

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 Writ of Certiorari to the
Supreme Court of Mississippi**

**BRIEF OF THE CHAMBER OF COMMERCE
OF THE UNITED STATES OF AMERICA,
COALITION FOR LITIGATION JUSTICE, INC.,
AND AMERICAN PROPERTY CASUALTY
INSURANCE ASSOCIATION AS *AMICI
CURIAE* SUPPORTING PETITIONERS**

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INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents around 300,000 members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country.¹

The Coalition for Litigation Justice, Inc. is a nonprofit association formed by insurers to address and improve the litigation environment for tort claims. The Coalition includes Century Indemnity Company; Great American Insurance Company; Nationwide Indemnity Company; San Francisco Reinsurance Company; Resolute Management, Inc., a third-party administrator for numerous insurers; and TIG Insurance Company.

The American Property Casualty Insurance Association is the primary national trade association for home, auto, and business insurers. APCIA members represent all sizes, structures, and regions—protecting families, communities, and businesses in the United States and across the globe.

Amici regularly represent their members' interests in *amicus curiae* briefs in cases raising issues of concern to the nation's business community. *Amici*

¹ Petitioners and respondent received timely notice of this brief under Rule 37(a) and have all filed blanket consents to *amicus* briefs. No counsel for a party authored this brief in whole or in part, and no person or entity, other than *amici*, their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

have a strong interest in ensuring that federal preemption is enforced correctly, clearly, and uniformly nationwide, thus alleviating the need for its members to navigate a patchwork of inconsistent state regulation *Amici* ask the Court to grant the petition for certiorari and reverse the decision below, restoring clarity and uniformity to federal preemption law.

SUMMARY OF ARGUMENT

This case presents a compelling opportunity for the Court to anchor preemption jurisprudence to the original understanding of the Supremacy Clause. In the decision below, the Mississippi Supreme Court allowed the State of Mississippi to impose a cosmetic labeling requirement that the Food and Drug Administration made an affirmative decision *not* to impose. That decision runs right into the express preemption clause in the Food, Drug, and Cosmetic Act (FDCA).

That provision preempts “any [state] 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.” 21 U.S.C. § 379s(a). While this clause seems abundantly clear, the Mississippi Supreme Court found it to be ambiguous, applied a presumption against preemption, and held that the only federal “requirement[s]” with preemptive effect are regulations enacted through notice and comment.

I. That decision violates basic principles of federal preemption. The Supremacy Clause grants preemptive effect to “the Laws of the United States,”

U.S. Const. art. VI, cl. 2, meaning “the statutory text that was produced through the constitutionally required bicameral and presentment procedures,” *Wyeth v. Levine*, 555 U.S. 555, 585 (2009) (Thomas, J., concurring). As this Court has held, this means that courts must interpret express preemption clauses according to their text, unmodified by any presumption against preemption. *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016). Doing otherwise, as the court below did, extends preemptive effect not to “the Laws of the United States,” but to individual judges’ extratextual speculation about congressional intent.

Section 379s(a)’s plain text preempts the claims in this lawsuit. Mississippi seeks to impose a state-law requirement that cosmetic talc products include a cancer warning. But the Food and Drug Administration, through its denial of two citizen petitions, affirmatively concluded that the FDCA’s requirements do *not* support such a warning. Under the ordinary meaning of the word “requirement,” therefore, Mississippi impermissibly seeks to impose a state-law “requirement” that is “not identical with” the FDCA’s “requirement[s].” 21 U.S.C. § 379s(a). The Mississippi Supreme Court could hold otherwise only by artificially restricting section 379s to notice-and-comment regulations, a limitation with no basis in the statutory text.

II. The decision below exacerbates a split in the lower courts about how to interpret express preemption clauses. Because of that split, different courts in different regions of the country apply identical preemption clauses differently, destroying

the nationwide uniformity that federal preemption is intended to foster. Without such uniformity, regulated businesses will face a crazy-quilt of inconsistent state legal requirements, multiplying the costs of compliance and discouraging innovation. Those costs, in turn, will drive up prices for consumers and hinder the development of life-saving medications and other valuable products.

ARGUMENT

I. The decision below misconstrues basic principles of federal preemption.

The Mississippi Supreme Court improperly disregarded this Court's clear holding that courts should "not invoke any presumption against preemption" when interpreting express preemption provisions. *Puerto Rico*, 136 S. Ct. at 1946. That erroneous decision conflicts with the Supremacy Clause and misinterprets the FDCA's express preemption provision.

A. Applying a presumption against preemption to express preemption provisions conflicts with the Supremacy Clause and basic rules of statutory interpretation.

1. Federal preemption enforces the "familiar and well-established principle that the Supremacy Clause invalidates state laws that interfere with, or are contrary to, federal law." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (cleaned up). Courts must, therefore, analyze preemption "in accordance with [the Supremacy

Clause’s] terms.” *Wyeth*, 555 U.S. at 585 (Thomas, J., concurring).

As relevant here, those terms grant supreme status “to ‘the *Laws* of the United States.” *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019) (quoting U.S. Const. art. VI, cl. 2). And more than that, to federal “Laws” that are “made in Pursuance” of “[t]his Constitution.” U.S. Const. art. VI, cl. 2. Under the Supremacy Clause, it is “the statute” that ultimately “strips state law of its force.” *Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1198 (2017).

It follows that when Congress enacts an express preemption clause, an analysis of whether that clause preempts state law begins and ends with the statutory text. *Puerto Rico*, 136 S. Ct. at 1946. In interpreting any statute, the goal is “neither liberally to expand nor strictly to constrict [the statute’s] meaning, but rather to get the meaning precisely right.” Antonin Scalia, *Assorted Canards of Contemporary Legal Analysis*, 40 Case W. Res. L. Rev. 581, 582 (1990); see *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1142 (2018) (refusing to interpret statute “narrowly” without “textual indication” requiring such a construction). That is no less true for express preemption clauses.

2. The Mississippi Supreme Court below departed from these first principles by applying a presumption against preemption to the FDCA’s express preemption clause for cosmetics. Pet. App. 11a. That decision conflicts with the Supremacy Clause by refusing to extend preemptive effect to “the *Laws* of the United States.” U.S. Const. art. VI, cl. 2.

The “presumption against pre-emption is rooted in” an “assum[ption] that Congress does not cavalierly pre-empt state laws.” *Tarrant Reg’l Water Dist. v. Herrmann*, 569 U.S. 614, 631 n.10 (2013) (internal quotation marks omitted). But an express preemption clause makes clear that Congress *deliberately* intended to preempt state law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008). In that case, there is no justification for assuming that Congress did not mean exactly what it said. A court may not depart from “what a pre-emption clause . . . does by its terms” by “speculat[ing] upon congressional motives.” *Id.*

Otherwise, state law would be preempted not—as the Supremacy Clause requires—by the “Laws” duly enacted by Congress and signed by the President, but by “extratextual considerations” conjured up by judges. *Wyeth*, 555 U.S. at 603 (Thomas, J., concurring). Such judicial guesses about unexpressed congressional intent “do not satisfy the [constitutional] requirements for enactment of federal law and, therefore, do not pre-empt state law under the Supremacy Clause.” *Id.* at 587-88. Instead, the Supremacy Clause “accords pre-emptive effect to only those policies that are actually authorized by and effectuated through the statutory text.” *Id.* at 602. And so it is that text that controls, unmodified by any presumption against preemption. *Puerto Rico*, 136 S. Ct. at 1946.

3. The text of the FDCA’s express preemption clause for cosmetics is straightforward. It provides that “no 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.” 21 U.S.C. § 379s(a). This “broad preemption provision” displaces “not only those state laws that are in conflict with it (*i.e.*, any law that is ‘different from’ the FDCA) but also *any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations (*i.e.*, any law that is ‘in addition to’ the FDCA).” *Critcher v. L’Oreal USA, Inc.*, 959 F.3d 31, 34-36 (2d Cir. 2020).

Whether the FDCA preempts a state law regulating cosmetics thus depends on whether the state law imposes “any requirement” that is “not identical” to a federal “requirement specifically applicable to a cosmetic or class of cosmetics.” 21 U.S.C. § 379s(a). That is the only analysis supported by the text.

B. The Mississippi Supreme Court’s holding that only notice-and-comment regulations can preempt state law cannot be squared with the text of the FDCA’s preemption provision.

Section 379s’s text provides no basis for the Mississippi Supreme Court’s holding that only notice-and-comment regulations can preempt state law. Pet. App. 15a-17a.

As explained, section 379s extends preemptive force to the FDCA’s “requirement[s].” 21 U.S.C. § 379s(a). This Court has held that “requirement” means “a rule of law that must be obeyed.” *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 445 (2005).

Confirming that holding, dictionaries in effect when the preemption clause was enacted² defined “requirement” as “something that is required.” Am. Heritage College Dictionary 1160 (3d ed. 1997).³ And the ordinary meaning of “require” is “[t]o direct, order, demand, instruct, command, claim, compel, request, need, [or] exact” or “to ask for authoritatively or imperatively.” Black’s Law Dictionary 1304 (6th ed. 1990).⁴ So anything the FDCA “direct[s], order[s], demand[s], instruct[s], command[s], claim[s], compel[s], request[s], need[s], exact[s],” or “ask[s] for,” *id.*, is a preemptive “requirement” under section 379s.

Nothing in the statute supports limiting those “requirements” to notice-and-comment regulations. Agencies can impose requirements—“rule[s] of law that must be obeyed,” *Bates*, 544 U.S. at 445—without going through notice and comment. To take just one example, the term “requirement” in the FDCA’s express preemption clause for medical devices, 21

² Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 412, 111 Stat. 2296, 2376.

³ *See also* Merriam-Webster Dictionary 627 (1997 ed.) (“something (as a condition or quality) required”); Random House Webster’s College Dictionary 1104 (2d ed. 1996) (“something required”).

⁴ *See also* Am. Heritage College Dictionary 1160 (3d ed. 1997) (“to call for as obligatory or appropriate; demand”); Random House Webster’s College Dictionary 1104 (2d ed. 1996) (“to order or enjoin to do something,” “to ask for authoritatively or imperatively,” “to make necessary or indispensable,” or “to place under an obligation”); Webster’s Dictionary of Am. English 628 (1st ed. 1997) (“to order (someone) to do something; demand, esp. with authority,” “to make necessary,” or “to place (someone) under an obligation to do something”).

U.S.C. § 360k(a), encompasses “premarket approval” of a medical device, even though the FDA does not approve devices through notice-and-comment rulemaking. *Riegel*, 552 U.S. at 322-23.

The same is true for the term “requirement” in section 379s. Congress tasked FDA with “ensuring that . . . cosmetics are safe and properly labeled.” 21 U.S.C. § 393(b)(2)(D). As long as the FDA “act[s] within the scope of [that] congressionally delegated authority,” it may enact binding requirements with preemptive effect whether or not it acts through “notice-and-comment rulemaking.” *Albrecht*, 139 S. Ct. at 1679 (internal quotation marks omitted). The statutory text, therefore, provides “no sound basis” for interpreting the term “requirement” narrowly, as the Mississippi Supreme Court did. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) (O’Connor, J., concurring in part).

C. The FDCA expressly preempts Mississippi’s lawsuit, which seeks to impose labeling requirements the FDCA does not impose.

Read according to its text, section 379s preempts Mississippi’s lawsuit. Mississippi seeks to impose on Johnson & Johnson a labeling “requirement” that the FDA specifically considered and rejected as not supported by the FDCA in its denial of two citizen petitions requesting the same requirement. Pet. 38-39. Because the FDCA tasks the FDA with interpreting its labeling provisions and the FDA has done so, *see* 21 U.S.C. §§ 371(a), 393(b)(2)(D), Mississippi seeks a warning label that is “not identical with” the label required under the FDCA’s prohibition

on false or misleading labels. *Id.* § 379s(a). Its lawsuit is preempted. *Id.*; *Critcher*, 959 F.3d at 35-38.

1. The two citizen petitions relevant to this case asked the FDA to require an ovarian cancer warning on the label for cosmetic talc products. Pet. 10-11. The FDA has authority to enforce the FDCA's prohibition on "false or misleading" labels. 21 U.S.C. §§ 362(a), 393(b)(2)(D). It has exercised this authority by requiring "[t]he label of a cosmetic product [to] bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." 21 C.F.R. § 740.1(a). FDA may thus "prescrib[e] a warning for a cosmetic," either on its own or in response to a citizen petition. *Id.* § 740.1(b). In exercising its authority to do so, or to decline to do so, the FDA is of course imposing an additional "requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter." 21 U.S.C. § 379s(a).

The FDA exercised its authority to interpret the FDCA when it reviewed the citizen petitions here. By denying those petitions, the FDA necessarily concluded that a cancer warning was *not* "necessary or appropriate" for talc products, 21 C.F.R. § 740.1(a), and thus that a label omitting such a warning would not be "false or misleading" under the FDCA, 21 U.S.C. § 362(a); *see* App'x 92 ("[T]he evidence is insufficient for FDA to require as definitive a warning as you are seeking."). The warning that Mississippi seeks is therefore "in addition to" and "not identical with" the FDCA's labeling requirements. 21 U.S.C. § 379s(a); *Critcher*, 959 F.3d at 38.

2. Indeed, Mississippi's lawsuit also contradicts the FDA's regulation addressing when a cosmetic manufacturer must provide a warning about "[a]n ingredient or product having a history of use in or as a cosmetic [that] ha[s] its safety brought into question by new information." 21 C.F.R. § 740.10(b). That regulation requires no warning "for such an ingredient or product" when "(1) [t]he safety of the ingredient or product had been adequately substantiated prior to development of the new information; (2) [t]he new information does not demonstrate a hazard to human health; and (3) [a]dequate studies are being conducted to determine expeditiously the safety of the ingredient or product." *Id.*

The FDA's denial of the citizen petitions shows that talc qualifies for this exemption. First, talc had been used as a cosmetic ingredient for decades before the first citizen petition, and the FDA found it sufficiently safe not to require a warning. App'x 89-92; *see* 21 C.F.R. § 740.10(b)(1). Second, the FDA found that "the new information" submitted in the citizen petitions did "not demonstrate a hazard to human health." 21 C.F.R. § 740.10(b)(2); *see* App'x 89-92. Third, the FDA "conducted" its own "exploratory survey" of talc and reviewed studies conducted after the citizen petitions, none of which established that talc was unsafe. App'x 90, 93; *see* 21 C.F.R. § 740.10(b)(3).

3. The FDA's denial of the citizen petitions in light of these requirements thus plainly satisfies the express preemption clause. Pet. 38-39. As the petition explains, far from constituting mere "inaction," Pet. App. 15a, the denial of a citizen petition is the

product of a considered administrative process that is final, appealable, and judicially reviewable. 21 C.F.R. § 10.45(d); *see, e.g., Nat. Res. Def. Council, Inc. v. FDA*, 760 F.3d 151, 172-76 (2d Cir. 2014) (reviewing FDA denial of citizen petitions). Here, the FDA thoroughly considered the petitions, analyzed decades of scientific evidence, and concluded that no warning was required. App’x 89-93. That is a final judgment, within the FDA’s congressionally delegated authority, as to what the FDCA does and does not require. Section 379s bars Mississippi’s attempt to displace this judgment and to impose a labeling requirement that the FDCA does not impose. *See Critcher*, 959 F.3d at 38 (holding states may not impose “labeling requirements that have not been imposed by Congress or the FDA” because “impos[ing] such *additional* labeling requirements” would “impose many ‘requirements’ that are not contained in the federal statute, or the regulations issued thereunder”).

That the FDA *can*—but need not—deny a citizen petition through notice and comment is of no moment. *See* 21 C.F.R. § 10.30(e)(3), (h). Whatever procedure the FDA uses, the legal force of its denial is identical: it conclusively determines that the FDCA does not require the requested warning. The FDA’s discretionary choice of procedure has no bearing on whether its final, binding decision qualifies as a “requirement” under section 379s.

Mississippi’s attempt to impose a warning not required by the FDCA and its implementing regulations is expressly preempted.

II. The Court should grant certiorari to provide clarity and national uniformity in federal preemption.

As the petition explains, the Mississippi Supreme Court’s decision exacerbates an entrenched split about the scope of express preemption clauses. Pet. 14-19. The Court frequently grants certiorari to correct similar mistaken preemption rulings. *E.g.*, *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 319 (2016); *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 487 (1987). It should do so again here to restore clarity and uniformity to federal preemption law.

A. *Amici’s* members include thousands of businesses subject to federal regulatory schemes like the FDCA, as well as those businesses’ insurers. These comprehensive regimes advance public ends (such as the safety of drugs, medical devices, and cosmetics), while also ensuring a nationwide marketplace for valuable—even life-saving—goods and services.

Compliance with these regulatory regimes imposes significant costs on businesses. *E.g.*, U.S. Chamber of Commerce Found., *The Regulatory Impact on Small Business: Complex. Cumberson. Costly.* 18 (2017), <https://perma.cc/G6SX-VTEC>. Those costs would be multiplied fifty-fold if states could impose different requirements on the same conduct. Such duplicative compliance costs stifle innovation, drive up prices for consumers, and constrain the job-creating powers of American businesses. Federal preemption reduces these harms by ensuring that the same federal regulatory standards apply uniformly nationwide. *See, e.g., Bates*, 544 U.S. at 452 (FIFRA expressly “pre-empts competing state labeling

standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers”); *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987) (“ERISA’s pre-emption provision was prompted by recognition that . . . [a] patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation.”).

The FDCA’s express preemption provisions serve the same need for clear, uniform national standards. The provision for medical devices, 21 U.S.C. § 360k(a), protects the “regime of detailed federal oversight” over devices. *Riegel*, 552 U.S. at 316. The provision for over-the-counter drugs ensures “[n]ational uniformity for nonprescription drugs.” 21 U.S.C. § 379r. And section 379s ensures that “national uniformity [in] the manufacture and sale of cosmetics” is not “obstructed by state law.” *Critcher*, 959 F.3d at 35.

B. For these reasons, federal preemption rules must be uniform nationwide. Regulators and regulated parties alike need federal standards to be clear and uniform. “Regulators want their regulations to be effective, and clarity promotes compliance.” *Kisor v. Wilkie*, 139 S. Ct. 2400, 2421 (2019) (plurality op.) (cleaned up). And regulated parties need to “know what they can and cannot do.” *Id.* But if some courts give less preemptive force to federal law than others, then businesses will be subject to an inconsistent patchwork of state and federal regulations, making compliance unreasonably difficult and undermining the effectiveness of federal regulatory schemes. *See Nw. Airlines, Inc. v. Duncan*, 121 S. Ct. 650, 651 (2000)

(O'Connor, J., dissenting) (“divergent pre-emption rules formulated by the Courts of Appeals” expose business “to inconsistent state regulations”).

The consequences can be severe. Conflicting interpretations of FDCA preemption could permit each state to impose its own labeling requirements for food, drugs, and cosmetics, “driving consumers . . . crazy.” *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). The FDA itself has explained that excessive warning requirements do more harm than good, since overwhelming consumers with warnings “can render the warnings useless and discourage [the] use of beneficial medications.” *Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017) (citing FDA guidance).

Worse still, the burden of complying with inconsistent state and federal requirements can prevent valuable products from being created in the first place. That is why, this Court explained, the FDCA preempts state regulation of medical devices: many people would “suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.” *Riegel*, 552 U.S. at 326. Similarly, the National Childhood Vaccine Injury Act (NCVIA) preempts most products-liability suits against vaccine manufacturers, 42 U.S.C. § 300aa-22(b)(1), in order to “stabilize the vaccine market,” *Bruesewitz v. Wyeth, LLC*, 562 U.S. 223, 228 (2011). This Court thus rejected a narrow interpretation of the NCVIA’s preemption clause, which would have increased manufacturers’ tort liability, “lead[ing] to . . . withdrawals of vaccines or vaccine manufacturers from the market” and “halt[ing] the future production

and development of childhood vaccines in this country.” *Id.* at 248-49 (Breyer, J., concurring) (cleaned up).

3. The Mississippi Supreme Court’s holding that, due to the presumption against preemption, the term “requirement” in express preemption clauses applies only to notice-and-comment regulations would have wide-ranging consequences. Take, for example, the FDCA’s preemption provision for medical devices, which (as explained above) also uses the word “requirement.” *Supra* at 8-9. This Court in *Riegel* held that language covered premarket approval of a device. 552 U.S. at 322-23. But the Mississippi Supreme Court’s rule would require the opposite outcome, since the FDA does not grant premarket approval through notice-and-comment rulemaking.

The Federal Meat Inspection Act likewise preempts certain state “requirements in addition to, or different than, those made under” federal law. 21 U.S.C. § 678. The Secretary of Agriculture can impose such requirements without going through notice and comment, and those requirements preempt state law under any reasonable reading of the preemption clause. *E.g.*, *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993, 1001-03 (2d Cir. 1985). The Mississippi Supreme Court would deprive all those requirements of preemptive force.

One final, timely example: the Public Readiness and Emergency Preparedness (PREP) Act immunizes individuals and entities from state liability for taking certain “countermeasures” against a pandemic when the Secretary of Health and Human Services “makes a determination that a disease or other health

condition or other threat to health constitutes a public emergency.” 42 U.S.C. § 247d-6d(a)(1), (b)(1). “During the effective period of [that] declaration,” the PREP Act preempts most state laws that differ from “any requirement applicable under” the PREP Act. *Id.* § 247d-6d(b)(8). But HHS issues emergency declarations under the PREP Act without going through notice and comment, so they could not qualify as “requirements” under the Mississippi Supreme Court’s decision. With the country still in the throes of a deadly pandemic—one that has prompted a PREP Act declaration and multiple amendments⁵—the danger of countervailing guidance from individual states should be apparent.

⁵ See 85 Fed. Reg. 15,198 (Mar. 17, 2020); 85 Fed. Reg. 21,012 (Apr. 15, 2020); 85 Fed. Reg. 35,100 (June 8, 2020); 85 Fed. Reg. 52,136 (Aug. 24, 2020); 85 Fed. Reg. 79,190 (Dec. 9, 2020); 86 Fed. Reg. 7872 (Feb. 2, 2021); 86 Fed. Reg. 9516 (Feb. 16, 2021); 86 Fed. Reg. 14,462 (Mar. 16, 2021); 86 Fed. Reg. 41,997 (Aug. 4, 2021); 86 Fed. Reg. 51,160 (Sept. 14, 2021).

CONCLUSION

The Court should grant the petition for certiorari.

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