No. 21-348

In The
Supreme Court of the United States

JOHNSON & JOHNSON, et al.,

Petitioners,

v.

MISSISSIPPI, ex rel. LYNN FITCH,
ATTORNEY GENERAL OF MISSISSIPPI,

Respondent.

On Petition For A Writ Of Certiorari
To The Mississippi Supreme Court

BRIEF OF ATLANTIC LEGAL FOUNDATION & DRI–LAWYERS REPRESENTING BUSINESS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

EMILY G. COUGHLIN
President
DRI–LAWYERS
REPRESENTING BUSINESS
222 South Riverside Plaza
Chicago, IL 60606
(312) 795-1101

LAWRENCE S. EBNER
Counsel of Record
ATLANTIC LEGAL FOUNDATION
1701 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 729-6337
lawrence.ebner@
atlanticlegal.org

Counsel for Amici Curiae

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INTEREST OF THE *AMICI CURIAE* [1]

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DRI–Lawyers Representing Business is an international membership organization composed of approximately 16,000 attorneys who defend the interests of businesses and individuals in civil litigation. The organization's mission includes enhancing the skills, effectiveness, and professionalism of civil litigation defense lawyers;

[1] Petitioners' and Respondent's counsel of record were provided timely notice in accordance with Supreme Court Rule 37.2(a), and each has lodged with the Clerk a blanket consent for the filing of amicus briefs. In accordance with Supreme Court Rule 37.6, *amici* certify that no counsel for a party authored this brief in whole or part, and that no party or counsel other than *amici* and their counsel made a monetary contribution intended to fund its preparation or submission.

promoting appreciation for their role in the civil justice system; anticipating and addressing substantive and procedural issues germane to defense lawyers and fairness in the civil justice system; and preserving the civil jury trial. To help foster these objectives, DRI, in conjunction with its Center for Law and Public Policy, participates as *amicus curiae* at both the petition and merits stages in Supreme Court cases presenting questions that significantly affect civil defense attorneys, their corporate or individual clients, and the conduct of civil litigation. *See* dri.org.

* * *

Amici are filing this brief because federal preemption of conflicting state law is exceedingly important to public health and safety where, as here, Congress has enacted legislation that vests an expert federal agency such as the Food and Drug Administration (FDA) with comprehensive authority to regulate the safety and labeling of widely used consumer products. Congress has manifested its intent to preempt state regulation of the cosmetic talcum powder product labeling at issue in this litigation by including in the Food, Drug, and Cosmetic Act (FDCA), an express preemption provision. It prohibits a State from establishing "any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is not otherwise identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics" under the Act. 21 U.S.C. § 379s(a).

Rather than repeating the express preemption arguments so persuasively presented in the Petition For a Writ of Certiorari, this amicus brief focuses on

implied preemption, a defense that the Mississippi Supreme Court rejected with virtually no legal analysis. *See* App. 16a. *Amici* agree with Petitioners ("J&J") that the Mississippi Attorney General's consumer protection suit is impliedly as well as expressly preempted. The suit not only conflicts with the FDCA's objectives, but also logically contradicts federal law. This brief builds upon the Petition's arguments by focusing on "logical contradiction" preemption—the fundamental, conflict preemption principle derived directly from the Supremacy Clause.

More specifically, one of the reasons that the State's suit is impliedly preempted is because the state-law warning requirement on which it is predicated *logically contradicts* FDA's explicit rejection of exactly the same warning requirement. This brief urges the Court to grant certiorari to recognize, and to clarify or refine, logical contradiction preemption, and also to decide definitively whether a "presumption against preemption" applies to conflict preemption in general, or at least to logical contradiction preemption.

SUMMARY OF ARGUMENT

"Logical contradiction" preemption is a constitutional principle established by the text and function of the Supremacy Clause, U.S. Const., Art. VI, cl. 2. It simply means that state law is supplanted to the extent that it directly conflicts with federal law. At least two Justices—Justices Thomas and Gorsuch—have embraced logical contradiction preemption as a broader, less nuanced, easier to apply preemption principle than the "impossibility" branch

of the Court's conflict preemption taxonomy. *See Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668, 1681 (2019) (Thomas, J., concurring) (discussing the "logical-contradiction standard" for preemption); *see also Kansas v. Garcia*, 140 S. Ct. 791, 807-08 (2020) (Thomas, J., concurring) (same); *Lipschultz v. Charter Advanced Servs. (MN), LLC*, 140 S. Ct. 6, 7 (2019) (Thomas, J., concurring in the denial of certiorari) (same).

The Mississippi Attorney General's so-called consumer protection suit is predicated on a state-law requirement for inclusion of an ovarian cancer warning on the labeling of J&J's cosmetic talcum powder products, such as Johnson's Baby Powder. This alleged state-law requirement directly and unavoidably clashes with FDA's carefully considered, scientifically based, final-agency-action determination that an ovarian cancer label warning is *not* required. Common sense dictates that the state-law requirement upon which Mississippi's suit is founded logically contradicts FDA's determination, which was made in accordance with the agency's comprehensive authority under the FDCA to regulate the safety and labeling of cosmetics.

The Supremacy Clause, therefore, automatically bars the State's suit because it logically contradicts federal law. The Court should grant review and hold that logical contradiction preemption is one of the reasons why the suit is preempted.

Under the straightforward test for logical contradiction preemption, the question of whether it would be possible for J&J to comply with both Mississippi's state-law label warning requirement and

the FDCA's label warning requirements as implemented by FDA is of no consequence. Nonetheless, it would be impossible for J&J to comply with both insofar as including an ovarian cancer warning on cosmetic talc product labeling would be false and misleading, and render those products misbranded, in light of FDA's determination that such a warning is unwarranted.

Similarly, logical contradiction preemption does not depend upon whether the Mississippi Attorney General's second-guessing of FDA's scientific review and determination interposes an obstacle to accomplishment or execution of the FDCA's purposes and objectives. J&J's Petition, however, presents compelling reasons why the State's suit does exactly that. *See* Pet. at 26-27. Indeed, preemption of a state-law label warning that would mislead consumers in a way that could impair their personal hygiene is consistent not only with the FDCA's public health objectives, but also with the purposes of state consumer protection statutes. And of course, as reflected in FDCA's express preemption provision for cosmetics, 21 U.S.C. § 379s(a), Congress recognized the need for national labeling uniformity. *See generally Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 452 (2005) (The provision "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.").

Finally, any "presumption against preemption" is wholly incompatible with logical contradiction preemption. If state law logically contradicts federal

law, the Supremacy Clause preempts it. Even if the Court is not prepared to hold categorically that a presumption against preemption does not apply to implied preemption, it should grant review and hold that the presumption plays no role in determining whether state law is in logical contradiction with federal law, and thus barred by the Supremacy Clause.

ARGUMENT

Mississippi's Consumer Protection Suit Presents The Court With an Ideal Opportunity To Address "Logical Contradiction" Preemption

A. Mississippi's suit not only is expressly preempted, but also impliedly preempted because it is premised on a state-law warning requirement that logically contradicts FDA's explicit rejection of the same warning requirement

"The Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (quoting U.S. Const., art. VI, cl. 2). Where, as here, state law logically contradicts, and thus directly conflicts with, federal law, the Supremacy Clause, by its own terms, operates to negate, i.e., preempt, the state law. Justice Thomas, joined by Justice Gorsuch, has referred to such direct constitutional preemption as "logical contradiction" preemption. Mississippi's suit fits squarely within the logical contradiction preemption framework.

1. Justice Thomas repeatedly has criticized the Court's traditional implied preemption jurisprudence. *See generally Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in the judgment) (expressing concern about "far-reaching implied pre-emption doctrines"). For example, Justice Thomas often has "reiterate[d] [his] view that [the Court] should explicitly abandon [its] 'purposes and objectives' pre-emption jurisprudence" as "contrary to the Supremacy Clause." *Kansas v. Garcia*, 140 S. Ct. 791, 807, 808 (2020) (Thomas, J., concurring). He also has "remain[ed] skeptical that 'physical impossibility' is a proper test for deciding whether a direct conflict exists between federal and state law." *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668, 1681 (2019) (Thomas, J., concurring). More specifically, Justice Thomas not only has rejected "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives," *Wyeth*, 555 U.S. at 588 (internal quotation marks omitted), but also has questioned "why a narrow 'physical impossibility' standard is the best proxy for determining when state and federal laws 'directly conflict' for purposes of the Supremacy Clause," *id.* at 590.

Justice Thomas's published opinions discussing logical contradiction preemption flow from these concerns. He has explained that "[e]vidence from the founding suggests that, under the original meaning of the Supremacy Clause, federal law pre-empts state law only if the two are in *logical contradiction*." *Albrecht*, 139 S. Ct. at 1681 (emphasis added) (citing Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 260-61 (2000) (proposing a "logical-contradiction test" for

preemption)); *Wyeth*, 555 U.S. at 590 (same); *see also* Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J. of Law & Liberty 63, 86 (2010) ("Justice Thomas acknowledges the constitutional authority for implied preemption [and] embraces . . . the 'logical contradiction' test.").

Justice Gorsuch appears to agree that "logical contradiction" is the most constitutionally appropriate way to determine whether state and federal law directly conflict. *See Garcia*, 140 S. Ct. at 807 (Thomas, J., with whom Justice Gorsuch joins, concurring); *Lipschultz v. Charter Advanced Servs. (MN), LLC*, 140 S. Ct. 6 (2019) (Thomas, J., with whom Justice Gorsuch joins, concurring in the denial of certiorari); *see also* Elizabeth Marley, Note, *Healing a Fractured Preemption Doctrine: The Impact of Merck Sharp & Dohme Corp. v. Albrecht On Impossibility Preemption Defenses*, 89 Fordham L. Rev. 265, 298 (2020) (the "'logical contradiction' method may be gaining support among the bench").

On the other hand, logical contradiction preemption has sparked debate, at least among legal scholars. *See, e.g.*, Jesse Merriam, *Consistency as a Preemption Doctrine*, 25 Wm. & Mary Bill Rts. J. 981, 984, 985 (2017) (discussing "the difficulty of determining what it means for laws to contradict each other" and "how the concept of 'logical contradictions' can be deployed in preemption law more effectively and predictably"); Daniel J. Meltzer, *Preemption and Textualism*, 112 Mich. L. Rev. 1, 31 (2013) (arguing that the "seemingly limited" logical contradiction

standard "is not necessarily so in practice," and that "the application of the standard does not free a judge from the need to make rather open-ended judgments about the nature of congressional purposes"). Scholarly debate about logical contradiction preemption is all the more reason why the Court should address its operation and application.

By way of historical background, the Supremacy Clause "contains a *non obstante* provision, a common device used by 18th-century legislatures to signal the implied repeal of conflicting statutes." *Lipschultz*, 140 S. Ct. at 7.

> The phrase "any [state law] to the Contrary notwithstanding" is a *non obstante* provision. . . .
>
> [T]he provision suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law. . . .
>
> The *non obstante* provision of the Supremacy Clause indicates that a court need look no further than the ordinary meanin[g] of federal law, and should not distort federal law to accommodate conflicting state law. . . .
>
> The *non obstante* provision suggests that pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties.

PLIVA, 564 U.S. at 621, 622, 623 (internal citations and quotation marks omitted).

Thus, "[u]nder this Clause, '[w]here state and federal law "directly conflict," state law must give way."' *Albrecht*, 139 S. Ct. at 1681 (Thomas, J., concurring) (quoting *PLIVA*, 564 U.S. at 617); *see also Garcia*, 140 S. Ct. at 807 ("The founding generation treated conflicts between federal and state laws as implied repeals."); *cf. Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("In the absence of an express congressional command, state law is preempted if that law actually conflicts with federal law . . . ."). "If we interpret the Supremacy Clause as the founding generation did, our task is straightforward. We must use the accepted methods of interpretation to ascertain whether the ordinary meaning of federal and state law 'directly conflict."' *Garcia*, 140 S. Ct. at 807-08 (quoting *Wyeth*, 555 U.S. at 590). State and federal law directly conflict where, as in this case, "the two are in logical contradiction." *Albrecht*, 139 S Ct. at 161.

Further, "[t]he logical-contradiction test is not confined to instances of what the Court calls 'conflict' preemption. It also comfortably accommodates both 'express' preemption and appropriate instances of 'field' preemption." Nelson, *supra* at 261. Where, as here, a state-imposed requirement for labeling clashes with the plain language of an express preemption provision, the state law logically contradicts federal law. *See* Pet. at 37-38. And since the presence of an express preemption provision, or even a saving clause, does not "foreclose or limit the operation of ordinary conflict pre-emption principles," *Geier v. American*

Honda Motor Co., 529 U.S. 861, 869 (2000), the logical contradiction test provides an additional reason why Mississippi's suit is impliedly preempted too.

2. The State's opportunistic failure-to-warn suit, brought by Mississippi's Attorney General against J&J under the State's Consumer Protection Act, *see* App. 5a, is based entirely on a state-law requirement to provide an ovarian cancer warning on the labeling of cosmetic talcum powder products. *See id.* 5a-6a ("The State argues that by failing to include warning labels on cosmetic talc products, Johnson & Johnson violated the Act by engaging in impermissible 'unfair or deceptive trade practices.'"). This alleged state-law labeling requirement logically, indeed inescapably, contradicts FDA's authoritative determination that an ovarian cancer label warning for cosmetic talcum powder products is scientifically unwarranted, and thus, *not* required. The State's suit, therefore, is preempted by direct operation of the Supremacy Clause.

The suit alleges that J&J engaged in "unlawful, unfair, and deceptive business practices related to its cosmetic talcum powder products [by] fail[ing] to warn of the risk of ovarian cancer in women." *Id.* 3a. But prior to commencement of the suit, FDA formally denied two citizen petitions urging FDA to require all cosmetic talc products to bear labels that include an ovarian cancer warning. *See* Pet. at 9-10. As the Mississippi Supreme Court acknowledged, "[a]fter a careful review" of scientific literature, FDA "denied both citizen petitions because it 'did not find that the data submitted'" (or FDA's own expanded literature search) "'presented conclusive evidence of a causal

association between talc use in the perineal area and ovarian cancer.'" App. 4a. In other words, the State's suit—which in addition to astronomical civil penalties requests "an injunction pursuant to the Consumer Protection Act to require Johnson & Johnson to warn of the hazards associated with talc use," *id.*—seeks to impose the same label warning requirement that FDA has rejected.

"The Supremacy Clause 'requires that pre-emptive effect be given only to those federal standards and policies that are set forth in, *or necessarily follow from*, the statutory text that was produced through the constitutionally required bicameral and presentment procedures.'" *Wyeth*, 555 U.S. at 586 (Thomas, J., concurring in the judgment) (emphasis added). This is the case here—FDA's scientifically based regulatory determination that an ovarian cancer warning on the labeling of cosmetic talcum powder products should not be required follows directly from that expert federal agency's duly enacted statutory authority.

The FDCA states that as part of FDA's mission, the agency "shall . . . promote the public health by ensuring that . . . cosmetics are safe and properly labeled." 21 U.S.C. § 393(b)(2)(D). (The Act, in pertinent part, 21 U.S.C. § 321(i), defines "cosmetic" as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.") To help accomplish its public health and safety objective, the FDCA prohibits the "misbranding of any . . . cosmetic," and "[t]he introduction . . . into interstate commerce of any . . .

cosmetic that is . . . misbranded." *Id.* §§ 331(a), (b). A cosmetic is misbranded "[i]f its labeling is false or misleading in any particular [or] is in violation of an applicable regulation." *Id.* § 362(a), (f).

FDA's implementing regulation on establishment of warning statements for cosmetics provides that "[t]he label of a cosmetic product shall 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). As J&J explains, FDA can impose a specific warning requirement for a cosmetic product's labeling either on its own initiative or in response to a citizen petition. *See* Pet. at 7-8; 21 C.F.R. § 740.1(b). FDA's final decision on such a citizen petition "constitutes final agency action reviewable in the courts." *Id.* § 10.45(d); *see also* App. 14.

Unlike the situation in *Lipschultz*, this appeal does not involve a federal agency's discretionary "policy of nonregulation," i.e., an agency policy forgoing regulation of an entire regulatory area (*Lipschultz* involved the FCC's policy of forgoing regulation of Internet voice call services). *See* 140 S. Ct. at 7. Here, the FDCA provides that FDA "shall" ensure that "cosmetics are safe and properly labeled." 21 U.S.C. § 393(b)(2)(D). In accordance with this statutory mandate and FDA's implementing regulations, the agency expressly denied citizen petitions requesting imposition of the same ovarian cancer label warning requirement that the Mississippi Attorney General nonetheless seeks to impose through this litigation. *See* Pet. at 10. Where, as here, "the FDA declines 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." *Albrecht*, 139 S. Ct. at 1684 (Alito, J., concurring in the judgment). Because the state-law warning requirement upon which the State's suit is founded logically contradicts the FDA's federal-law determination that the warning is scientifically unwarranted and thus not required, the suit is impliedly preempted by direct operation of the Supremacy Clause.

3. The Mississippi Supreme Court's superficial analysis of implied preemption occupies only one paragraph. *See* App. 16a. According to the court's opinion, because "there is no existing requirement in place . . . the [FDA] chose not to exercise its regulatory authority, allowing the states the freedom to regulate cosmetics instead." *Id.* 17a. But as discussed above, and as the court acknowledged, App. 14, FDA *did* exercise its regulatory authority by considering the two citizen petitions for imposition of an ovarian cancer warning requirement, and then taking final agency action, *see* 21 C.F.R. § 10.45(d), when it denied those petitions on the ground that such a warning is not warranted by the available scientific data. As is the case here, "a final agency action with the force of law [is] 'Law' with pre-emptive effect" within the meaning of the Supremacy Clause. *Albrecht*, 139 S. Ct. at 1883 (Thomas, J. concurring). Because the state-law ovarian cancer label warning requirement that the State seeks to impose through this suit is in logical contradiction to FDA's decision not to impose such a requirement, that final agency action has preemptive force. The court's opinion acknowledges

the stark contradiction between the State's suit and the FDA's determination, *see* App. 4a, but is oblivious to its preemptive effect.

State and federal law also are in logical contradiction because providing an ovarian cancer warning on cosmetic talcum powder labeling would be false and misleading or otherwise render such products misbranded under the FDCA. "Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are without effect." *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). Statutory misbranding prohibitions like those in 21 U.S.C. § 331(a)-(c) are a type of requirement, i.e., "a rule of law that must be obeyed." *Bates*, 544 U.S. at 445; *cf. Cipollone*, 505 U.S. at 527 ("a *prohibition*" against advertising and promotional materials that minimize the hazards of smoking "is merely the converse of a . . . *requirement* that warnings be included in advertising and promotional materials."). Since compliance with the State's label warning requirement would violate the FDCA's requirement that cosmetics not be misbranded, the state-law requirement would logically contradict federal law, and therefore, is preempted for this reason too.

4. Regardless of whether Mississippi's ovarian cancer label warning requirement violates the FDCA's misbranding prohibition, it logically contradicts FDA's final agency action rejecting imposition of that requirement. This is true even if the FDCA's misbranding prohibition, as implemented by FDA, would not bar including on cosmetic talcum powder labels, the same warning that FDA determined is

scientifically unwarranted and should not be required. "Sometimes, federal law will logically contradict state law even if it is possible for a person to comply with both." *Albrecht*, 139 S. Ct. at 1681 (Thomas, J., concurring); *see also Wyeth*, 555 U.S. at 590 ("There could be instances where it is not 'physically impossible' to comply with both state and federal law, even when the state and federal laws give directly conflicting commands."). For example, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Id.* (citing *Nelson*, *supra* at 260-61). Thus, the "logical-contradiction test should not be confused with . . . physical impossibility . . . . There are plenty of circumstances in which it is physically possible for *individuals* to comply with both state and federal law even though *courts* would have to choose between them—that is, even though state and federal law contradict each other." Nelson, *supra* at 260-61; *see also* Sharkey, *supra* at 86.

Here, the State's suit is preempted because it would "set a standard for a product's labeling" that logically contradicts the federal standard, as determined by FDA, for the same product's labeling. *Bates*, 544 U.S. at 446. The Mississippi Supreme Court erred by choosing between these contradictory standards. Under the Supremacy Clause, the state supreme court had no discretion to favor state law over federal law: The Supremacy Clause demands that the federal standard—which does not require the label

warning that the state standard would impose—must prevail.

B. There can be no presumption against logical contradiction preemption

As the Petition explains, in *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938 (2016), the Court finally put to rest the question of whether a presumption against preemption applies to express preemption. It does not. *See id.* at 1946; Pet. at 14. Now the Court should do the same with regard to implied preemption. The Court should grant review not only to clear up the circuits' (and some state supreme courts') continuing (and in light of *Franklin*¸ unjustifiable) confusion about when, if ever, a presumption against preemption applies to express preemption provisions, *see* Pet. at 14-19, but also whether, or under what circumstances, such a presumption applies to implied preemption, including logical contradiction preemption.

1. The Court's precedents regarding whether, or when, a presumption against preemption applies to implied preemption are difficult to reconcile, and reflect pronounced divisions within the Court.

For example, in *Geier v. American Honda Motor Co.* (2000), the Court declined to apply a presumption against preemption when holding that federal motor vehicle safety standards impliedly preempted an automobile airbag-related product liability suit. *See* 529 U.S. at 874, 888; *see also Wyeth*, 525 U.S. at 623-24 (Alito, J., dissenting) ("[T]he *Geier* Court specifically rejected the argument . . . that the 'presumption against preemption' is relevant to the

conflict pre-emption analysis."). The dissent in *Geier* argued that "the presumption against pre-emption should control . . . Our presumption against pre-emption is rooted in federalism. . . . While the presumption is important in assessing the pre-emptive reach of federal statutes, it becomes crucial when the pre-emptive effect of an administrative regulation is at issue." 529 U.S. at 906, 907, 908 (Stevens, J., dissenting).

The same year, in *United States v. Locke*, 529 U.S. 89 (2000), a unanimous Court, holding that the federal regulatory scheme governing oil tankers impliedly preempted more stringent state regulations, cautioned that "an 'assumption' of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence." *Id.* at 108; *see also Buckman Co. v. Plaintiffs' Legal Cmte.*, 541 U.S. 341, 347 (2001) ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action.").

Unlike the conflict preemption analysis in *Geier*, the Court in *Wyeth v. Levine* (2009) applied a presumption against preemption in holding that the FDCA's prescription drug provisions, implemented by FDA regulations, did not impliedly preempt a state-law failure-to-warn claim involving a brand-name drug. *See* 555 U.S. at 565 (asserting that a "cornerstone[] of our pre-emption jurisprudence" is that "[i]n all pre-emption cases, and particularly in

those in which Congress has legislated . . . in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress") (internal quotation marks omitted). In response to the dissent, the majority opinion stated as follows: "[T]he dissent argues that the presumption against pre-emption should not apply to claims of implied conflict pre-emption at all . . . but this Court long has held to the contrary." *Id.* at 565 n.3. In his separate opinion, Justice Thomas raised, but left for another day, the question of "whether, or to what extent, the presumption should apply in a case . . . where Congress has not enacted an express–pre-emption clause." *Id.* at 589 n.2 (Thomas, J., concurring in the judgment); *see also* Sharkey, *supra* at 85.

Then in *PLIVA, Inc. v. Mensing* (2011) the Court, without referring to a presumption against preemption, held that the FDA regulations governing generic prescription drug manufacturers directly conflict with, and thus impliedly preempt, failure-to-warn claims. *See* 564 U.S. at 609. The dissenting opinion stated that "[w]e apply [the] presumption against pre-emption both where Congress has spoken to the pre-emption question and where it has not. . . . [W]hen the claim is that federal law impliedly pre-empts state law, we require a strong showing of a conflict to overcome the presumption that state and local regulation . . . can constitutionally coexist with federal regulation." *Id.* at 641-42 (Sotomayor, J., dissenting) (internal quotation marks omitted).

Similarly, in *Mutual Pharmaceutical Co. v. Bartlett* (2013) the Court did not mention any presumption against preemption when it held that under the *PLIVA* decision, state-law design defect claims that are based on the adequacy of a prescription drug's warnings are impliedly preempted by FDA's regulations. *See* 570 U.S. at 476. The dissent criticized "the majority's failure to adhere to the presumption against pre-emption . . . a more careful inquiry into congressional intent is called for, and that inquiry should be informed by the presumption against pre-emption." *Id.* at 498 n.6, 503 (Sotomayor, J., dissenting).

Most recently, in *Merck Sharp & Dohme Corp. v. Albrecht,* (2019), another prescription drug failure-to-warn case, the Court addressed questions regarding application of "impossibility" preemption, *see* 139 S. Ct. at 1672, but nowhere referred to a presumption against preemption.

These are just examples of the Court's often fractured and inconsistent precedents on the role, if any, of a presumption against preemption where implied preemption is at issue. As was the case with express preemption prior to *Franklin*, "the Court's track record with respect to the presumption against preemption is murky." Sharkey, *supra* at 78; *see also* Jay B. Sykes & Nicole Vanatko, Cong. Rsch. Serv., R45825, *Federal Preemption: A Legal Primer* 3-4 (July 23, 2019) ("The Court regularly appealed to this principle in the 1980s and 1990s, but has invoked it inconsistently in recent cases."); *id.* at 3 n.21 & 4 n.22

(collecting cases).[2] Further, too many courts and litigants routinely treat the *presumption* against preemption as an *irrebuttable* presumption, i.e., as a mandate against preemption. Lower courts and litigants, and even legal scholars, need the Court's further guidance on this frequently recurring subject.

2. Regardless of whether a presumption against preemption applies to implied preemption in general, the Court should hold that it does not apply to logical contradiction preemption. As discussed above, logical contradiction preemption is derived directly from the Supremacy Clause. *See Garcia*, 140 S. Ct. at 807-08 (Thomas, J., concurring); *Albrecht*, 139 S. Ct. at 1681 (Thomas, J., concurring). If the Supremacy Clause is interpreted "as the founding generation did," determining whether federal law preempts state law is "straightforward" and depends only on "whether the ordinary meaning of federal and state law 'directly conflict.'" *Garcia*, 140 S. Ct. at 807-08. As Justice Alito explained in his *Wyeth* dissent, a presumption against preemption is not relevant to conflict preemption analysis because "the sole question is whether there is an 'actual conflict' between state and federal law; if so, then *pre-emption follows automatically by operation of the Supremacy Clause*." 555 U.S. at 624 (Alito, J., dissenting) (emphasis added). In short, where state law logically contradicts, and thus directly conflicts with, federal law, the Supremacy Clause operates mechanically to preempt

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[2] Available at https://sgp.fas.org/crs/misc/R45825.pdf

the state law; there is no room for consideration of a presumption against preemption.

In his frequently cited article, *Preemption*, Professor Caleb Nelson further explains why a presumption against preemption does not apply to logical contradiction preemption:

> [T]he Supremacy Clause is not silent on this subject at all. *Its non obstante provision rejects a general presumption that federal law does not contradict state law*. This, indeed, is the whole point of the last fourteen words of the Supremacy Clause. To the extent permitted by state law, courts are certainly free to alter their construction of state law in order to harmonize it with federal law. But the mere fact that a particular interpretation of federal law would contradict (and therefore pre-empt) a state law is not, in and of itself, reason to seek a different interpretation of the federal law.

Nelson, *supra* at 293 (emphasis added); *see also* Merriam, *supra* at 1014 n.176 (Professor Nelson "argues that his interpretation of the Supremacy Clause requires eliminating the presumption against preemption because the Supremacy Clause, as a *non obstante* clause, dispels the notion that Congress intends not to displace state law through its enactment of the relevant federal law."). Although Professor Nelson asserts that "[i]n the realm of 'implied' preemption, the presumption against preemption may help counterbalance the excesses of the Court's other doctrines," Nelson, *supra* at 292, he

advocates against it: "Instead of sowing confusion by coupling a broad general test for 'implied' preemption with an equally general presumption against preemption, *it seems more reasonable for courts to apply the logical-contradiction test* in conjunction with a realistic inquiry into the rules that particular federal statutes actually establish." *Id.* at 291 (emphasis added).

Not all legal scholars agree. Professor Meltzer's article, *Preemption and Textualism*, for example, "criticizes the Nelson/Thomas understanding that the Supremacy Clause calls for rejection of the presumption against preemption and explains the significant role that the presumption continues to play." Meltzer, *supra* at 1. Ongoing scholarly debate concerning the nature and operation of the Supremacy Clause—more than 230 years after the Constitution was ratified (and more than 200 years after Mississippi agreed to be bound by it) only provide additional reason for the Court to further address the fundamental principles of federal preemption implicated by this appeal.

CONCLUSION

The Court should grant the Petition For a Writ of Certiorari.

Respectfully submitted,

EMILY G. COUGHLIN
President
DRI–LAWYERS
REPRESENTING BUSINESS
222 South Riverside
Plaza
Chicago, IL 60606
(312) 795-1101

LAWRENCE S. EBNER
Counsel of Record
ATLANTIC LEGAL
FOUNDATION
1701 Pennsylvania
Avenue, NW
Washington, DC. 20006
(202) 729-6337
lawrence.ebner@
atlanticlegal.org

Counsel for *Amici Curiae*

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