No. 17-1337

In the
Supreme Court of the United States

ALCON LABORATORIES, INC., ET AL.,

PETITIONERS,

v.

LEONARD COTTRELL, ET AL.,

RESPONDENTS.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Third Circuit

BRIEF OF AMERICAN TORT REFORM ASSOCIATION, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NATIONAL ASSOCIATION OF MANUFACTURERS, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

PETER TOLSDORF
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th St. NW, Suite 700
Washington, D.C. 20001
(202) 637-3000

Counsel for National Association of Manufacturers

JEFFREY S. BUCHOLTZ
Counsel of Record
PAUL ALESSIO MEZZINA
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, D.C. 20006
(202) 737-0500
jbucholtz@kslaw.com

Counsel for Amici Curiae*

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* Additional counsel on inside cover

SHERMAN JOYCE
LAUREN SHEETS JARRELL
AMERICAN TORT REFORM ASSOCIATION
1101 Connecticut Ave. NW
Suite 400
Washington, D.C. 20036
(202) 682-1168

Counsel for American Tort Reform Association

WARREN POSTMAN
JANET GALERIA
U.S. CHAMBER LITIGATION
CENTER, INC.
1615 H Street NW
Washington, D.C. 20062
(202) 463-5685

Counsel for Chamber of Commerce
of the United States of America

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH
& MANUFACTURERS OF AMERICA
950 F Street NW
Washington, D.C. 20004
(202) 835-3400

Counsel for Pharmaceutical Research
& Manufacturers of America

QUESTION PRESENTED

Whether, for purposes of standing under Article III, a plaintiff's speculation that he might have paid less for treatment if a pharmaceutical product were packaged differently is sufficient to establish an economic injury in fact.

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INTEREST OF *AMICI CURIAE*[1]

Founded in 1986, the American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus* briefs in cases that have addressed important liability issues.

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million businesses of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases raising issues of concern to the nation's business community.

The National Association of Manufacturers ("NAM") is the nation's largest manufacturing association, representing small and large manufacturers in every industrial sector and in all 50 states. Manu-

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[1] All parties' counsel received timely notice of the intent to file this brief. The parties have given blanket consent to the filing of *amicus* briefs. No counsel for a party authored this brief in whole or in part, and nobody other than *amici*, their members, and their counsel made a monetary contribution to fund the preparation or submission of the brief.

facturing employs over 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines that help patients lead longer, healthier, and more productive lives. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as *amicus* in cases raising matters of significance to its members.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court rarely encounters such a clear circuit split. Two courts of appeals, addressing materially identical class-action claims brought by the same lawyers about the same pharmaceutical products, reached opposite conclusions as to Article III standing. The plaintiffs in both cases received what they were promised: effective, FDA-approved prescription ophthalmic medications. The Seventh Circuit rightly rejected the plaintiffs' speculative theory that they might have paid less for those medications if petitioners had packaged them differently—a claim that is not supported by concrete factual allegations and that runs contrary to basic economic logic, not to mention decades of precedent from this Court and the courts of appeals.

Two judges of the Third Circuit, however, held—over vigorous dissents from both the panel decision and the denial of rehearing en banc—that respondents had standing because they alleged that petitioners "*could have* manufactured a more efficient product, which in turn *could have* lowered [respondents'] overall treatment costs." Pet. App. 36a (Roth, J., dissenting). As a result, petitioners face further litigation and the prospect of potentially having to redesign their FDA-approved prescription drug products to satisfy the demands of respondents' counsel—even though seven of the ten appellate judges to consider the issue have concluded that petitioners' challenged conduct has not injured respondents at all.

Resolving this split and correcting the Third Circuit's egregious error has importance well beyond

this case. The decision below departs from bedrock principles of Article III standing. It has the potential to trigger a new wave of abusive, no-injury class-action litigation, with devastating effects on businesses and consumers. It will encourage plaintiffs' lawyers to bring large class actions challenging the design not only of pharmaceutical products, but of any other product or business practice that could be portrayed as inefficient, based on conjecture that greater efficiency might have translated into savings for customers. No one but the lawyers would benefit from such suits—not the businesses that would pay millions in litigation and nuisance settlement costs; not the employees, investors, and consumers who would ultimately bear those costs; and certainly not the patients who take the medications at issue and who could be denied those critical medications if respondents' theory were accepted.

The Court should grant the petition and reverse the decision below.

REASONS FOR GRANTING THE PETITION

I. The Third Circuit's novel theory of injury-by-inefficiency departs from fundamental principles of Article III standing.

"[N]o principle is more fundamental to the judiciary's proper role in our system of government" than the requirement that a plaintiff demonstrate standing under Article III of the Constitution to sue in federal court. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quotation marks omitted). When courts entertain lawsuits brought by plaintiffs who have not been injured by the defendants' putatively unlawful

conduct, they overstep their "proper—and properly limited—role . . . in a democratic society." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006) (quotation marks omitted).

This is such a lawsuit. Respondents did not adequately plead that they were injured as a result of petitioners' failure to adopt (and seek FDA approval for) a supposedly more efficient product design. Even if respondents were right that petitioners' products could have been designed to dispense smaller drops, "[t]he fact that a seller does not sell the product that you want, or at the price you'd like to pay, is not an actionable injury; it is just a regret or disappointment." *Eike v. Allergan, Inc.*, 850 F.3d 315, 318 (7th Cir. 2017); *see also* Pet. App. 36a (Roth, J., dissenting) (respondents cannot "manufacture" standing by asserting "that the defendants *could have* manufactured a more efficient product, which in turn *could have* lowered plaintiffs' overall treatment costs"); *id.* at 3a (Smith, C.J., dissenting from denial of rehearing en banc) (while respondents "would prefer that the eye drops prescribed for them be sold in a different type of packaging," their "unfulfilled preferences do not constitute an 'injury'" under Article III).

While respondents insist that they have standing because they are seeking reimbursement for money spent, "[m]erely asking for money does not establish an injury in fact." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319–20 (5th Cir. 2002). In *Rivera*, the court found no Article III standing where the plaintiff had "paid for an effective pain killer, and she received just that—the benefit of her bargain." *Id.* at 320.

Here, too, respondents got what they paid for—FDA-approved medications that worked as promised.

Respondents do not assert *any* traditional theory of injury. For instance, they do not claim that the medications they purchased were ineffective or failed to work as intended, nor that they suffered any physical or emotional harm from using the medications. They do not claim that they were misled into purchasing products they would not otherwise have purchased or into paying more for those products than they otherwise would have paid. Nor do they claim that petitioners acted in concert to prevent any seller from marketing a competing product with a smaller drop size. Instead, respondents rely on a novel theory of standing: that they might have saved money if petitioners had redesigned their products to be more efficient. They contend that their injury is the money they spent on medication that petitioners "forced them to waste," Pet. App. 11a, by not using respondents' alternative, supposedly more efficient product design. The Court should grant certiorari and reject this theory of injury-by-inefficiency.

Respondents' claim that an alternative product design would have saved them money is inherently speculative. Worse, it requires illogical and implausible speculation. It is far more likely that petitioners would have priced their pharmaceutical products based on how many therapeutic doses (not how many milliliters of fluid) they contained, so that improvements in the products' efficiency would not have saved respondents any money. *See* Pet. 18. Petitioners are businesses operating in a market where prices reflect supply and demand—and patients demand

treatment, not fluid volume. *See* Pet. App. 43a–44a (Roth, J., dissenting). By analogy, if a pharmaceutical manufacturer discovered a way to make its pain-relieving pills equally effective with half as much ibuprofen powder, that might or might not make the pills less costly to manufacture when the cost of developing the more-efficient design and obtaining FDA approval for it is taken into account. But it certainly would not reduce demand for them—because consumers demand pain relief, not powder. The packaging changes urged by respondents likewise would not have reduced demand for petitioners' products in any meaningful sense. Patients would still have demanded the same number of therapeutic doses, and petitioners would thus have been able to charge the same price per dose—even assuming that petitioners did not need to charge a *higher* price per dose to recoup the costs of developing the more-efficient design and obtaining FDA approval for it.

While respondents' theory would be impermissibly speculative in any market, it is a "particularly bad fit" for the pharmaceutical market. *Id.* at 42a. The overwhelming majority of the cost of delivering most FDA-approved medications lies not in the cost of manufacturing the liquid in the bottle, but in the research, clinical trials, regulatory approvals, and numerous other costs associated with getting the medication to market. *See, e.g.*, *In re Brand Name Prescription Drugs Antitrust Litig.*, 288 F.3d 1028, 1030 (7th Cir. 2002) ("Many of the costs of a new drug are incurred before manufacturing for sale begins—costs of research, of development, of obtaining patents, of obtaining FDA approval, and so forth."); Joseph A. DiMasi *et al.*, *Innovation in the Pharma-*

ceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 31 (2016) (estimating that it costs, on average, more than $2.5 billion to develop and obtain marketing approval for a new drug). So it is baseless conjecture to suppose, as respondents do, that any marginal reduction in the cost of manufacturing a pharmaceutical product will lower the per-dose price paid by consumers.

Respondents nonetheless persuaded two-thirds of the panel below to "assume"—contrary to common sense, basic economic logic, and the Seventh Circuit's holding on materially identical facts—"that a Defendant would not charge more for a bottle capable of delivering more doses." Pet. App. 7a (Smith, C.J., dissenting from denial of rehearing en banc). That result cannot be squared with fundamental, longstanding principles of Article III standing. As numerous courts have held, a plaintiff's standing cannot be based on speculative (and, in this case, highly dubious) assumptions about prices and behaviors in a hypothetical marketplace. *See, e.g.*, *Katz v. Pershing, LLC*, 672 F.3d 64, 77 (1st Cir. 2012) (no standing based on plaintiff's "bare hypothesis" that brokerage company "might push [one] aspect of its operational costs onto her"); *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012) (no standing based on "speculation . . . that United would continue to offer discounted tickets if it could no longer price discriminate"); *cf. Cuno*, 547 U.S. at 344 (no standing where establishing injury and redressability required "speculating" about "how legislators [would] respond to a reduction in revenue").

It would eviscerate Article III's limitations on federal jurisdiction if respondents could overcome the fact that their claim of standing is conjectural by pointing to a handful of "articles and studies" that "state in passing and conclusory terms that smaller drop volume would likely produce lower costs." Pet. App. 55a, 57a. The authors of those articles were not economists, did not claim any expertise in drug pricing, and did not explain their offhand suggestions that smaller drops might save patients money. That they appear to have made the same assumption as respondents does not make that assumption any more valid as a basis for standing. *Cf. Gerlinger v. Amazon.com Inc.*, 526 F.3d 1253, 1255–56 (9th Cir. 2008) (affirming dismissal for lack of standing where plaintiff relied on "academic articles" that "did not establish that [he] personally paid a higher price for a book" as a result of the challenged conduct).

This Court has rejected a similar attempt to have third parties bolster a speculative claim of standing. In *DaimlerChrysler v. Cuno*, certain *amici* asserted that it was "well-documented" that the challenged corporate tax breaks had raised the plaintiffs' taxes and interfered with their receipt of public services. *Amicus* Br. of Fiscal Policy Institute, *et al.* Supporting Respondents, *DaimlerChrysler Corp. v. Cuno*, No. 04-1704, 2006 WL 189947, at *8 (U.S. Jan. 23, 2006). The *amici*'s confident pronouncement notwithstanding, the Court had no difficulty concluding that the plaintiffs' claim of standing rested on "pure speculation." 547 U.S. at 344.

Respondents fail Article III's traceability requirement as well as its injury-in-fact requirement.

Even if it had been appropriate for the Third Circuit to assume that petitioners would have charged the same price for a bottle containing more doses, respondents still would not have standing, because it is undisputed that petitioners had discretion to price their drugs on a per-dose basis (or on another basis) and were not obligated to price them on a per-milliliter basis. While respondents claim that state law required petitioners to redesign their products, they do not claim that petitioners would have been *compelled* (by law or market forces) to price those redesigned products in a way that would have saved respondents money—only that petitioners *might* have done so in their discretion. So any additional cost that respondents paid for petitioners' actual products, as compared to what they might have paid for hypothetical, more-efficient products, was "fairly traceable" not to "the conduct being challenged," *Wittman v. Personhuballah*, 136 S. Ct. 1732, 1736 (2016), but to petitioners' lawful and separate price-setting decisions.

This case therefore does not implicate decisions affording standing to consumers who plausibly allege that a defendant business could not have charged them the same price if it had complied with the law. *See, e.g.*, *In re Aqua Dots Prods. Liab. Litig.*, 654 F.3d 748, 750–51 (7th Cir. 2011) (plaintiffs had standing because "they paid more for the toys than they would have, had they known of the risks"); *Doyle v. Chrysler Grp., LLC*, 663 F. App'x 576, 578 (9th Cir. 2016) (plaintiffs had standing because defendant "would not have been able to charge as much for the product" had it disclosed a safety defect).

Unlike the plaintiffs in those cases, respondents cannot plausibly claim that petitioners would have *had* to charge a lower per-dose price if they had designed their medications to use a smaller drop, only that they might have *chosen* to do so. But they cannot base their standing on the possibility that petitioners might have made a completely discretionary choice that would have saved respondents money. Consider, by analogy, the challenge that low-income Medicare patients brought to a statute limiting what physicians could charge high-income patients. The plaintiffs claimed that the statute caused physicians to raise their rates for low-income patients. The Second Circuit held that they lacked standing because "[a]ny increases in the amounts charged . . . would be the product of independent choices by physicians" rather than "a necessary product of the challenged legislative scheme." *Garelick v. Sullivan*, 987 F.2d 913, 919–20 (2d Cir. 1993).

So too here. Any savings respondents would have realized in their hypothetical world would have resulted from petitioners' "independent choices" about how to price their products and would not have been a "necessary product" of the design changes respondents claim the law required. *Id.*; *see also, e.g.*, *DH2, Inc. v. SEC*, 422 F.3d 591, 597 (7th Cir. 2005) (plaintiff lacked standing to challenge rules requiring "fair value pricing" for certain securities where mutual funds would have had "discretion to use fair value pricing" regardless).

II. Left undisturbed, the decision below will invite abusive consumer class-action litigation.

Acceptance of respondents' novel theory of standing to challenge allegedly inefficient product design will open up a wide new frontier for abusive, "no-injury" consumer class actions. *Rivera*, 283 F.3d at 320. And if that theory were accepted as a basis for demanding that manufacturers redesign even FDA-approved pharmaceutical products (like those at issue here) that are subject to strict federal regulation, the effect would be even more pronounced. That would hurt everyone but the lawyers.

It is no secret that class actions are a "powerful tool [that] can give a class attorney unbounded leverage." S. Rep. No. 109-14, at 21 (2005) (Class Action Fairness Act). One of the most important limitations on that tool is the need to show that the class members suffered a common injury. Courts are not supposed to certify large classes of consumers claiming to have suffered physical or emotional injuries, because such injuries generally require individualized proof. As a result, enterprising class-action lawyers are always on the lookout for expansive theories of injury that can be applied to thousands of consumers at once and that make it possible to bypass the need to prove that each class member was truly injured.

The novel standing theory the Third Circuit adopted in this case would provide countless opportunities for adventurous consumer class actions. As petitioners point out, there are numerous everyday products, from toothpaste to hairspray to peanut butter, that could be said to involve "forced" wastage.

See Pet. 21–22. It would only take a creative lawyer to argue that those products should be packaged more efficiently and that the failure to do so "injures" consumers.

Consider, for example, the recent invention of non-stick bottles for ketchup and mustard so that less of the condiment goes to waste. *See, e.g.*, Nick McDermott, *No More Whacking the Ketchup Bottle: Scientists Develop Non-Stick Coating To Help the Sauce Slide Out*, Daily Mail, July 5, 2013, https://goo.gl/WYxUzt (claiming that each year "one million tonnes of condiments are thrown away globally because leftovers cannot be scraped from jars and bottles, with up to 15 per cent of a product remaining in its container"). A clever idea, but it hardly follows that every company selling ketchup in traditional jars is injuring consumers.

Or consider the unsuccessful attempt to bring a class action against a lip-balm manufacturer for designing its products in a way that did not allow consumers to access all of the balm in the tube. *See Ebner v. Fresh, Inc.*, 838 F.3d 958 (9th Cir. 2016). That suit was premised on a claim that the defendant's conduct was deceptive, a claim that failed because no reasonable consumer would have been misled. *Id.* at 965. But if respondents' theory were correct, then the would-be class in *Ebner* should not have bothered alleging deception. Instead, they should have just alleged that the defendants' lip-balm tubes *could* have been redesigned to be more efficient and that the defendants *might* have chosen to charge the same price for a more efficiently designed product.

Nor would the adventures end there. Nothing about respondents' novel theory of injury-by-inefficiency is logically limited to inefficiency at the point of use. If the decision below is allowed to stand, it is easy to imagine other lawyers arguing that businesses are "injuring" their customers through any number of allegedly uneconomical practices, from using suboptimal manufacturing techniques to employing too many workers (or too many lawyers) to spending money on ineffective advertising. After all, if respondents here can create standing by speculating that petitioners might have charged less for their products if they had used fewer microliters of fluid per drop, why not suppose that a defendant that eliminated inefficiencies in its factories, its work force, or its outside counsel program might have passed the resulting savings on to consumers?

As Chief Judge Smith observed, if respondents can "establish standing simply by speculating about the additional efficiencies they might have captured had a defendant acted in accordance with the rules of a hypothetical marketplace," then "everyday business decisions may be subject to litigation by creative plaintiffs capable of theorizing a way that those business decisions could have been made to serve plaintiffs more efficiently." Pet. App. 8a (opinion dissenting from denial of rehearing en banc). In short, the decision below, if left undisturbed, will encourage a new wave of abusive consumer class actions claiming that companies could have produced their products more efficiently and sold them more cheaply—even where, as here, a regulatory scheme precludes the proposed change.

Class actions already take an enormous toll on U.S. businesses, and ultimately on the public at large, even without opening up a new frontier of no-injury claims. Class actions often drag on for years. *See, e.g.*, U.S. Chamber Inst. for Legal Reform, *Do Class Actions Benefit Class Members? An Empirical Analysis of Class Actions* 1 (Dec. 2013), http://goo.gl/um3toQ ("Approximately 14 percent of all class action cases remained pending four years after they were filed, without resolution or even a determination of whether the case could go forward on a class-wide basis." (emphasis omitted)). And the costs of defending against them continue to rise. *See* Carlton Fields Jorden Burt, *Class Action Survey: Best Practices in Reducing Cost and Managing Risk in Class Action Litigation* 17 (2017), http://goo.gl/mKjnJn (in the highest-risk class actions, companies spend between $3 and $30 million per year per case on outside counsel). In 2017 alone, companies spent a total of $2.17 *billion* on legal services related to class actions, which accounted for 11.2 percent of all litigation spending in the United States. *See id.* at 2–3.[2]

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[2] Although those costs are high enough to impact the bottom line of even large companies like petitioners here, the ramifications of meritless and overreaching class actions for small businesses are particularly concerning "because it is the small business that gets caught up in the class action web without the resources to fight." 151 Cong. Rec. 1664 (Feb. 8, 2005) (statement of Sen. Grassley). *See, e.g.*, *Creative Montessori Learning Ctrs. v. Ashford Gear LLC*, 662 F.3d 913, 916 (7th Cir. 2011) (class certification turned a minor, $3,000 dispute into an $11 million suit against a home-furnishings retailer with three employees and annual sales of $500,000).

The costs of defending against meritless no-injury class actions, as well as the costs of settlement payouts forced by the unique pressures of class litigation, are ultimately borne by businesses' customers, employees, and investors. Consumers are further harmed when products they like and depend on are changed or removed from the market entirely. This suit, for example, threatens to prevent patients from accessing important medications while compelling petitioners to incur millions of dollars in costs to seek FDA approval for product changes that will do nothing to make the products safer or more effective. Left undisturbed, the decision below will result in many more consumers, who doubtless do not consider themselves injured, being wrongly caught up in litigation that runs counter to their interests.

Class actions will probably always "present opportunities for abuse." *Hoffman-La Roche Inc. v. Sperling*, 493 U.S. 165, 171 (1989). But the likelihood of abuse is particularly great in cases like this one, where respondents cannot plausibly allege that the challenged conduct has injured *anyone*. These sorts of baseless class actions can and should be resolved quickly through challenges to standing in order to deter such meritless suits and spare defendants the costs and settlement pressures that accompany such litigation.[3] In this "era of frequent litigation [and]

[3] "[W]hen damages allegedly owed to tens of thousands of potential claimants are aggregated and decided at once, the risk of an error will often become unacceptable. Faced with even a small chance of a devastating loss, defendants will be pressured into settling questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011); *see also Blue Chip Stamps v.*

class actions . . . , courts must be more careful to insist on the formal rules of standing, not less so." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 146 (2011).

Manor Drug Stores, 421 U.S. 723, 740 (1975) (class certification gives a case "settlement value to the plaintiff out of any proportion to its prospect of success at trial"). A "study of certified class actions in federal court in a two-year period (2005 to 2007) found that all 30 such actions had been settled." *Eubank v. Pella Corp.*, 753 F.3d 718, 720 (7th Cir. 2014) (citing Emery G. Lee III, et al., *Impact of the Class Action Fairness Act on Federal Courts* 2, 11 (Fed. Judicial Ctr. 2008)).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

PETER TOLSDORF
MANUFACTURERS' CENTER FOR LEGAL ACTION
733 10th St. NW, Suite 700
Washington, D.C. 20001
(202) 637-3000

Counsel for National Association of Manufacturers

WARREN POSTMAN
JANET GALERIA
U.S. CHAMBER LITIGATION CENTER, INC.
1615 H Street NW
Washington, D.C. 20062
(202) 463-5685

Counsel for Chamber of Commerce of the United States of America

JEFFREY S. BUCHOLTZ
Counsel of Record
PAUL ALESSIO MEZZINA
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, D.C. 20006
(202) 737-0500
jbucholtz@kslaw.com

Counsel for Amici Curiae

SHERMAN JOYCE
LAUREN SHEETS JARRELL
AMERICAN TORT REFORM ASSOCIATION
1101 Connecticut Ave. NW
Suite 400
Washington, D.C. 20036
(202) 682-1168

Counsel for American Tort Reform Association

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL
RESEARCH &
MANUFACTURERS OF
AMERICA
950 F Street NW
Washington, D.C. 20004
(202) 835-3400

Counsel for Pharmaceutical Research & Manufacturers of America

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