No. 21-348

In The
Supreme Court of the United States

JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.,

Petitioners,

v.

MISSISSIPPI, ex rel. LYNN FITCH, Attorney General of Mississippi,

Respondent.

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

BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

INTEREST OF *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit professional association with scores of corporate members from a broad cross-section of American and international product manufacturing.[2] These companies seek to contribute to legal improvement and reform in the United States and elsewhere, emphasizing law governing liability of product manufacturers and others in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership spanning a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred leading product liability defense attorneys are sustaining (non-voting) members of PLAC.

PLAC's primary purpose is to file *amicus curiae* briefs in cases affecting the development of product related litigation that impact PLAC's members. Since

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[1] The parties submitted blanket *amicus curiae* consent letters, and timely notice has been provided, pursuant to S.Ct. Rule 37.2. Pursuant to S.Ct. Rule 37.6, *amicus* states that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

[2] PLAC's current corporate membership is listed at https://plac.com/PLAC/Membership/Corporate_Membership.aspx.

1983, PLAC has filed more than 1,200 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of its members, and product suppliers generally, and seeking fairness and balance in the application and development of the law as it affects product risk management.

PLAC's interest in this matter is the profound impact on federally regulated businesses of state-law claims seeking to impose conflicting obligations. Many PLAC members, especially FDA-regulated entities, are subject to federal restrictions governing what they can, and cannot, state in product labeling. To avoid being sitting ducks in litigation, regulated businesses depend on federal supremacy to preclude state-law liability where they comply with federal requirements. Here, FDA denied, as scientifically unfounded, two citizen petitions that sought precisely the same labeled warning that the State of Mississippi now demands. The federal Food, Drug and Cosmetic Act ("FDCA"), 52 Stat. 1040, *as amended*, 21 U.S.C. §§301, *et seq.*, expressly preempts state cosmetic labeling "requirements" (with inapplicable exceptions) that are "different from," "in addition to," or "otherwise not identical with" "requirements" created through FDA's expert determinations. Thus, this matter presents express preemption questions under cases such as *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011) (vaccines), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (medical devices).

PLAC's federally-regulated members cannot serve two masters imposing conflicting obligations. If forced

by massive state-law liability to ignore FDA labeling decisions, their products will eventually resemble unregulated consumer products – festooned with multiple warning about questionable risks that consumers tend to ignore. In *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668 (2019) ("*Albrecht*"), the Court recognized that, to enforce the FDCA, FDA has repeatedly sought to prevent overwarning in labels of products it regulates.

INTRODUCTORY STATEMENT AND SUMMARY OF ARGUMENT

As the Petition argues, this appeal presents critical preemption issues. Indisputably: (1) the relief sought by the State of Mississippi directly contradicts FDA's scientific determination that cosmetic talc labels should not warn about ovarian cancer; and (2) FDA considered and rejected the very risk warning the State demands. FDA did so by denying two citizen petitions after "careful review." Pet. App. at 4a. Although that decision was final and appealable, 21 U.S.C §10.45(d), nobody appealed. Rather, within months, the Mississippi Attorney General commenced the current collateral attack on FDA's decision.

1. The Decision Below.

As discussed more fully in the Petition, plaintiff/respondent, Attorney General of the State of Mississippi, brought this state-law consumer protection

action against defendants/petitioners (collectively "J&J") in 2014. The State contends that J&J's talc-containing cosmetics not warning about a claimed risk of ovarian cancer violated Mississippi's statute and exposed J&J to liability – $10,000 for each unit sold in Mississippi since 1974. Pet. App. 3a-4a.

J&J raised federal preemption, arguing that Mississippi's suit differed from FDA's scientific-basis requirement, as applied to talc labeling by denial of two citizen petitions involving the same risk. The State admittedly demanded the same warning that FDA had rejected. Pet. App. 13a-15a. Nevertheless, the Mississippi Supreme Court found no preemption, following a presumption against federal preemption – "a duty to accept the reading that disfavors pre-emption" in cases implicating "the historic police powers of the States." Pet. App. 11a, 16a-17a.

Under this presumption, the court narrowly interpreted an FDA "requirement" to exclude agency actions this Court has found preemptive. "[T]o be binding on the public, the [FDA] must follow the notice and comment rule making process." Pet. App. 15a.

2. State-Law Demands For Scientifically Unsupported Warnings Creates Overwarning And Reduces The Effectiveness Of FDA-Required Warnings.

The FDCA expressly preempts state cosmetic "requirements" that fail to meet the degree of scientific support mandated by FDA. "[N]o state . . . may

establish . . . 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[n FDA] requirement specifically applicable to [that] cosmetic under this chapter." 21 U.S.C. §379s.[3]

In addition to the deep and profound differences of opinion, thoroughly discussed in the Petition, between federal appellate courts and state high courts on the two key preemption-related issues, the Mississippi court ruling is inimical to long-held FDA labeling policy. For over forty years, the Agency has developed and enforced requirements that all warnings for regulated products have specified levels of scientific support. FDA's scientific requirements have been developed, *inter alia*, to prevent excessive and unsupported warnings from drowning out more important label information and from diluting the impact of warnings generally. This Court has joined the vast majority of lower courts, as well as commentators and the American Law Institute, to recognize the validity of FDA's concerns.

The Mississippi court's refusal to give preemptive effect to a recent FDA labeling decision that the warning in question was, and is, scientifically unsupported strikes at the heart of this longstanding basis for FDA decisionmaking. Even more than private litigation, untrammeled state enforcement of disparate and less

[3] The three exceptions in §379s(b,d-e), an FDA-approved state exemption, product liability litigation, and certain state initiatives, are inapplicable.

rigorous warning requirements – backed by potentially astronomical liability – is especially likely to cause regulated product manufacturers to engage in precisely the sort litigation-averse overwarning that FDA has spent decades trying to prevent.

3. The Presumption Against Preemption Applied Here Directly Flouts The Court's Contrary Precedents.

The Mississippi court negated Congress' express preemption clause, and disregarded this Court's precedents, first by applying a presumption against preemption, Pet. App. 15a (invoking "a duty to accept the reading that disfavors preemption").

In *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S.Ct. 1938 (2016), the Court explicitly repudiated such presumptions in cases involving express preemption clauses, as such presumptions fail to accord due respect to statutory language. Congress' words control over extratextual considerations, such as whether the subject is of "historic" state concern. Pet. App. 11a. "Only the written word is the law." *Bostock v. Clayton Cty., Georgia*, 140 S.Ct. 1731, 1737 (2020).

Indeed, even before *Puerto Rico v. Franklin*'s explicit rejection, the Court twice declined to apply such presumptions in prescription medical product express preemption cases, despite dissents urging that it do so. For example in *Bruesewitz v. Wyeth*, the Court's even-handed construction of an express preemption clause required finding that the National Childhood Vaccine

Injury Act of 1986 preempted design defect claims. But in an almost identical case, a state high court applying a legally improper presumption reached a directly contrary result.

4. Limiting Preemption To Notice-And-Comment Rulemaking Would Eliminate Most Existing Grounds For Preemption And Disrupt Federal Decisions.

Second, the Mississippi court held it could disregard FDA's decision altogether, since denial of citizen petitions seeking identical relief did not involve "notice-and-comment rule making." Pet. App. 15a. That restrictive rationale would eliminate preemption for most of what FDA does, including actions that the Court held supported preemption in previous FDA-related cases. Notice-and-comment rulemaking has not been the exclusive basis for preemption. Other recognized grounds include formally rejecting a warning label, and any agency action carrying the force of law.

The Court has consistently recognized FDA requirements as supporting both express and implied preemption. For decades, FDA has regulated product warnings as it did here, through product-specific labeling decisions, including adjudication of citizen petitions. FDA has not approved a product-specific label through notice-and-comment rulemaking in decades. The ruling below is incompatible with virtually all of the Court's recent FDCA preemption precedent.

The ramifications extend well beyond the FDCA. The Public Readiness & Emergency Preparedness Act, 119 Stat. 2818, 42 U.S.C. §§247d-6d, *et. seq*. ("PREP Act"), provides immunity from suit, enforced by federal preemption, for persons responding to public health emergencies such as the COVID-19 pandemic. *Id.* §247d-6d. This immunity is not created through notice-and-comment rulemaking, but rather by formal administrative "declarations" that are published in the Federal Register. *Id.* §247d-6d(b). Making notice-and-comment rulemaking a prerequisite to express federal preemption would expose everyone responding to the current pandemic to state-law litigation and liability.

REASONS FOR GRANTING *CERTIORARI*

I. Allowing States To Require Warnings FDA Finds Scientifically Unsupported Would Lead To Overwarning And Reduce The Effectiveness Of All Product Warnings.

A primary function of FDA, and other federal agencies regulating products, is to evaluate the risks and benefits of those products and to ensure that their labeling accurately warns of product dangers. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005). Where, as here, the agency formally acted, "[i]t is enough for us that the expert agency charged with the enforcement of remedial legislation has determined [what] is desirable for the public health, for we are hardly qualified to second-guess

[FDA]." *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 791-92 (1969).

FDA's "label information is designed to 'prevent overwarning' so that less important information does not 'overshadow' more important information." *Albrecht*, 139 S.Ct. at 1672 (2019). Therefore, FDA labeling requirements are "designed to exclude '[e]xaggeration of risk, or inclusion of speculative or hypothetical risks,' that 'could discourage appropriate [product] use.'" *Id.*[4]

More generally, a product label's "*[m]eaningful* disclosure does not mean *more* disclosure. Rather, it describes a balance between competing considerations of complete disclosure and the need to avoid informational overload." *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 568 (1980) (citation and quotation marks omitted) (emphasis original). Likewise, the Court rejected an overbroad foreseeability-based approach to asbestos warnings as "impos[ing] a difficult and costly burden on manufacturers, while simultaneously overwarning users." *Air & Liquid Sys. Corp. v. DeVries*, 139 S.Ct. 986, 994 (2019). The national economy is greatly burdened when manufacturers of products sold nationwide are subjected to "diverse, nonuniform, and confusing . . . labeling and advertising regulations." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 514 (1992) (footnote omitted).

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[4] *Quoting* 73 Fed. Reg. 49603, 49605-606 (FDA Aug. 22, 2008), and 73 Fed. Reg. 2848, 2851 (FDA Jan. 16, 2008).

Dilution of significant product warnings through overwarning is a well-known and longstanding product liability concern:

> Requiring too many warnings trivializes and undermines the[ir] entire purpose . . . , drowning out cautions against latent dangers of which a user might not otherwise be aware. Such a requirement would neutralize the effectiveness of warnings as an inexpensive way to allow consumers to adjust their behavior based on knowledge of a product's inherent dangers.

Liriano v. Hobart Corp., 700 N.E.2d 303, 308 (N.Y. 1998) (citation omitted).

In a case involving an FDA-regulated over-the-counter product, another state high court held that "a truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the [product's] dangers," leading to "medically unwise decision[s]." *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 14 (Cal. 2004). "Requiring manufacturers to warn their products' users in all instances" would create "an onerous burden" and "invite mass consumer disregard and ultimate contempt for the warning process." *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (citation and quotation marks omitted). In a prescription drug case:

> [C]ommon sense and experience suggest 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.

Finn v. G.D. Searle & Co., 677 P.2d 1147, 1153 (Cal. 1984) (citations omitted). Additional warnings can be "ineffective or even counterproductive if the warning inserts became so large and cumbersome that a user could not easily find the warning." *Ramirez v. Plough, Inc.*, 863 P.2d 167, 175-76 (Cal. 1993).[5]

Numerous federal courts of appeal agree. Applying Mississippi law, *Thomas v. Hoffman-LaRoche*, *Inc.*, 949 F.2d 806 (5th Cir. 1992), noted that "forc[ing] drug manufacturers to list, and perhaps contraindicate, every possible risk" would be unwise:

> [P]hysicians will begin to ignore or discount the warnings provided by the drug manufacturers. Permitting a jury to find liability on such a basis would undermine the important

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[5] *See Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 360-61 (Tex. 1993) ("the more instructions and warnings that are printed in one place . . . the less likely that any one instruction or warning will be noticed"); *Aetna Casualty & Surety Co. v. Ralph Wilson Plastics Co.*, 509 N.W.2d 520, 523 (Mich. App. 1993) ("excessive warnings" are "counterproductive, causing 'sensory overload' that literally drowns crucial information in a sea of mind-numbing detail") (citation omitted); *Broussard v. Continental Oil Co.*, 433 So.2d 354, 358 (La. App. 1983) (consumers would "read none of the warnings if the [product] became cluttered with the warnings").

> role of warnings as a device to communicate vital information to physicians.

Id. at 816 n.40.

Treating "strengthen[ing] warnings" as "something always to be encouraged" is "mistaken." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017). "FDA views overwarnings as problematic because they can render the warnings useless" and "discourage use of beneficial" products. *Id.* "If pharmaceutical companies were required to warn of every suspected risk . . . , the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings." *Doe v. Miles Laboratories, Inc.*, 927 F.2d 187, 194 (4th Cir. 1991).

> [T]he proliferation of label detail threatens to undermine the effectiveness of warnings altogether. . . . Well-meaning attempts to warn of every possible accident lead over time to voluminous yet impenetrable labels – too prolix to read and too technical to understand.

Hood v. Ryobi America Corp., 181 F.3d 608, 611 (4th Cir. 1999) (citation omitted).

"Space on product labeling material is also a factor," since "the most effective labels are those with large, bold warnings and a simple design." *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796-97 (8th Cir. 2001) (en banc) (citations omitted). *See Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) ("information overload" from overwarning "would make label warnings worthless to consumers") (Posner, J.)

(citations omitted); *Cotton v. Buckeye Gas Products Co.*, 840 F.2d 935, 938 (D.C. Cir. 1988) ("inclusion of each extra item dilutes the punch of every other item," creating "obvious information costs").

District court decisions decrying overwarning are legion, and most common in preemption contexts. Last year, preemption vindicated a federal agency order rejecting scientifically unfounded cellphone radiation risk warnings, contrary to a municipal ordinance:

> Given the specificity of the warning required . . . , the implied risk to safety if the warning is not followed (a risk the FCC has concluded does not exist), and the acknowledged controversy . . . , the FCC could properly conclude that the [local] ordinance – as worded – overwarns.

CTIA – The Wireless Ass'n v. City of Berkeley, 487 F. Supp.3d 821, 834 (N.D. Cal. 2020) (citation and quotation marks omitted).

This year, "FDA's approach to warning labels" preempted multi-district litigation demanding scientifically unsupported cancer warnings. Unlike unregulated products bearing "dozens of warnings, with little regard for . . . remoteness or obviousness":

> FDA is concerned not only with avoiding insufficient warnings . . . , but also avoiding over-warning (that is, warning against risks that are unduly speculative, hypothetical, or not adequately supported by science). . . . FDA takes a more measured approach that is

> intended to provide accurate information to medical professionals and patients without unduly discouraging the use of the product.

In re Zofran (Ondansetron) Prod. Liab. Litig., ___ F. Supp.3d ___, 2021 WL 2209871, at *2 (D. Mass. June 1, 2021).[6]

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[6] *See*, *e.g.*, *In re Incretin-Based Therapies Prod. Liab. Litig.*, ___ F. Supp.3d ___, 2021 WL 880316, at *8 (S.D. Cal. March 9, 2021) (following *Albrecht*); *Cohen v. Apple Inc.*, 497 F. Supp.3d 769, 785 (N.D. Cal. 2020) (cell phone class action; same reasoning as *CTIA*, *supra*); *Ridings v. Maurice*, 444 F. Supp.3d 973, 992 (W.D. Mo. 2020) ("FDA prefers a cautious approach" so that "only scientifically accurate information appears in the approved labeling") (citation and quotation marks omitted); *Sabol v. Bayer Healthcare Pharmaceuticals, Inc.*, 439 F. Supp.3d 131, 147 (S.D.N.Y. 2020) (following *Albrecht*); *Greager v. McNeil-PPC, Inc.*, 414 F. Supp.3d 1137, 1141 (N.D. Ill. 2019) ("[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health") (citation and quotation marks omitted); *McGrath v. Bayer HealthCare Pharmaceuticals, Inc.*, 393 F. Supp.3d 161, 169 (E.D.N.Y. 2019) (following *Albrecht*); *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp.3d 644, 659-60 (S.D.N.Y. 2017) (quoted in *Ridings*), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp.3d 1163, 1175 (S.D. Cal. 2016) (rejecting liability that "would encourage prophylactic labeling changes by manufacturers" and "lead to overwarning"); *Heckman v. Ryder Truck Rental, Inc.*, 962 F. Supp.2d 792, 803 (D. Md. 2013) ("tak[ing] into account" whether more warnings would "undermine the effectiveness of warnings altogether") (citation omitted); *Sykes v. Glaxo-SmithKline*, 484 F. Supp.2d 289, 312 (E.D. Pa. 2007) (plaintiffs seek "the very result the FDA wants to avoid, *i.e.*, overwarning, exaggeration, and defensive labeling"); *Ames v. Apothecon Inc.*, 431 F. Supp.2d 566, 573 (D. Md. 2006) ("warnings must be brief and focused to be effective").

As this case demonstrates, prevention of over-warning has a strong regulatory component. For over 40 years, FDA has opposed warnings about unsubstantiated risks. In 1975, it cautioned that scientifically dubious warnings "would result in such uncertainty and confusion that the usefulness of [existing] warnings in protecting the public against possible harm would be severely undermined, if not destroyed." 40 Fed. Reg. 28582, 28583 (FDA July 7, 1975). Four years later FDA rejected inclusion of "general statements on good professional practice" because they could "transform labeling into small text-books of medicine." 44 Fed. Reg. 37434, 37436 (FDA June 26, 1979).

This remains FDA's bottom-line position. Support includes, of course, the 2008 Federal Register statements cited in *Albrecht*, *supra*.[7] Current agency guidance on warning effectiveness states:

> Including too many warnings and precautions, over-warning, dilutes the strength of all of the hazard alerts. . . . Careless designation can have the same diluting effect as over-warning. . . . Repeated exposure to unnecessary hazard alerts (not relevant or already

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[7] *See*, *supra*, n.4. *See also* 71 Fed. Reg. 3922, 3935 (FDA Jan. 24, 2006) ("labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance") (citation and quotation marks omitted); 53 Fed. Reg. 30522, 30530 (FDA Aug. 12, 1988) ("too many warning statements reduce the impact of important statements"); 43 Fed. Reg. 1101, 1104 (FDA Jan. 6, 1978) ("A plethora of warnings about insubstantial questions would be difficult for consumers to evaluate.").

> known) reduces the effectiveness of the important warnings and precautions.

FDA, CDRH, Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers, at 42 (2001). "[E]xhaustive lists" of "minor risks detract from, and make it difficult for, consumers to comprehend and retain information about the more important risks." FDA, CDER, "Brief Summary & Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements & Promotional Labeling for Prescription Drugs," at 4 (Aug. 2015) (revised draft guidance).[8]

Drawbacks of product overwarning have also been addressed by scholarly commentators. The American Law Institute's *Third Restatement of Torts* recognizes that excessive warnings "may be ignored by users and consumers and may diminish the significance of warnings about [other] risks" and "could reduce the efficacy of warnings generally." *Restatement (Third) of Torts, Products Liability* §2, comment j (1998). Professors Prosser and Keeton criticized overwarning as reflecting a "naive belief that one can warn against all significant risks. Too much detail can be counterproductive." W. Page Keeton, *et al.*, *Prosser & Keeton on the Law of Torts* §96, at 686 (5th ed. 1984).

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[8] The cited FDA documents are available at: https://www.fda.gov/media/71030/download (last visited Sept. 23, 2021), and http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf (last visited Sept 23, 2021), respectively.

Law review articles by the ALI's reporters for the *Third Restatement* exemplify academic commentary on overwarning. "[T]he greatest part of the costs of overwarning are nonmonetary and easily ignored." James A. Henderson, Jr., & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U.L. REV. 265, 297 (1990) (footnote omitted). "[A]n environment crowded with warnings of remote risks," leads consumers to "overreact, investing too heavily in their versions of 'safety.' " *Id.* at 296 (footnote omitted).

> [W]arning about relatively remote risks generates substantial social costs which in most cases outweigh any corresponding benefits in reducing accident costs. The most significant social cost . . . is the reduced effectiveness of potentially helpful warnings directed towards risks which are not remote.

Id. (footnote omitted).

Unnecessary or unsupported warnings "diminish the significance of warnings and tend to clutter warning labels with useless information." James A. Henderson, Jr. & Aaron D. Twerski, "*The Products Liability Restatement in the Courts: An Initial Assessment*," 27 WM. MITCHELL L. REV. 7, 16 (2000). "[W]arnings, in order to be effective, must be selective. . . . If even remote risks are to be forced to the consumer's attention, the danger signal is diluted." Aaron D. Twerski, *et al.*, *The Use & Abuse of Warnings in Products Liability – Design*

Defect Litigation Comes of Age, 61 CORNELL L. REV. 495, 514, 517 (1976).[9]

Similar commentary decries overwarning in FDCA-specific contexts. Liability pressures cause companies to "add information to the label based on singular instances of harm[] that the FDA may have deemed unnecessary." Jenny Ange, *Am I My Competitor's Keeper? Innovator Liability in the Fifty States*, 21 COLUM. SCI. & TECH. L. REV. 1, 23-24 (2019).

> Multiple studies have shown that too many warnings . . . decrease the effectiveness of each warning, lead to information overload for patients, and discourage patients from using an otherwise beneficial drug. . . . Over-warning may also result in information clutter – important information about researched side effects may be lost in the label among the

[9] *See also*, *e.g.*, W. Bradley Wendel, *Technological Solutions to Human Error and How They Can Kill You: Understanding the Boeing 737 Max Products Liability Litigation*, 84 J. AIR L. & COM. 379, 405 (2019) ("Over-warning and unhelpful presentation of warnings are already well-recognized problems in flight deck design."); Elizabeth Grotewohl, *Chapter 830: Cleaning Products Are Coming Clean*, 49 U. PAC. L. REV. 333, 349 (2018) ("too much information on a product's label reduces the chance that consumers and domestic workers will accurately evaluate the information"); Jeff Todd, *A Rhetoric of Warning Defects*, 54 S. TEX. L. REV. 343, 374, 377 (2012) ("the aggregation of nonmaterial disclosures will make the cost of reading and remembering outweigh the benefits to the average user, who will not read them") (footnote omitted); Robert G. Knaier, *An Informed-Choice Duty to Instruct?* 88 CORNELL L. REV. 814, 853 (2003) ("The more that product manufacturers warn of risks that never materialize, the less likely product users are to heed those warnings.").

> other miscellaneous warnings, leading to negative information costs.

Id. at 24 (footnotes omitted). "Underapplication of the preemption doctrine may lead manufacturers to seek to include warnings in product labeling that are not supported by science." Douglas G. Smith, *A Shift in the Preemption Landscape?*, 87 TENN. L. REV. 213, 244 (2019).[10] The Mississippi court's refusal to recognize preemption threatens all the detrimental effects that

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[10] *See also*, *e.g.*, Joshua E. Perry, *et. al.*, *Trust in the Balance: Prescription Drug Risks, Patient Perspectives, & Legal (Re)considerations*, 24 J. HEALTH CARE L. & POL'Y 27, 49-50 (2021) ("overwarning of prescription drug side effects which can lead to adverse impacts on prescribing decisions") (footnote omitted); Andrew Andrzejewski, *Direct-to-Consumer Calls to Action: Lowering the Volume of Claims & Disclosures in Prescription Drug Broadcast Advertisements*, 84 BROOK. L. REV. 571, 573 (2019) (overwarning can "dilute the warnings for the most serious side effects" and cause "'therapeutic noncompliance' with prescriptions") (footnotes omitted); Jon Duke, *et al.*, *A Quantitative Analysis of Adverse Events and 'Overwarning' in Drug Labeling*, 171 ARCH. OF INT. MED. 944, 945 (2011) (survey showing that the average prescription drug package insert included 49 potential adverse drug events; 10% listed over 500); 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) (if "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") (footnote omitted); Richard M. Cooper, *Drug Labeling & Products Liability: The Role of the Food & Drug Administration*, 41 FOOD & DRUG L.J. 233, 238 (1986) (rational physician prescribing "is not advanced if a drug is made to appear riskier . . . due to the over-dramatization of risk information or the presentation of risk information that should not rationally influence prescribing (or treatment) decisions").

have been acknowledged by FDA, the Court, the lower courts, commentators, and the American Law Institute.

The risks of overwarning are only magnified here, where plaintiff is a political branch of government, not a private litigant. Although this litigation involves an FDA-regulated cosmetic, Mississippi's next target could easily be an essential vaccine. Some state governments have participated in the torrent of attacks on COVID-19 vaccines (and vaccination generally) despite the vaccines being approved or authorized by FDA based on the best available scientific evidence. One state has prohibited mandatory COVID-19 vaccination of school children,[11] and another state's Department of Health "issued a directive halting all child vaccination outreach efforts."[12]

In this environment, should the decision below stand, it is hardly far-fetched to envision state attorneys general, or other state actors, suing to demand scientifically questionable vaccine warnings that flunk FDA's rigorous standards. Overwarning has always been an issue in vaccine litigation. *See Dunn v. Lederle Laboratories*, 328 N.W.2d 576, 580-81 (Mich. App. 1983) (vaccine users' "susceptibility to danger" is individualized; "excessive warnings" lead to "sensory

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[11] Ala. Code §22-11B-5(c).

[12] Meghan Mangrum, "As Tennessee Halts Vaccine Outreach to Kids, Nashville Youth Still Get COVID-19 Shots," *Nashville Tennessean* (July 16, 2021).

overload" and "may be counterproductive") (citation omitted).

Even before the Court rejected presumptions against express preemption, it recognized preemption where it could not "imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005).

II. Presumptions Against Preemption In FDCA Express Preemption Cases Conflict With This Court's Preemption Precedent.

In *Puerto Rico v. Franklin*, 136 S.Ct. 1938, the Court flatly rejected any "presumption" where, as here, Congress expressly mandates preemption. Where a federal "statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption." *Id.* at 1946 (citation and quotation marks omitted). Instead, courts "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.* (citations and quotation marks omitted). The Court "has explained many times" that "people are entitled to rely on the law as written, without fearing that courts might disregard its plain terms based on some extratextual consideration." *Bostock*, 140 S.Ct. at 1749 (citations omitted).

> When the express terms of a statute give us one answer and extratextual considerations

> suggest another, it's no contest. Only the written word is the law.

Id. at 1737.

Even before abolishing presumptions against express preemption, the Court twice declined to apply such a presumption in prescription medical product cases. Like this case, *Riegel* involved the term "requirement," as used in a similar FDCA preemption clause for medical devices. 552 U.S. at 323-25.[13] Despite the dissent's criticism for not "accept[ing] the reading that disfavors preemption," *id.* at 335 (Ginsburg, J., dissenting) (citation and quotation marks omitted), *Riegel* gave "requirement" its ordinary meaning. *Id.* at 325 (refusing to "turn somersaults to create" a preemption limitation "not required or even suggested by the broad language Congress chose"). "[G]eneral tort duties" imposed preempted "requirements." *Id.* at 327-28.

The Mississippi court here did what *Riegel* would not – impose an extratextual limit on the "broad" term "requirement," as employed by Congress in an FDCA express preemption clause. It invoked the identical "accept the reading that disfavors pre-emption" presumption as the *Riegel* dissent.

Bruesewitz likewise eschewed any presumption against preemption in holding that the Vaccine Act expressly preempted state-law claims attacking vaccine

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[13] *See* 21 U.S.C. §360k(a)(1) (preempting state "requirements" that are "different from, or in addition to, any [FDA] requirement applicable . . . to the device").

design. The statutory preemption clause barred suits over "side effects that were unavoidable even though the vaccine was properly prepared" and carried "proper directions and warnings." 42 U.S.C. §300aa-22(b)(1). Despite Congress not explicitly mentioning "design," *Bruesewitz* held that "[i]f a manufacturer could be held liable for failure to use a different design, the word 'unavoidable' would do no work." 562 U.S. at 232.

Almost simultaneously, the same supposed obligation to "disfavor[] preemption," led the Georgia Supreme Court to a conclusion diametrically opposed to *Bruesewitz*. The Georgia court unanimously found no preemption – with the same presumption a central element. *See Ferrari v. Am. Home Prods. Corp.*, 668 S.E.2d 236, 242 (Ga. 2008), *vacated*, 710 S.E.2d 771 (Ga. 2011). "[R]esolv[ing] any ambiguity . . . against preemption," *Ferrari* wrongly concluded that the statute "does not preempt all design defect claims against vaccine manufacturers." *Id.*[14]

Riegel and *Bruesewitz* demonstrate how this presumption against preemption acts as an invitation to error and presaged such presumptions' outright abolition in *Puerto Rico v. Franklin*. Otherwise, vaccination – "one of the greatest achievements of public health in the 20th century," *Bruesewitz*, 562 U.S. at 226

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[14] *Ferrari* was decided while *Bruesewitz* was pending. This Court vacated and remanded *Ferrari* in light of *Bruesewitz*, *Am. Home Prods. Corp. v. Ferrari*, 562 U.S. 1254 (2011), and the Georgia court reversed its position, *Am. Home Prods. Corp. v. Ferrari*, 710 S.E.2d 771, 772 (Ga. 2011).

(quotation marks and footnote omitted) – could be attacked in innumerable lawsuits.

Granting *certiorari* will prevent perpetuation of an obsolete preemption standard that still frequently leads courts into serious error. "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments." *Riegel*, 552 U.S. at 324 (the term "requirement").

III. Presumptions Against Preemption Create Unavoidable Conflicts With Agency Decisions Having Force of Law.

Limiting preemptive agency actions to only those decisions reached by notice-and-comment rulemaking would be a recipe for chaos. Such rulemaking, which usually takes several years, is not normally how FDA or other agencies regulate product warnings.

Tampons are the only FDA-regulated product in the last forty years with labeling created by notice-and-comment rulemaking. *See* 21 C.F.R. §801.430(c-e) (specifying exact text of tampon labeling for toxic shock syndrome). The rule was proposed on October 21, 1980. 45 Fed. Reg. 69840 (FDA Oct. 21, 1980). It became effective on December 20, 1982. 47 Fed. Reg. 26982, 26990 (FDA June 22, 1982). Even in an extraordinary situation, creating a product warning through notice-and-comment rulemaking took more than two years. Ordinary FDA product-specific regulations simply incorporate general labeling requirements. *E.g.*, 21 C.F.R. §73.1550(d) (labeling for talc, used as a color

additive, "shall conform to the requirements of §70.25 of this chapter").

Since FDA regulates tens of thousands of products,[15] creation of individual product labeling through notice-and-comment rulemaking would be an impossibility.

Moreover, all of the Court's FDCA-related preemption cases since *Hillsborough Cty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707 (1985), address agency requirements created by means other than notice-and-comment rulemaking:

- *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), FDA medical device clearance;
- *Buckman Co. v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001), FDA medical device clearance;
- *Riegel*, 552 U.S. 312, FDA medical device premarket approval;
- *Wyeth v. Levine*, 555 U.S. 555 (2009), FDA-approved prescription drug label change;
- *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), FDA abbreviated generic drug approval;

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[15] *See* Fact Sheet: FDA at a Glance (listing approximate number of FDA-regulated products by category), available at https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited Sept. 23, 2021).

- *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013), FDA abbreviated generic drug approval;
- *Albrecht*, 139 S.Ct. 1668, FDA-approved prescription drug labeling.

This Court recently identified FDA's "formal[] rejecti[on of] a warning label," and any "other agency action carrying the force of law" as preempting state law. *Albrecht*, 139 S.Ct. at 1679 (citations omitted). If notice-and-comment rulemaking were essential to preemption, as the Mississippi court held, then all the above decisions would have reached the same result – no preemptive FDCA "requirement," and therefore, no preemption. However, the Court shuns anti-preemption arguments that would "render . . . pre-emption largely meaningless," *PLIVA*, 564 U.S. at 620, or "mean that . . . the vast majority – if not all" preemption precedent was "wrongly decided." *Mut. Pharm.*, 570 U.S. at 489. It should do so again, here.

Again, the ramifications of the Mississippi court's decision extend well beyond the FDCA. No notice-and-comment rulemaking occurred in *Bruesewitz*, 562 U.S. 223, only an individual vaccine compensation proceeding. *Id.* at 230-31. The governmental action found potentially preemptive in *Bates*, like here, was an agency's registration of an individual product label under generally applicable labeling regulations. 544 U.S. at 434-35, 440.

The Mississippi court's reasoning would also sink ongoing efforts to control the COVID-19 pandemic into

a swamp of state-law litigation. The PREP Act authorizes broad immunity from pandemic-related litigation. "[C]overed person[s]" are "immune from suit and liability under Federal and State law," for "all claims" involving "administration" or "use" of a "covered [pandemic] countermeasure." 42 U.S.C. §247d-6d(a)(1). PREP Act immunity is triggered by a formal "declaration" from the Secretary of Health & Human Services – not by notice-and-comment rulemaking. *Id.* §247d-6d(b)(1-6). Immunity is enforced by the Act's express preemption clause, which, as here, uses "requirement" to describe preemptive federal actions. *Id.* §247d-6d(b)(8)(A-B). In March 2020, the HHS secretary issued the statutorily authorized declaration, which has been broadened and extended multiple times.[16]

In Mississippi, without notice-and-comment rulemaking, the COVID-19 PREP Act declaration provides no immunity because it is not a preemptive federal "requirement[ ] applicable under this section." *Id.* §247d-6d(b)(8)(A). Unless the Petition is granted and that decision reversed, everyone combatting the COVID-19 pandemic – from vaccine manufacturers to hospital administrators faced with limited treatment resources – remains exposed to state-law litigation and liability, in direct contravention of manifest congressional intent.

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[16] *See* 85 Fed. Reg. 15198 (HHS March 17, 2020), *as amended*, 85 Fed. Reg. 21012 (April 15, 2020); 85 Fed. Reg. 35100 (June 5, 2020); 85 Fed. Reg. 52136 (Aug. 24, 2020); 85 Fed. Reg. 79190 (Dec. 9, 2020); 86 Fed. Reg. 7872 (Feb. 2, 2021); 86 Fed. Reg. 9516 (Feb. 16, 2021); 86 Fed. Reg. 14462 (March 16, 2021), 86 Fed. Reg. 41977 (Aug. 4, 2021); 86 Fed. Reg. 51160 (Sept. 14, 2021).

Thus, this case is of critical importance, not only to FDA's regulatory scheme, but to public health generally.

CONCLUSION

The Petition for a Writ of *Certiorari* should be granted.

Respectfully submitted,

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