No. 17-290

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

DORIS ALBRECHT, ET AL.,

Respondents.

On Petition For a Writ of Certiorari
To the United States Court of Appeals
For the Third Circuit

BRIEF OF AMICUS CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines. PhRMA members produce innovative medicines, treatments, and vaccines that save and improve the lives of countless individuals every day. PhRMA members have invested more than half a trillion dollars in R&D since 2000, and in 2016 alone invested $65.5 billion in discovering and developing new medicines. PhRMA, *Biopharmaceuticals in Perspective: Spring 2017*, at 35 (2017), http://phrma-docs.phrma.org/files/dmfile/Biopharmaceuticals-in-Perspective-2017.pdf [hereinafter *Biopharmaceuticals in Perspective*].

This case presents a question of critical importance for PhRMA's members: whether, after the Food and Drug Administration (FDA) rejects a company's proposed warning for a medicine, the company may nonetheless be held liable under state law for failing to provide the warning the FDA rejected. This question has arisen repeatedly in lawsuits brought

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[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no person other than *amicus*, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. A list of PhRMA members is available at http://www.phrma.org/about/members. Merck & Co. is a member of PhRMA, but did not contribute financially to the preparation of this brief. The parties were timely notified of *amicus*'s intent to file this brief and consented to its filing.

against PhRMA's members and has perplexed the lower courts. The Court should grant the Petition and establish clear, consistent, and fair preemption rules for FDA-rejected warnings.

INTRODUCTION AND SUMMARY OF ARGUMENT

The FDA brings extensive scientific expertise to bear in approving medically-appropriate labeling for prescription medicines both before and after they are brought to market. Congress granted the FDA this authority in recognition of its unique institutional ability to evaluate the scientific basis for proposed warnings and assess how best to communicate complex risk and benefit information about medicines. In recognition of that authority, this Court held in *Wyeth v. Levine*, 555 U.S. 555 (2009), that state-law tort claims are preempted when the FDA would have rejected the labeling that a plaintiff asserts was required by state law.

The Third Circuit's decision undermines the FDA's authority to control the content of medicine labeling and at the same time places manufacturers in the impossible position of facing civil liability for not adopting warnings that the FDA prohibited them from adopting. In this case, after considering the available scientific evidence, the FDA rejected Merck's proposal to include a warning for the precise risk Plaintiffs subsequently claimed should have been included in the label. The FDA's decision was not based on some narrow objection to the specific language of Merck's proposal. To the contrary, the FDA's rejection was accompanied by no counter-proposal, notwithstanding the agency's statutory obligation to

work collaboratively with manufacturers to develop warnings for safety issues that the agency believes should be reflected in labeling.

Yet the Third Circuit reversed the district court's determination that these facts warrant preemption of Plaintiffs' state-law claims, holding that preemption is a factual determination reserved for jury resolution absent a "'smoking gun' rejection letter" laying out the FDA's rationale for rejecting the warnings sought. Pet. App. 55. That standard is untenable. The Third Circuit's unrealistic preemption standard will expose manufacturers to immense liability that will hamper innovation and endanger public health. In addition, the Third Circuit's standard will incentivize manufacturers to inundate the FDA with linguistic variants of labeling requests in the hope that multiple rejections will be sufficient to trigger preemption.

As numerous courts have indicated, and as the decision below reflects, lower courts have struggled to apply Levine's "clear evidence" standard. The Court should grant the Petition to provide much-needed guidance.

ARGUMENT

I. The Court Should Address An Important and Recurring Issue that Lower Courts Have Struggled to Resolve

In *Levine*, the Court held that Wyeth had presented no "clear evidence" that the FDA would not have approved a change to Phenergan's label. 555 U.S. at 571. In that case, moreover, the Court emphasized that FDA had never given "more than passing

attention" to the instruction plaintiffs sought. *Id.* at 572. Lacking guidance from this Court about the type and quantum of evidence that suffices to demonstrate the FDA "intended to prohibit [the manufacturer] from strengthening the warning," *Levine*, 555 U.S. at 572, lower courts have struggled to faithfully apply *Levine*'s holding. *See, e.g.*, Pet. App. 29 ("This [clear evidence] standard is cryptic and open-ended, and lower courts have struggled to make it readily administrable."); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 391 (7th Cir. 2010) ("The Supreme Court . . . did not clarify what constitutes 'clear evidence.' Therefore, the only thing we know for sure is that the evidence presented in *Levine* did not meet this exacting standard.").

That difficulty is confirmed by inconsistencies in *Levine*'s application. *Compare, e.g.*, *Mason*, 596 F.3d at 396 (finding the record did not show "clear evidence" FDA would have rejected an enhanced suicidality warning for an SSRI), *with Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1277-80 (W.D. Okla. 2011) (finding "clear evidence" FDA would have rejected an enhanced suicidality warning for an SSRI and distinguishing SSRI cases with different outcomes); *also compare Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010) (finding "clear evidence" the FDA would have rejected a children's Motrin label warning for SJS/TEN where FDA did not require mention of SJS/TEN on the label), *with Reckis v. Johnson & Johnson*, 471 Mass. 272 (2015), *cert. denied*, 136 S. Ct. 896 (2016) (finding the record did not show "clear evidence" under facts similar to *Robinson*).

In the eight years since this Court decided *Levine*, the issue of preemption and the meaning of "clear evidence" has arisen in over 100 decisions available on Westlaw from trial and appellate courts around the country, and the issue of preemption figures prominently in every one of the tens of thousands of pharmaceutical product liability lawsuits nationwide. Absent further guidance, lower courts will continue to struggle with *Levine*'s application. This case presents an excellent opportunity for the Court to refine *Levine*'s "clear evidence" standard in the context of a detailed regulatory record.

II. The Third Circuit's Decision Disregards the Realities of FDA Labeling Review, Thereby Threatening Its Effectiveness

The Third Circuit's decision gives insufficient deference to the FDA's extensive labeling oversight. It also creates conditions under which the FDA's review capabilities will be strained, thus weakening FDA's ability to protect public health.

A. The Comprehensive FDA Regulatory Regime Ensures that Labeling Contains a Summary of the Essential, Scientifically-Grounded Safety Information

Effective pharmaceutical labeling strikes a delicate balance. Labeling must convey a wealth of information necessary for the safe and effective use of a medicine. At the same time, this information must be communicated in a manner that is useful to healthcare professionals. One way in which labeling

achieves this balance is by providing information only when it is scientifically-based.

Striking this balance is critically important because patients may be harmed when labeling communicates unfounded safety information. First, physicians may disregard lengthy labeling weighted down with speculative warnings, thereby overlooking important, scientifically-founded safety information. *See, e.g.*, *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) ("The resulting information overload [from describing every remote risk] would make label warnings worthless to consumers."); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 816 n.40 (5th Cir. 1992) (explaining that if manufacturers were required to clutter their warnings with "every possible risk," then "physicians [would] begin to ignore or discount the warnings"); FDA, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605–06 (Aug. 22, 2008) (final rule) (unfounded statements in FDA labeling may cause "more important warnings" to be "overshadow[ed]").

Second, warnings that are not grounded in science discourage the beneficial use of medicines. *See, e.g.*, *Mason*, 596 F.3d at 392 (7th Cir. 2010) ("[O]verwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted . . . ."); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 14 (Cal. 2004) ("[A] truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently

making a medically unwise decision."); 73 Fed. Reg. at 49,605–06 ("[O]verwarning . . . may deter appropriate use of medical products . . . ."). All medicines have risks, and all prescribing decisions are based on balancing those risks against the medicine's potential benefits. Distorting the true nature of that balance, by overstating unfounded or speculative risks, fundamentally inhibits medical professionals from making the most appropriate and medically-optimal prescribing decisions.

In order to ensure that "the public get[s] the accurate, science-based information they need," the FDA tightly regulates the labeling for all prescription medicines. *Statement of FDA Mission*, FDA, http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf. FDA regulations provide detailed labeling requirements, dictating required categories, precise information each category should include, and, in many cases, exact formatting standards. *See* 21 C.F.R. §§ 201.56-57, 201.66, 201.80. As relevant here, medicine labeling must warn about any serious hazard for which there is "reasonable evidence of a causal association." 21 C.F.R. § 201.57(c)(6).

The FDA must approve labeling before a medicine can be marketed, and it continues to scrutinize labeling thereafter. Before a manufacturer can amend its labeling, it generally must obtain the FDA's approval through the submission of a "prior approval supplement" ("PAS") to its New Drug Application. *See* 21 C.F.R. § 314.70(b)(2)(v). Manufacturers can, in some circumstances, add or strengthen a warning to reflect "newly acquired information." *See id.*

§ 314.70(c)(6)(iii). Even then, however, a manufacturer cannot distribute the new labeling until it submits a "changes being effected" ("CBE") supplement to the FDA. *See id.* § 314.70(c)(3)–(6). Unless the FDA finds that "the evidence of a causal association satisfies the standard for inclusion in the labeling," *id.* § 314.70(c)(6)(iii)(A), it must retroactively reject the change and require the manufacturer to stop distributing products with the new labeling, *see id.* § 314.70(c)(6)–(7); 73 Fed. Reg. at 49,603 ("[A] CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug . . . .").

In addition to reviewing changes that manufacturers propose, the FDA independently considers whether labeling remains adequate in light of FDA's continuous monitoring of adverse event reports and other research.[2] Once it "becomes aware of new safety information" that it "believes should be included in the labeling," the FDA must notify the manufacturer, which must either propose a change or explain why no change is warranted. *See* 21 U.S.C. § 355(o)(4)(A).[3] If

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[2] Manufacturers are required to report "serious and unexpected" adverse events to the FDA within 15 days of receipt and to periodically report all other adverse events. 21 C.F.R. § 314.80. The FDA also receives adverse event reports through a voluntary reporting system, MedWatch. *MedWatch: The FDA Safety Information and Adverse Event Reporting Program*, FDA, https://www.fda.gov/Safety/MedWatch/default.htm.

[3] Section 355(o)(4) was passed as part of the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No.

the FDA disagrees with the manufacturer's response, it is required to "initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes." *Id.* § 355(o)(4)(C).

In short, the FDA brings to bear on all pharmaceutical labeling its expert judgment about whether a risk should appear in a medicine's label and, if so, how best to convey that information, all without diluting the labeling with warnings unfounded by the scientific record.

B. The Third Circuit's Preemption Rule Incentivizes Manufacturers to Overwhelm the FDA's Review Capabilities

As interpreted by the Third Circuit, "clear evidence" requires a "'smoking gun' rejection letter." Pet. App. 55. That requirement mistakes the nature of FDA review by assuming that review is limited to the precise verbiage submitted. Under the FDAAA, the

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110–85, 121 Stat. 823. Even before the FDAAA expressly delegated this responsibility, the FDA possessed considerable practical ability to generate labeling changes through its ability to (1) withdraw approval of a medicine whose labeling was "false or misleading in any particular," 21 U.S.C. § 355(e), and (2) bring an enforcement action against the manufacturer for misbranding, *see id.* § 352(a). The FDAAA was passed after the occurrence of the events in *Levine,* and thus the Court did not have occasion to consider the import of the FDAAA on the preemption analysis. *See Levine*, 555 U.S. at 567 ("In 2007, *after Levine's injury and lawsuit*, Congress again amended the FDCA." (emphasis added)).

FDA cannot let linguistic disagreements stand in the way of medically-warranted warnings. If the FDA believes that a new risk should be included in a medicine's labeling, but "disagrees with the [manufacturer's] proposed changes," it "shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, *and if so, the contents of such labeling changes*." 21 U.S.C. § 355(o)(4)(C) (emphasis added).

The FDA's outright rejection of Merck's labeling supplement without initiating a discussion about any particular wording provides dispositive confirmation that FDA did not believe any additional warning was appropriate at that juncture. Otherwise, the FDA would have been in direct violation of its statutory obligations. No rational preemption framework should presume such a dereliction of agency duty. Nor does it make sense to apply such a backwards presumption unless the agency has written a comprehensive "smoking gun" exposition of all the reasons why no change was scientifically warranted. But that is precisely the result reached by the Third Circuit. *Levine* does not impose such an upside-down outcome.

In this case, the evidence is clear that the FDA would have rejected *any* warning for atypical femoral fractures in 2009. After reviewing the evidence Merck submitted in support of its labeling change, the FDA instructed Merck to "hold off" on adding a warning while a task force considered whether any warning was "warranted." Pet. App. 17–18. Only after receiving the task force's recommendation did the FDA

conclude that atypical femoral fractures were "'potentially more closely related to'" Fosamax use than it had previously appreciated. Pet. App. 21.

The Third Circuit's contrary holding will also have the effect of impairing the FDA's ability to carry out its mission. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that state law "fraud-on-the-FDA" claims are preempted, reasoning that such claims incentivize manufacturers "to submit a deluge of information that the [FDA] neither wants nor needs" out of "fear that their disclosures . . . will later be judged insufficient in state court," thereby creating "additional burdens on the FDA[]." *Id.* at 351. The Third Circuit's preemption standard creates the same incentives that *Buckman* found impermissible.

As this case demonstrates, the FDA rarely takes the time to memorialize the full scientific rationale for its labeling decisions, especially in the post-approval setting where it is constantly assessing a developing scientific record. Powerless to generate the evidence the Third Circuit's ruling demands through their own actions, manufacturers will have an incentive to seek other ways to generate proof that the FDA believed a warning to be scientifically unfounded. For instance, pharmaceutical manufacturers may submit variations of the same warning, as the FDA's rejection of multiple iterations of a warning provides strong evidence that the FDA's rejection stemmed from a disagreement over the necessity of a warning rather than the specific language proposed.

Diverting the attention of the FDA toward litigation-defensive submissions would place an

excessive burden on the agency, and so would be an exercise fraught with peril. *See* 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA reviews all [CBE] submissions . . . ."); *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012) (when manufacturers are compelled "to flood the FDA with information" to protect against liability, the FDA "loses control over its ability, based on scientific expertise, to prescribe — and intelligently limit — the scope of disclosures necessary for its work"); Br. for the United States as Amicus Curiae Supporting Pet'r at 25, *Levine*, 555 U.S. 555 (2009) (No. 06-1249) ("[The FDA] could not reasonably be expected to *expressly* reject every possible variant of approved labeling as part of its decisional process. Indeed, it would underestimate the post hoc imagination of lawyers to think such an exhaustion of potential variants by the manufacturer or the agency is even possible."). *Levine* could not have intended such an illogical result.

III. The Third Circuit's Decision Will Disincentivize Innovation and Harm Public Health

Bringing a new medicine to market is a lengthy and expensive process. Before studying a new medicine in humans, a pharmaceutical company must conduct a broad range of laboratory and animal studies to test how the medicine works and assess its safety. 21 C.F.R. § 312.23(a)(8). If the results are promising, the company submits an Investigational New Drug application ("IND") to the FDA, outlining the preclinical study results and offering a plan for clinical trials in humans. 21 U.S.C. § 355(i)(2); 21 C.F.R. § 312.20(a)–(b). Only upon FDA approval of

the IND can a company begin to study the prospective medicine in humans. Those human clinical trials generally occur in three phases, each of which typically must be completed before the potential new medicine may undergo FDA review and approval. 21 C.F.R. § 312.21. On average, the clinical trial phase alone takes six to seven years to complete. PhRMA, *Modernizing Drug Discovery, Development and Approval* 1 (2016), http://phrmadocs.phrma.org/sites/default/ files/pdf/proactive-policy-drug-discovery.pdf. If clinical trial results show that the medicine's benefits outweigh its risks, the sponsoring company can seek the FDA's approval to market the medicine by submitting a New Drug Application ("NDA"). 21 U.S.C. § 355(b)(1). The NDA, which must contain, among other things, the results of the clinical and preclinical testing, proposals for manufacturing, and proposed labeling for the new medicine, *id.*, often exceeds 100,000 pages in length, PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines* 14 (2015), http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

Innovative companies undertake this process at tremendous expense. On average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion. *Biopharmaceuticals in Perspective, supra*, at 29; *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health

Econ. 20 (2016).[4] PhRMA's member companies invest approximately one quarter of their total annual domestic sales on research and development — an estimated $65.6 billion in 2016. *Biopharmaceuticals in Perspective*, *supra*, at 35.

These research efforts also involve tremendous risk, as most compounds invented never attain FDA approval. Just one out of every 5,000 to 10,000 compounds under development, and just one out of every eight medicines entering clinical trials, obtains FDA approval. Press Release, PhRMA, PhRMA Statement Regarding Benefits of New Medicines (Apr. 30, 2013), http://www.phrma.org/press-release/phrma-statement-regarding-benefits-of-new-medicines; *Biopharmaceuticals in Perspective*, *supra*, at 29; *see also, e.g.*, Jared S. Hopkins & Michelle Cortez, *Lilly's Alzheimer's Disease Drug Fails in Final-Stage Trial*, Bloomberg (Nov. 23, 2016, 6:52 AM), https://www.bloomberg.com/news/articles/2016-11-23/lilly-s-alzheimer-s-disease-drug-fails-in-final-

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[4] These estimates understate the cost of approval, as the FDA frequently conditions approval on a requirement that a sponsor undertake additional clinical studies after approval. *See* 21 U.S.C. § 355(o)(3)(A). According to one estimate, more than three quarters of all new medicine approvals are accompanied by a commitment from the sponsor to conduct one or more post-marketing, or "Phase IV," studies. Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 Food & Drug L.J. 295, 300 (2006). PhRMA's member companies spend more than $8.8 billion annually conducting these studies. PhRMA, *Annual Membership Survey* 6 tbl.4 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/annual-membership-survey-results.pdf.

stage-trial (discussing an innovator's $3 billion investment in an Alzheimer's treatment medication that failed at the final stage of clinical testing).

Given the enormous costs associated with researching and developing a new medicine, the scope of litigation risk bears heavily on a company's decision to invest in innovation. *See* W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1419 (1994) ("[T]he net effect of the surge in liability costs ha[s] been to discourage innovation in the pharmaceutical industry."); Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 Cardozo L. Rev. 1139, 1153 (1987) ("If in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made."). The scope of litigation against pharmaceutical companies is already immense and rapidly expanding. Last year, 21,517 product liability lawsuits were filed against pharmaceutical companies in federal courts alone, up from 6,791 lawsuits just five years ago and just 2,700 lawsuits in 2001.[5] Today, out of seventy-three pending product liability multidistrict litigation proceedings, twenty-eight involve pharmaceuticals.[6] By comparison, between 1960 and

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[5] *See* Admin. Office of the U.S. Courts, Table C-2A: *U.S. District Courts--Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2012 Through 2016*, http://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf; Lisa Girion, *State Vioxx Trial Is Set as Drug Suits Boom*, L.A. Times, June 27, 2006, at C1.

[6] *See* U.S. Judicial Panel on Multidistrict Litig., MDL Statistics Report - Distribution of Pending MDL Dockets by District (Aug.

1999, there were only five MDL product liability actions involving FDA-approved medicines.[7]

The anti-nausea drug Bendectin, used to treat severe morning sickness in pregnant women, illustrates how unpredictable and unfounded litigation risks heavily influence a company's decision to invest in innovation. After Bendectin was named as the cause of birth defects in thousands of lawsuits, its manufacturer withdrew the medicine from the market in 1983, only later to be vindicated by scientific studies showing that Bendectin posed no maternal fetal risk.[8] In 2013, after nearly thirty years off the market, Bendectin returned under a new name.[9] In the interim, however, hospital admissions for excessive vomiting during pregnancy had doubled, costing the

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15, 2017), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2017.pdf.

[7] *See* Deborah R. Hensler, *Has the Fat Lady Sung? The Future of Mass Toxic Torts*, 26 Rev. Litig. 883, 897–902 tbl.1 (2007).

[8] *See* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 Stan. L. Rev. 1, 7 (1993); Robert Brent, *Medical, Social, and Legal Implications of Treating Nausea and Vomiting of Pregnancy*, 186 Am. J. Obstetrics & Gynecology S262, S262–63 (2002); *see also* David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 460 (1999); Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 371, 392 (2002).

[9] *See* News Release, Food & Drug Admin., *FDA Approves Diclegis for Pregnant Women Experiencing Nausea and Vomiting* (Apr. 8, 2013).

U.S. economy $1.7 billion annually in time lost from work, caregiver time, and hospital expenses.[10]

The development of medicines for high-risk and vulnerable populations is especially susceptible to this phenomenon. It is thus no surprise that by 1990, eight of the nine major U.S. pharmaceutical companies that had been involved in researching and developing new contraceptives had abandoned their efforts.[11] According to a contemporaneous report from the National Research Council and the Institute of Medicine, "recent products liability litigation and the impact of that litigation on the cost and availability of liability insurance have contributed significantly to the climate of disincentives for the development of contraceptive products." *Id.* at 141. In 1989, the inventor of the birth control pill, Carl Djerassi, recommended changes to the product liability regime, commenting that "the United States is the only country other than Iran in which the birth-control clock has been set backward during the past decade."[12] The

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[10] *See* Nina Nuangchamnong & Jennifer Niebyl, *Doxylamine Succinate–Pyridoxine Hydrochloride (Diclegis) for the Management of Nausea and Vomiting in Pregnancy: An Overview*, 6 Int'l J. Women's Health 401, 401–02 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3990370/pdf/ijwh-6-401.pdf.

[11] Nat'l Research Council, Comm. on Contraceptive Dev., & Inst. of Med., Div. of Int'l Health, *Developing New Contraceptives: Obstacles and Opportunities* 59 (Luidi Mastroianni et al. eds., 1990), https:// www.nap.edu/read/1450.

[12] Carl Djerassi, *The Future of Birth Control*, Wash. Post (Sept. 10, 1989), https://www.washingtonpost.com/archive/opinions/1989/09/10/the-future-of-birth-control/7e25f2cc-ae35-4a79-8daf31db02f81be/31db02f81be/?utm_term=.dd4d8bbcf626.

executive director of the Society for the Advancement of Women's Health Research similarly testified before Congress that "the current liability climate is preventing women from receiving the full benefits that science and medicine can provide." S. Rep. No. 104-69, at 7 (1995).

To be sure, the Court in *Levine* accepted the notion that diminished incentives for research and production of medicines might be offset by the possibility of uncovering "unknown drug hazards" and "incentives for drug manufacturers to disclose safety risks promptly." 555 U.S. at 579. But where the manufacturer promptly brings the potential safety risks to the FDA and the agency disagrees about the necessity of a warning, subsequent civil litigation serves no such purpose and works only to undermine the FDA's supremacy over the labeling process under the FDAAA. *See Levine,* 555 U.S. at 582 ("But it is also possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions.") (Breyer, J., concurring); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (whereas "the experts at the FDA" apply a "cost-benefit analysis," a jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court"); 150 Cong. Rec. S8657-01 (daily ed. July 22, 2004) (statement of former FDA Chief Counsels) ("If every state judge and jury could fashion their own labeling requirements for drugs and medical devices, . . . FDA's ability to advance the public health by allocating

scarce space in product labeling to the most important information would be seriously eroded.").

CONCLUSION

The petition for a writ of certiorari should be granted.

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