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

BRIEF FOR THE PERSONAL CARE PRODUCTS COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Thomas T. Locke
Counsel of Record
Esther Slater McDonald
Renée B. Appel
SEYFARTH SHAW LLP
975 F Street, NW
Washington, D.C. 20004
(202) 828-5000
tlocke@seyfarth.com

Counsel for Personal Care Products Council

THE LEX GROUP[DC] ♦ 1050 Connecticut Avenue, N.W. ♦ Suite 500, #5190 ♦ Washington, D.C. 20036
(202) 955-0001 ♦ (800) 856-4419 ♦ www.thelexgroup.com

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTIONAL PROVISION

STATUTES

REGULATIONS

OTHER AUTHORITY

INTEREST OF *AMICUS CURIAE*[1]

Personal Care Products Council ("PCPC") is the leading national trade association representing cosmetics and personal care products companies. PCPC's membership consists of over 600 companies that represent more than 90% of the U.S. beauty industry. These members manufacture, distribute and supply the vast majority of personal care products sold in the U.S. and are global leaders in their field. PCPC is an important voice on legal, regulatory, legislative, scientific, and international issues regarding personal care products. One of the trade association's key functions is to advocate for legislation, regulations and judicial decisions grounded in science to ensure the safety, quality, and innovation of personal care products.

PCPC supports the comprehensive, national, and uniform regulation of cosmetics. Congress vested the United States Food & Drug Administration (FDA) with the authority to determine appropriate labeling of cosmetics. The FDA has the expertise to perform that task through its Center for Food Safety and Applied Nutrition Office of Cosmetics and Colors. Federal regulation prevents consumer confusion by prohibiting a confusing patchwork of differing state and local labeling requirements.

---

[1] This brief was authored in whole by PCPC's outside counsel and funded entirely by PCPC. Counsel gave record notice to all parties of this intended filing at least ten days before the filing and all parties consented to the filing of PCPC's brief pursuant to their letter notices of blanket consent filed with the Court.

Federal preemption of state and local laws that purportedly require supplemental cosmetic labels is appropriate: (1) where such laws conflict with the FDA's regulation of cosmetics; and (2) where such laws conflict with an FDA determination that has confirmed the safety of a cosmetic ingredient. This matter involves both scenarios because, in a final agency action, after considering the safety of cosmetic talc, the FDA determined that a warning regarding ovarian cancer is not required for cosmetic talc products. Federal preemption of conflicting state and local laws is particularly important where, as here, the purported labeling requirements impose significant penalties for violations that allegedly took place decades earlier, even though the state made no effort to enforce or to clarify its own purported labeling requirements.

Without the Court's intervention, PCPC's members would be required to guess how cosmetic products should be labeled in different states based on the varying application of each state's consumer protection act, even though the FDA has determined that a cosmetic product does not need a warning label. Accordingly, PCPC supports Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s (the "Petitioners") petition for review.

SUMMARY OF THE ARGUMENT

At issue is whether the Federal Food, Drug, & Cosmetic Act (FDCA) and the FDA's denial of two citizen petitions preempt the application of the Mississippi Consumer Protection Act (MCPA), Mississippi Code Section 75-24-5, to require a warning label on a cosmetic product that the FDA has

expressly rejected. Through the MCPA and state judicial system, the Mississippi Attorney General (the "State AG") seeks to circumvent the FDA's authority and regulations, and to penalize a manufacturer for following the FDA's determination.[2]

By allowing the underlying case to proceed, the Mississippi Supreme Court rejects the FDA's authority to regulate cosmetic labeling, even though the FDCA expressly preempts state action on that issue. The Mississippi Supreme Court also deprives the preemptory effect of the FDA's rejection of two citizen petitions seeking warnings on talcum powder products. In short, the Mississippi Supreme Court's decision abridges the FDA's Congressionally-mandated powers.

The implications of the Mississippi Supreme Court's decision are far-reaching. Federal preemption as it relates to cosmetics is necessary to preserve uniform labeling that ensures consistency across interstate commerce. This consistency benefits both manufacturers and consumers. Manufacturers are held to the same standards and consumers can both recognize and understand reliable labeling practices. Manufacturers and consumers depend on the FDA to protect the public health by ensuring the safety, efficacy, and security of personal care products and on the Federal Trade Commission (FTC) to prevent

---

[2] This case is unlike lawsuits in which plaintiffs were users of talcum powder and brought product liability claims against manufacturers for harm allegedly caused by talc use. In those cases, plaintiffs seek monetary relief for their injuries. *See, e.g.*, Master Compl. (DE 132), *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litig.*, MDL No. 16-2738 (D.N.J).

unfair business practices that may mislead consumers.

The Mississippi Supreme Court's decision contravenes the responsibilities that Congress delegated to the FDA. The decision jeopardizes the federal agency's role and reliance thereon by shifting these responsibilities to dissimilar state laws that are unevenly interpreted and applied. Application of the Mississippi Supreme Court's decision would turn over regulation of cosmetic products to myriad state and local officials with limited or no scientific expertise regarding cosmetics and varying agenda. Consumers and manufacturers would be unable to determine or rely upon the inconsistent warning label requirements that would be imposed by various state attorneys general as interpreted by courts across the country. For these reasons, PCPC supports granting the Petition.

ARGUMENT

I. The Mississippi Supreme Court's Decision Threatens the Role of the FDA and the Congressional Mandate for the FDA to Establish a Uniform Regulatory Framework for Cosmetics.

The Mississippi Supreme Court's decision undermines the authority and role of the FDA related to cosmetics labeling, erroneously applies the narrow FDCA exemptions regarding state-specific labeling requirements, and subjects manufacturers to indiscernible state labeling requirements.

A. Congress granted the FDA with the authority to regulate cosmetics labeling, ensuring uniform requirements.

The FDCA "was enacted in 1938 as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics." *O'Connor v. Henkel Corp.*, No. 14-CV-5547 ARR MDG, 2015 WL 5922183, at *3 (E.D.N.Y. Sept. 22, 2015). "In doing so, Congress intended to create a **national and uniform regulatory scheme** for cosmetics, among other items, which up until the FDCA's passage, had been subject to the disparate laws of the states." *Young v. L'Oreal, Inc.*, No. 21CV0446GHWKHP, 2021 WL 2295625, at *2 (S.D.N.Y. May 20, 2021), *report and recommendation adopted sub nom. Young v. L'Oreal USA, Inc.*, No. 1:21-CV-00446-GHW, 2021 WL 2292341 (S.D.N.Y. June 4, 2021) (emphasis added). The FDCA charges the FDA "with protecting public health by ensuring, *inter alia*, … cosmetics are safe and properly labeled." *Id.* (citing 21 U.S.C. § 393(b)(2)(D)). "To accomplish these aims, the FDA may promulgate regulations and enforce those regulations through administrative proceedings." *O'Connor*, 2015 WL 5922183, at *3.

The FDCA gives the FDA the authority to regulate cosmetic labeling. *See* 21 U.S.C. § 362(a); 21 C.F.R. § 1.21; *see also* Miss. Sup. Ct. Decision, Dec. 18, 2018 (acknowledging that "the FDCA vested the [FDA] with the authority to require labels for cosmetics") (citing 21 U.S.C. § 371(a)). The term "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or

wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

Pursuant to this authority, the FDA has promulgated regulations with requirements for cosmetics labels. *See* 21 C.F.R. §§ 701, 740. The FDA's regulations detail the format and content of cosmetic labels, inclusive of product warning statements. *See* 21 C.F.R. § 740(1). In particular, the FDA requires that all cosmetics must "bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." *Id.* § 740.1(a). In addition, the FTC requires that product labels be truthful, cannot be deceptive or unfair, and must be evidence-based. *See* 15 U.S.C. § 45. After careful consideration, the FDA determined that a warning for talcum powder is unnecessary. And, the FTC has not pursued an enforcement action for failing to include a warning on talcum powder.

B. Absent qualifying for an exemption, a state's labeling requirement is preempted by the FDCA.

Permitting a state to impose new labeling requirements bypasses the federal regulatory framework that has been in place for over 80 years. The FDCA includes an expansive preemption provision specific to cosmetics to "ensure that these various federal requirements are not obstructed by state law." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35 (2d Cir. 2020) (citing 21 U.S.C. § 379s). As used in Section 379s, the term requirement, "sweeps broadly and suggests no distinction between positive enactments and common law" and also encompasses an attempt to enforce "negative *prohibitions*." *Cipollone v. Liggett Group,*

Inc., 505 U.S. 504, 521-522 (1992). Under Section 379s, states are prohibited 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). This prohibition is subject to limited exemptions under what is referred to as the "savings clause." None of the exemptions apply here.

First, Section 379s(b) permits "a State or political subdivision thereof" to apply for an exemption. Mississippi did not apply for an exemption. And, even if Mississippi had, the exemption likely would have been denied because the proposed labeling requirement would not have protected "an important public interest" as the FDA expressly determined that no warning is required for talcum powders. Moreover, the exemption would be inapplicable as the proposed labeling requirement would "unduly burden interstate commerce" because it would create inconsistent labeling requirements in different states and penalize violations of requirements that were unknown and unenforced for decades by the states. 21 U.S.C. § 379s(b)(1) and (3). Accordingly, the first exemption is inapplicable.

Second, Section 379s(d) explains that the statute shall have no effect on any action brought under any State product liability law. The underlying claim is not a product liability lawsuit but rather was brought under the MCPA. Thus, the second exemption is inapplicable.

Third, Section 379(e) exempts state requirements that were adopted by public initiative or referendum prior to September 1, 1997. *See, e.g., Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 919 (2004) (observing that "Proposition 65 is the only state enactment that falls within the savings clause") (interpreting 21 U.S.C. § 379r(d)(2) (National uniformity for nonprescription drugs for state initiatives and referendums), which contains the same exemption language as Section 379(e)). The MCPA was enacted by the Mississippi Legislature, not by public initiative or referendum. Therefore, the third exemption is inapplicable.

Having failed to qualify for any exemption under Section 379s, the State AG's attempt to impose a labeling requirement in state court via the MCPA runs afoul of the FDCA.

C. The Mississippi Supreme Court's decision will subject consumers and manufacturers to inconsistent and often indiscernible labeling requirements.

The State AG's lawsuit seeks to penalize Petitioners for not providing a warning label, even though the FDA expressly declined to require a warning label. "In other words, the practical effect of allowing the claims to proceed would contravene Congress' desire to preempt any state requirement on labeling that was not identical to the requirements of federal law." *Young v. L'Oreal, Inc.*, 2021 WL 2295625, at *5; *see, e.g., Moe v. MTD Prod., Inc.*, 73 F.3d 179, 182 (8th Cir. 1995) (holding that if plaintiff's "failure to warn claim were successful, it would create a state standard requiring additional warnings on

lawn mowers or in owner manuals related to the same risk of injury addressed by the federal standard").

As explained in *Critcher*:

> If Plaintiffs were permitted to move forward with their claims, they would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder. These would be requirements "different from" or "in addition to"—or otherwise "not identical with"—those requirements that federal law already imposes. This is exactly what the FDCA does not permit. Congress or the FDA could have chosen to mandate such additional labeling when they established the comprehensive regulatory regime governing cosmetics, but they did not. And because of the broad preemption provision that Congress did choose to include, Plaintiffs cannot now seek to impose those requirements through alternative means grounded in state law.

959 F.3d at 36–37. Here, like *Critcher*, the State AG seeks to disrupt the FDA's uniform regulatory regime governing cosmetics labeling.

The effect of the State AG's efforts would be unpredictable and inconsistent labeling requirements. Cosmetic manufacturers would not be able to discern the labeling requirements because, as here, they would not align with the FDA's science-

based determinations. And, other state attorneys general could seek alternative warning labels pursuant to other consumer protection statutes. This would prompt new compliance requirements on a state-by-state basis. Moreover, here, the issue is compounded by the State AG's effort to penalize manufacturers for the lack of warnings on products sold decades ago, even though Mississippi did not previously assert that the MCPA required warning labels.

PCPC's members would be in limbo, waiting for litigation like this one, where challenges are made that directly affect the print and copy of product packaging. Novel litigation like this case would lead to never-ending repackaging and relabeling at great expense as each state determines its unique labeling requirement, each of which could be inconsistent with the FDA's determination.

Products sold in multiple states could become covered with incomprehensible text if each state imposes different warnings. This would inevitably result in consumer confusion rather than consumer education. Consequently, the overstatement of warnings would dilute their import so that consumers would become immune to the warnings. This scenario becomes even more complicated, where, as here, a state seeks to impose a labeling requirement that has been rejected by the FDA.

For these reasons, the FDCA preempts Mississippi and other states from adopting labeling requirements that would wreak havoc with interstate commerce by creating a patchwork of

indiscernible requirements and *ex post facto* penalties.

II. Ignoring the FDA's Response to the Citizen Petitions Denies the Effect of Federal Regulators' Final Agency Action.

As discussed in the Petition, the Cancer Prevention Coalition (CPC) filed two citizen petitions with the FDA, one in November 1994 and one in May 2008. *See* Petition at 9. Both citizen petitions requested that the FDA mandate a warning on talcum powder. Consistent with its regulations, the FDA published the citizen petitions to allow public comment. 21 C.F.R. § 740.1(b). In 2014, after carefully considering both petitions and reviewing scientific information, the FDA denied the request for a warning label. Neither the CPC nor any other entity sought judicial review of the FDA's decision.

The FDA's actions conformed with the Administrative Procedure Act (APA). The APA provides that, "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). The Citizen Petition process is part of the FDA's broader regulatory effort to "encourage public participation in all agency activities." 21 C.F.R. § 10.10. "An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). Citizen petitions "provid[e] a forum for individuals or businesses to express and support genuine concerns about the safety, scientific, or legal issues regarding a product at any time before, or after, market entry."

In re Suboxone (Buprenorphine Hydrochloride and Nalaxone) Antitrust Litig., No. 13-md-2445 (MDL No. 2445), 2019 WL 4735520, at *3 (E.D. Pa. Sept. 27, 2019). The consuming public and industry alike may comment and submit supplemental materials to the FDA regarding a citizen petition. Thus, it is a thorough and comprehensive process that leads to the FDA's final decision on a citizen petition. That occurred with respect to the CPC petitions and the FDA's decision. Disregarding FDA's decision not only undermines the FDA but also ignores thoroughly considered and longstanding administrative process.

A. Failing to give the FDA's decision preemptive effect undermines the role of federal agencies and invites unnecessary litigation.

The Supremacy Clause provides that "the Laws of the United States … shall be the supreme law of the land." U.S. Const. art. VI, cl. 2. Federal agency actions that have the force of law preempt state law without regard to how that federal law was created. As Petitioners argue, to privilege "notice-and-comment rule-making" above all the other forms of agency law-making "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).

"[A]gency action carr[ies] the force of law to establish preemption" by "whatever the means the FDA uses to exercise its authority" as long as those means "lie within the scope of the authority Congress has lawfully delegated." *In re Incretin-Based Therapies Prod. Liab. Litig.*, No. 13-MD-2452-AJB-

MDD, 2021 WL 880316, at *14 (S.D. Cal. Mar. 9, 2021) (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679, 203 L. Ed. 2d 822 (2019)). A state claim should be "preempted upon 'clear evidence' that the FDA would have rejected the desired label change." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098 (10th Cir. 2017) (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). Where, as here, the "FDA decline[d] to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. at 1684 (Alito, J., concurring). The FDA carefully considered the material presented by the CPC and denied its request for a warning.

Denying the preemptive effect of the FDA's decision renders the citizen petition process superfluous. And, denying preemptive effect would set precedent that federal agency action is preemptive only where the agency acts pursuant to an alternative mechanism (*e.g.*, notice-and-comment rulemaking under the APA (5 U.S.C. Chapter 5). But, the type of responsive decision to a citizen petition, whether approval of the petition with further administrative action or denial of the petition, is not subject to varying treatment. The Mississippi Supreme Court erroneously concludes that, where the FDA makes a decision to reject a citizen's petition seeking the adoption of a warning, the decision bears no weight—although had the FDA required a warning, state action would be preempted. That dangerous conclusion is illogical and impractical.

Consumers and cosmetic manufacturers rely on the FDA's decisions. As to cosmetics labeling and warning requirements, manufacturers turn to the FDA for instruction, including decisions regarding citizen petitions concerning warning labels. In making their decisions on proper language and key components of product labels and packaging, manufacturers place special value on the FDA's determinations. In disregarding the FDA's decision, the Mississippi Supreme Court erroneously undermines manufacturers' reasonable reliance on the FDA.

B. The FDA has the expertise and resources to decide the very issue that the State AG seeks to reconsider.

The failure to credit the FDA's decision also discounts the expertise and resources that the FDA has dedicated to the topic on multiple occasions. *See Comment on Proposed Regulations and Submit Petitions*, https://www.fda.gov/regulatory-information/dockets-management/comment-proposed-regulations-and-submit-petitions (last visited Oct. 1, 2021) ("FDA spends considerable time and staff resources processing petitions."). The FDA considered the CPC's petitions on the topic for which, as discussed in the next section, the State AG seeks a procedurally improper reconsideration. The FDA concluded a warning was not supported by science. *See id.* ("FDA regulatory decisions are based largely on law and science, and agency reviewers look for reasoning, logic, and good science in comments they evaluate.").

Allowing the State AG to proceed with its claim undermines the science-driven approach that the

FDA employs when it makes decisions about food, drug and cosmetic labeling. The FDA's team of scientists and experienced professionals undergo a thorough investigative process with materials presented by experts and current medical and scientific literature before determining whether a warning or label change is even appropriate. Pursuant to that process, the FDA declined to adopt the warning requirement proposed by the State AG.

C. Enabling parties to challenge the FDA's final agency action through purported consumer protection litigation improperly disregards the APA.

Allowing the State AG to proceed without regard to the FDA's decision disregards the well-established administrative process. In effect, the State AG seeks an appeal of the FDA's decision. Critically, there is an administrative process in place for appeals of final agency action. The State AG chose not to follow that process. The APA precludes the State AG's attempt to avoid that process.

The FDA's response to the CPC "constitutes final agency action" that is "reviewable in the courts under 5 U.S.C. 701 et. seq." *See* 21 C.F.R. § 10.45(d); *see also Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 6 (D.D.C. 1989) ("The Commissioner's determination on a citizen petition is final agency action subject to judicial review."); *In re Nat. Res. Def. Council*, 645 F.3d 400, 405 (D.C. Cir. 2011) (observing that "lawsuits involving citizen petitions are regularly heard in the district courts"); *e.g., Schering Corp. v. Shalala*, 995 F.2d 1103, 1104 (D.C. Cir. 1993) (holding that the FDA's response to a citizen petition

denying requested relief for a declaration about bioequivalence constituted "final agency action" from which relief could be sought in United States District Court). Section 702 of the APA provides that a party adversely affected by agency action is "entitled to judicial review thereof." 5 U.S.C. § 702. The FDA's website further instructs, "[a]fter FDA grants or denies the petition, the agency will notify the petitioner directly. If not satisfied, the petitioner can take the matter to court." *See Comment on Proposed Regulations and Submit Petitions*, *supra*.

A court may review the FDA's response to a citizen petition "to determine if it was arbitrary or capricious, an abuse of discretion or unlawful under APA § 706(2)(A)." *Henley v. Food & Drug Admin. (Dep't of Health & Hum. Servs.)*, 873 F. Supp. 776, 782 (E.D.N.Y. 1995), *aff'd sub nom. Henley v. Food & Drug Admin.*, 77 F.3d 616 (2d Cir. 1996). Giving credence to the FDA's function, "[i]n applying this standard, the Court is mindful that when it reviews agency action that is based upon scientific inquiry and technical expertise, a high degree of deference is appropriate." *Id.* This highly deferential standard of review "presumes agency action to be valid." *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976). This "rationale for deference is particularly strong" when an agency is "evaluating scientific data within its technical expertise[.]" *Int'l Fabricare Inst. v. U.S. E.P.A.*, 972 F.2d 384, 389 (D.C. Cir. 1992). As the D.C. Circuit explained, "[a]s we are not scientists and must defer to the Agency's judgments on matters within its technical competence, our task is to assure that they be reasoned, not that they be right." *Id.* at 400.

No judicial review was sought by the State AG or CPC in reaction to the FDA's decision to the citizens petitions. Instead, the State AG seeks an improper reconsideration of the FDA's "scientific inquiry and technical expertise." The State AG should have sought reconsideration through the administrative process. This requirement is fatal to the State AG's lawsuit. *See, e.g.*, *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 6 (D.D.C. 1989) ("The company will not be allowed to circumvent the administrative process in order to have its labeling dispute judicially resolved.").

CONCLUSION

For the foregoing reasons. PCPC respectfully requests that the Court grant the Petition.

Respectfully submitted,

Thomas T. Locke
Counsel of Record
Esther Slater McDonald
Renée B. Appel
SEYFARTH SHAW LLP
975 F Street, NW
Washington, D.C. 20004
(202) 828-5000
tlocke@seyfarth.com

Date: October 4, 2021