 (2008) ("These criteria—in economic parlance, economies of scope or scale and the existence of interstate externalities—tend to favor regulation at the national level.").

This economic analysis aligns with common sense. Without uniformity, manufacturers are forced to either comply with a multitude of conflicting and burdensome state laws and federal agency edicts or risk being subjected to numerous lawsuits or state regulatory sanctions. Regardless of the choice made, these increases in risk will increase the costs of doing business on a nationwide level. Manufacturers must be able to predict the risks and requirements of participating in the market, and be able to create reliable, efficient, and cost-effective operations.

3. Thus, preemption encourages a consistent standard and protects interstate commerce from the undue burdens imposed by diverse, nonuniform, and often conflicting state laws and regulatory schemes. *See, e.g.*, Justin W. Aimonetti & Christian Talley, *Game Changer: Why and How Congress Should Preempt State Student-Athlete Compensation Regimes*, 72 Stan. L. Rev. Online 27, 35 (2019) (arguing preemption "is likely critical to ensure national uniformity," and that it would "compel all states to 'play by the same set of rules' preventing one state from gaining a competitive advantage"); Alan Untereiner, *The Defense of Preemption: A View From the Trenches*, 84 Tul. L. Rev. 1267, 1262 (2010) (opining that "multiplicity of government

actors below the federal level virtually ensures that, in the absence of federal preemption, businesses with national operations that serve national markets will be subject to complicated, overlapping, and sometimes even conflicting legal regimes.' "); Frank S. Alexander, *Federal Intervention in Real Estate Finance: Preemption and Federal Common Law*, 71 N.C. L. Rev. 294, 340 (1993) ("The overlapping and ambiguous nature of the constitutional doctrines of preemption and federal common law has been a primary cause of the chaos in judicial reasoning and judicial results in real estate finance cases."); Charles D. Nyberg, *The Need for Uniformity in Food Labeling*, Food Drug Cosm. L.J. 229, 229-30 (1985) ("The need for uniformity in government regulation of the food industry is long-standing and widely recognized" and noting that the White House Conference on Food, Nutrition, and Health recommended in 1970 that there be "uniform application of all regulatory requirements throughout the nation, enforceable by federal, state, and local officials.").

4. Further, uniformity facilities international, as well as interstate, movement of product. *See, e.g.*, Nyberg *supra*, 235 ("It is important to U.S. interests that the national food policy be articulated and defended in international policymaking organizations. Under the present mixed system of federal/state regulation, however, it is difficult for U.S. representatives to express what the national policy is on number of important food labeling issues."). That difficulty is fostered by a regulatory framework bereft of uniformity. Where manufacturing is no longer a national,

but an international affair, U.S. policy makers must be able to speak with one voice. Never has this need for predictability been more urgent given the global upheaval across all industries from the COVID-19 pandemic.

Opinions such as the one issued by the Mississippi Supreme Court interfere with the market-driven uniformity, predictability, and efficiency that Congress intended with preemptive clauses.

CONCLUSION

For all the foregoing reasons, the Court should grant the Petition.

Respectfully submitted,

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